GUIDELINES ON
File Content of Stability Dossier

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TABLE OF CONTENTS

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 425/2015 , 645/2018 or296/2009)

Folder 1	Box Approval	
	Naming Approval	
	Composition of Central Administration of Drug Control	When available
	Certificate of analysis of Central Administration of Drug Control	When available
	Stability summary sheet	(Template 1) Shall be presented by Applicant company in two formats: • Word format • PDF format (signed and stamped)
	Composition	• Shall be presented by Applicant company (signed and stamped) in tabular form listing all components of finished product and their amounts in unified units, the function of each component and its reference (e.g.: pharmacopoeia or manufacturer's specifications) • Shall state equivalence weight of salt in case of using active moiety • Shall include all finished product components (e.g.: components of capsule shell, components of ink…...) • Shall include all components used in the manufacturing process, including those that may not be added to every batch (e.g.: acid and alkali…), those that may be removed during processing (e.g.: solvents….) and any others (e.g.: nitrogen….) and any note to be reflected in footnote • Shall separate active ingredients from inactive ingredients • Shall separate core and coat in case of film coated tablet • Shall separate cap and body in case of capsule shell • Shall include solvent for reconstitution if it is co-packaged with finished product • Shall indicate the use of an over-fill or overage when applicable and its rationale • Shall state total weight or total volume • Shall state grade of any component (when applicable) and color index of any coloring agent Shall state composition statement for purchased mixture as flavor or capsule shell

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 425/2015 , 645/2018 or296/2009)

		or pellets (when applicable)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by Stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by Applicant company (signed and stamped)
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Report from Central Administration of Operations	Shall state batch type (e.g.: pilot, production…), batch order (e.g.: 1st,2nd…)
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For the batch of finished product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 425/2015 , 645/2018 or296/2009)

		and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, batch number on which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified by the site responsible for stability testing • May include (when applicable): • In-use stability study • Shall include results within shelf-life specifications
	Stability study contract (عقد دراسة الثبات) (when applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and dosage form are stated

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 425/2015 , 645/2018 or296/2009)

		Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval • Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy

	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable)
		• Shall include the following:
		  • For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections
		  • For precision: 6 injections are required
		  • For linearity: 5 concentrations are recommended with 1 injection required for each concentration
		  • For accuracy: 3 concentrations are recommended with 3 injections required for each concentration
		  • For ruggedness: 3 injections are required for each random variation

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 425/2015 , 645/2018 or296/2009)

		• For robustness: 3injections are required for each small variation in method parameters • Shall be stamped by stability testing site

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (re- registration according to ministerial decree 425/2015 or 296/2009)

Folder 1	Registration License and attached composition (if applicable)	
	Transfer Letter and attached composition in case of (296/2009) Preliminary Re-registration Approval in case of(425/2015)	
	Central Administration of Drug Control Composition (in case composition is not attached to registration license or variation approval for changing composition)	Required if ministerial decree 425/2015 In case the composition is not inferred by EDA Labs, Stability General Administration accredits the composition
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
	Stability summary sheet	(Template 1) Shall be presented by Applicant company in two formats: • Word format • PDF format (signed and stamped)
	Composition	• Shall be presented by Applicant company (signed and stamped) in tabular form listing all components of finished product and their amounts in unified units, the function of each component and its reference (e.g.: pharmacopoeia or manufacturer's specifications) • Shall state equivalence weight of salt in case of using active moiety • Shall include all finished product components (e.g.: components of capsule shell, components of ink…...) • Shall include all components used in the manufacturing process, including those that may not be added to every batch (e.g.: acid and alkali…), those that may be

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (re- registration according to ministerial decree 425/2015 or 296/2009)

		removed during processing (e.g.: solvents….) and any others (e.g.: nitrogen….) and any note to be reflected in footnote • Shall separate active ingredients from inactive ingredients • Shall separate core and coat in case of film coated tablet • Shall separate cap and body in case of capsule shell • Shall include solvent for reconstitution if it is co-packaged with finished product • Shall indicate the use of an over-fill or overage when applicable and its rationale • Shall state total weight or total volume • Shall state grade of any component (when applicable) and color index of any coloring agent • Shall state composition statement for purchased mixture as flavor or capsule shell or pellets (when applicable)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by Stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by Applicant company (signed and stamped)
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s)

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (re- registration according to ministerial decree 425/2015 or 296/2009)

		(when applicable) ▪ Microbiological analysis Biological analysis (when applicable)
	Report from Central Administration of Operations (in case of any variations)	Shall state batch type (e.g.: pilot, production…), batch order (e.g.: 1st,2nd…) and type of variation (when applicable)
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For the batch of finished product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, batch number on which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis

Dossier content for stability study submitted for locally manufactured human pharmaceutical products (re- registration according to ministerial decree 425/2015 or 296/2009)

		▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified by the site responsible for stability testing • May include (when applicable): • In-use stability study • Shall include results within shelf-life specifications
	Stability study contract (عقد دراسة الثبات) (when applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and dosage form are stated • Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content

		of preservative(s) and/or antioxidant(s) (when applicable)
		• Shall include the following:
		  • For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections
		  • For precision: 6 injections are required
		  • For linearity: 5 concentrations are recommended with 1 injection required for each concentration
		  • For accuracy: 3 concentrations are recommended with 3 injections required for each concentration
		  • For ruggedness: 3 injections are required for each random variation
		  • For robustness: 3injections are required for each small variation in method parameters
		Shall be stamped by stability testing site

Dossier content for stability study for locally manufactured pharmaceutical products submitted for fulfillment of variation committee or registration license requirements

Folder 1	Registration License and attached composition (in case of minster decree 425/2015 and 645/2018) or Tentative Registration License and attached composition (in case of mister decree 296/2009)	Tentative Registration License is not valid, time frame extension shall be submitted
	Valid Registration License and attached composition	Is a must in case of shelf life extension or storage condition change
	Stability general administration technical report for approval of Accelerated study	Only in case of products following ministerial decree 296/2009 and submitted for long term production
	Evidence for submission of product for re-registration (in case of invalid Registration License)	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license

Dossier content for stability study for locally manufactured pharmaceutical products submitted for fulfillment of variation committee or registration license requirements

	Stability general administration technical reports approval for other variations in submitted product	
	Composition of Central Administration of Drug Control	When available
	Certificate of analysis of Central Administration of Drug Control	When available
	Stability summary sheet	(Template 1) Shall be presented by Applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by Stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical	(Template 5) Shall be presented by Applicant company (signed and stamped)

Dossier content for stability study for locally manufactured pharmaceutical products submitted for fulfillment of variation committee or registration license requirements

	ingredient(s) entering in the manufacture of finished product	
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis Biological analysis (when applicable)
	Report from Central Administration of Operations	Shall state batch type (e.g.: pilot, production…), batch order (e.g.: 1st,2nd…) and type of variation
	Payment receipt	Required when stability study is submitted for the purpose of change of storage conditions
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For the batch of finished product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical, chemical

Dossier content for stability study for locally manufactured pharmaceutical products submitted for fulfillment of variation committee or registration license requirements

		and microbiological analysis Shall submit reference if analytical procedure used found in a pharmacopoeia
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, batch number on which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified by the site responsible for stability testing • May include (when applicable): • In-use stability study • Shall include results within shelf-life specifications
	Stability study contract (عقد دراسة الثبات) (when applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and dosage form are stated • Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval • Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s)

Dossier content for stability study for locally manufactured pharmaceutical products submitted for fulfillment of variation committee or registration license requirements

		and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: • For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections • For precision: 6 injections are required • For linearity: 5 concentrations are recommended with 1 injection required for each concentration • For accuracy: 3 concentrations are recommended with 3 injections required for each concentration • For ruggedness: 3 injections are required for each random variation • For robustness: 3injections are required for each small variation in method parameters Shall be stamped by stability testing site

Dossier content for stability study submitted for locally manufactured veterinary product (new registration or re-registration)

Folder 1	Veterinary Committee Approval	
	Transfer Letter (in case of re-registration) and attached composition	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
	Composition of Central Administration of Drug Control	When available
	Certificate of analysis of Central Administration of Drug Control	When available
	Stability summary sheet	(Template 1) Shall be presented by Applicant company in two formats: • Word format • PDF format (signed and stamped)
	Composition	• Shall be presented by Applicant company (signed and stamped) in tabular form listing all components of finished product and their amounts in unified units, the function of each component and its reference (e.g.: pharmacopoeia or manufacturer's specifications) • Shall state equivalence weight of salt in case of using active moiety • Shall include all finished product components (e.g.: components of capsule shell, components of ink…..) • Shall include all components used in the manufacturing process, including those that may not be added to every batch (e.g.: acid and alkali…), those that may be removed during processing (e.g.: solvents….) and any others (e.g.: nitrogen….) and any note to be reflected in footnote • Shall separate active ingredients from inactive ingredients • Shall separate core and coat in case of film coated tablet • Shall separate cap and body in case of capsule shell

Dossier content for stability study submitted for locally manufactured veterinary product (new registration or re-registration)

		• Shall include solvent for reconstitution if it is co-packaged with finished product • Shall indicate the use of an over-fill or overage when applicable and its rationale • Shall state total weight or total volume • Shall state grade of any component (when applicable) and color index of any coloring agent Shall state composition statement for purchased mixture as flavor or capsule shell or pellets (when applicable)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25^{o}	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by the stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by Applicant company (signed and stamped)
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis Biological analysis (when applicable)
	Report from Central Administration of	Shall state batch type (e.g.: pilot, production…), batch order (e.g.:

Dossier content for stability study submitted for locally manufactured veterinary product (new registration or re-registration)

	Operations	1st,2nd…) and type of variation (when applicable)
	Payment Receipt	Required when stability study is submitted for the purpose of shelf-life extension or change of storage conditions
	Reference Product insert	Shall state storage conditions
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For the batch of finished product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, batch number on which stability study was done, manufacturing and expiry date,

Dossier content for stability study submitted for locally manufactured veterinary product (new registration or re-registration)

		date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified by the site responsible for stability testing • May include (when applicable): • In-use stability study • Shall include results within shelf-life specifications
	Stability study contract عقد دراسة الثبات (When applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and dosage form are stated • Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval • Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay

Dossier content for stability study submitted for locally manufactured veterinary product (new registration or re-registration)

		of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy

	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable)
		• Shall include the following:
		  • For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections
		  • For precision: 6 injections are required
		  • For linearity: 5 concentrations are recommended with 1 injection required for each concentration
		  • For accuracy: 3 concentrations are recommended with 3 injections required for each concentration
		  • For ruggedness: 3 injections are required for each random variation
		  • For robustness: 3injections are required for each small variation in method parameters
		• Shall be stamped by stability testing site

Dossier content for stability study submitted for locally manufactured biocides (new registration or re-registration)

Folder 1	Biocides Committee Approval and attached composition	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
	Composition of Central Administration of Drug Control	When available
	Certificate of analysis of Central Administration of Drug Control	When available
	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Composition	Shall be presented by applicant company (signed and stamped)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25^{o}C	(Template 3) Shall be presented by applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by applicant company (signed and stamped)
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis
	Payment receipt	• Required in case of stability study is submitted for the purpose of shelf-life/in-use shelf-life extension or change

Dossier content for stability study submitted for locally manufactured biocides (new registration or re-registration)

		of storage conditions/in-use storage conditions
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For batches of product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s)
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical and chemical analysis • Shall submit reference if analytical procedure used found in a reference
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, strength, formulation, batch number on which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), • May include (when applicable): • In-use stability study

Dossier content for stability study submitted for locally manufactured biocides (new registration or re-registration)

	Stability study contract (عقد دراسة الثبات) (When applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and formulation are stated • Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s) • Shall include 3 injections for standard and test at each time interval • Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay of active ingredient(s) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a reference, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy

	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s)
		• Shall include the following:
		  ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections
		  ▪ For precision: 6 injections are required
		  ▪ For linearity: 5 concentrations are recommended

Dossier content for stability study submitted for locally manufactured biocides (new registration or re-registration)

		with 1 injection required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3injections are required for each small variation in method parameters • Shall be stamped by stability testing site

Dossier content for stability study submitted for locally manufactured herbal medicines and dietary supplements (new registration or re-registration)

Folder 1	Herbal Medicine and Dietary Supplements committee approval and attached composition	
	Registration license (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
	Composition of Central Administration of Drug Control	When available
	Certificate of analysis of Central Administration of Drug Control	When available
	Stability summary sheet	(Template 1) Shall be presented by Applicant company in two formats: • Word format • PDF format (signed and stamped)
	Composition	• Shall be presented by Applicant company (signed and stamped) in tabular form listing all components of finished product and their amounts in unified units, the function of each component and its reference (e.g.: pharmacopoeia or manufacturer's specifications) • Shall state equivalence weight of salt in case of using active moiety • Shall include all finished product components (e.g.: components of capsule shell, components of ink…..) • Shall include all components used in the manufacturing process, including those that may not be added to every batch (e.g.: acid and alkali…), those that may be removed during processing (e.g.: solvents….) and any others (e.g.: nitrogen….) and any note to be reflected in footnote • Shall separate active ingredients from inactive ingredients

Dossier content for stability study submitted for locally manufactured herbal medicines and dietary supplements (new registration or re-registration)

		• Shall separate core and coat in case of film coated tablet • Shall separate cap and body in case of capsule shell • Shall include solvent for reconstitution if it is co-packaged with finished product • Shall indicate the use of an over-fill or overage when applicable and its rationale • Shall state total weight or total volume • Shall state grade of any component (when applicable) and color index of any coloring agent • Shall state composition statement for purchased mixture as flavor or capsule shell or pellets (when applicable)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by Stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by Applicant company (signed and stamped)
	Finished product specification	• Shall be presented by stability testing site signed and stamped • Shall include list of tests, specifications and reference to analytical procedures and acceptance criteria • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)

Dossier content for stability study submitted for locally manufactured herbal medicines and dietary supplements (new registration or re-registration)

	Report from Central Administration of Operations	Shall state batch type (e.g.: pilot, production…), batch order (e.g.: 1st,2nd…) and type of variation (when applicable)
	Payment receipt	Required when stability study is submitted for the purpose of shelf-life extension or change of storage conditions
	Reference product insert	Shall state storage conditions
Folder 2	Certificate of analysis	• Shall be presented by stability testing site signed and stamped • For the batch of finished product on which stability study was done • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
	Method of analysis	• Shall be presented by stability testing site signed and stamped • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Stability study table(s)	• Shall be presented by stability testing site signed and stamped • Shall clearly state product name, batch number on which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, storage conditions, testing intervals and product pack in details • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of

Dossier content for stability study submitted for locally manufactured herbal medicines and dietary supplements (new registration or re-registration)

		impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified by the site responsible for stability testing • May include (when applicable): ▪ In-use stability study • Shall include results within shelf-life specifications
	Stability study contract (عقد دراسة الثبات) (when applicable)	• Required when stability testing site is different from applicant company or manufacturer of finished product • Shall include annex in which product name, strength and dosage form are stated • Both contract and annex shall be legalized by bank and EDA legal affairs
Folder 3	Assay chromatograms annex	• Shall state product name, batch number and injection date • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval • Shall be stamped by stability testing site
	Validation of analytical procedure	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy

Dossier content for stability study submitted for locally manufactured herbal medicines and dietary supplements (new registration or re-registration)

	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 1 injection required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3injections are required for each small variation in method parameters • Shall be stamped by stability testing site

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

EDA Approvals	Box Approval	Shall state that the dossier shall be submitted as full Common Technical Dossier CTD (i.e.: Both drug substance and drug product)
	Naming Approval	
Product Documents	Composition	• Shall be presented by Applicant company (signed and stamped) in tabular form listing all components of finished product and their amounts in unified units, the function of each component and its reference (e.g.: pharmacopoeia or manufacturer's specifications) • Shall state equivalence weight of salt in case of using active moiety • Shall include all finished product components (e.g.: components of capsule shell, components of ink…...) • Shall include all components used in the manufacturing process, including those that may not be added to every batch (e.g.: acid and alkali…), those that may be removed during processing (e.g.: solvents….) and any others (e.g.: nitrogen….) and any note to be reflected in footnote • Shall separate active ingredients from inactive ingredients • Shall separate core and coat in case of film coated tablet • Shall separate cap and body in case of capsule shell • Shall include solvent for reconstitution if it is co-packaged with finished product • Shall indicate the use of an over-fill or overage when applicable and its rationale • Shall state total weight or total volume

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		• Shall state grade of any component (when applicable) and color index of any coloring agent Shall state composition statement for purchased mixture as flavor or capsule shell or pellets (when applicable)
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C	(Template 3) Shall be presented by Applicant company signed and stamped
	Certificate of responsibility	(Template 4) Shall be presented by Stability testing site (signed and stamped)
	Declaration letter for manufacturer of active pharmaceutical ingredient(s) entering in the manufacture of finished product	(Template 5) Shall be presented by Applicant company (signed and stamped)
	Report from Central Administration of Operations	• Shall state batch type (e.g.: pilot, production…), batch order (e.g.: 1st,2nd…)
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data submitted	(Template 2) Shall be presented by applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by applicant company signed and stamped
Required CTD Sections for Drug Product	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Manufacturer(s)	
	Section 3.2.P.5.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following:

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Section 3.2.P.5.2: Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3: Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.4: Batch Analyses	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	
	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances,

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters
Required CTD Sections for Drug Substance	In case of availability of valid Certificate of Suitability of the European Pharmacopoeia (CEP): *CEP specifying a retest period that is the same as or longer than that proposed by the applicant, and storage conditions are the same or at a higher temperature and humidity than those proposed by the applicant, the applicant is waived from submission of CTD Sections for Drug Substance OR *CEP stating a container closure system while not stating a retest period and storage condition, the applicant is waived from submission of analytical procedure and validation of analytical procedure	
	Section 3.2.S.2.1: Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.S.3.2: Impurities	
	Section 3.2.S.4.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable)

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

		▪ Biological analysis (when applicable)
	Section 3.2.S.4.2: Analytical Procedures	• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Section 3.2.S.4.3: Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.S.4.4: Batch analyses	
	Section 3.2.S.4.5: Justification of Specification(s)	
	Section 3.2.S.6: Container Closure System	
	Section 3.2.S.7.1: Stability Summary and Conclusions	
	Section 3.2.S.7.2: Post-approval Stability Protocol Commitment	

Common Technical Dossier content for stability study submitted for locally manufactured human pharmaceutical products (new registration according to ministerial decree 820/2016 and 645/2018 where CTD is a condition for registration)

	Section 3.2.S.7.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable) ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • Shall include results within shelf-life specifications
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s) and quantitation of impurities and related substances • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation

		▪ For robustness: 3 injections are required for each small variation in method parameters

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

EDA Approvals	Box Approval	Shall state that the dossier shall be submitted as full Common Technical Dossier CTD (i.e.: Both drug substance and drug product)
	Naming Approval	
Product Documents	Certificate of Pharmaceutical Product (CPP) and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate shall establish up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (when applicable) and in-use storage conditions (when applicable) • Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

		• In case of legalization is not available at time of submission due to current situation, applicant company shall submit commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized composition shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, applicant company shall submit commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data submitted	(Template 2) Shall be presented by applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by applicant company signed and stamped
Required CTD Sections for Drug Product	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Manufacturer(s)	
	Section 3.2.P.5.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Section 3.2.P.5.2: Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

	Section 3.2.P.5.3: Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	
	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

		Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following:

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

		▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters
Required CTD Sections for Drug Substance	In case of availability of valid Certificate of Suitability of the European Pharmacopoeia (CEP): *CEP specifying a retest period that is the same as or longer than that proposed by the applicant, and storage conditions are the same or at a higher temperature and humidity than those proposed by the applicant, the applicant is waived from submission of CTD Sections for Drug Substance OR *CEP stating a container closure system while not stating a retest period and storage condition, the applicant is waived from submission of analytical procedure and validation of analytical procedure	
	Section 3.2.S.2.1: Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.S.3.2: Impurities	
	Section 3.2.S.4.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

		Shall include identification and assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable) ▪ Biological analysis (when applicable)
	Section 3.2.S.4.2: Analytical Procedures	• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Section 3.2.S.4.3: Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.S.4.4: Batch analyses	
	Section 3.2.S.4.5: Justification of Specification(s)	
	Section 3.2.S.6: Container Closure System	
	Section 3.2.S.7.1: Stability Summary and Conclusions	

Common Technical Dossier content for stability study submitted for human pharmaceutical products imported from reference or non-reference countries (new registration according to ministerial decree 820/2016 and 645/2018)

	Section 3.2.S.7.2: Post-approval Stability Protocol Commitment	
	Section 3.2.S.7.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable) ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • Shall include results within shelf-life specifications
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s) and quantitation of impurities and related substances • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration

		▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

EDA Approvals	Box Approval	
	Naming Approval	
Product Documents	Certificate of Pharmaceutical Product (CPP) and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation,

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

		Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Declaration letter stating manufacturer of active pharmaceutical ingredient(s)	• Declaration letter shall be presented from License Holder Shall state product name, its strength, formulation, name of active pharmaceutical ingredient(s) and its/their manufacturer
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

		impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
Stability data	Finished Product Specification	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) Shall include results within shelf-life specifications
	Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

		validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (new registration)

		▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

EDA Approvals	-Transfer Letter and attached composition (in case of 296/2009) -Preliminary Re-registration Approval (in case of 425/2015)	
	Registration License and attached composition	
	EDA Labs composition (in case composition is not attached to Registration License or variation approval for changing composition)	In case the composition is not inferred by EDA Labs, Stability General Administration accredits the composition
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP, free sale or if not attached registration license, no EDA Labs composition or variation approval for changing composition)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Declaration letter stating manufacturer of active	• Declaration letter shall be presented from License Holder

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

	pharmaceutical ingredient(s)	Shall state product name, its strength, formulation, name of active pharmaceutical ingredient(s) and its/their manufacturer
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
Stability data	Finished product specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

		▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis Biological analysis (when applicable)
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) Shall include results within shelf-life specifications
	Analytical Procedures	• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

		preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (re-registration)

		▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

EDA Approvals	Veterinary Committee Approval	
	Transfer Letter (in case of re-registration) and attached composition	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or Free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder,

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

	storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

		▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Stability data	Finished Product Specification	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

		active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

		• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval

Dossier content for stability study submitted for veterinary products imported from non-reference countries non-CTD (new registration, registration or variation)

	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (submitted for variation)

EDA Approvals	Variation Committee Approval (if applicable)	
	Valid Registration License and attached composition	
	Evidence for submission of product for re-registration (in case of invalid Registration License)	
	EDA Labs composition (if not attached to Registration License or variation approval for changing composition)	
Product Documents	Certificate of Pharmaceutical Product (CPP) or Free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use	• Declaration letter for the product shall be presented from License Holder and legalized by

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (submitted for variation)

	shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (submitted for variation)

	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Stability data	Finished Product Specification	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (submitted for variation)

		substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Analytical Procedures	• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and

Dossier content for stability study submitted for human pharmaceutical products imported from non-reference countries non-CTD (submitted for variation)

		related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

EDA Approvals	Herbal Medicine Committee Approval and attached composition	
	Name Approval (in case of new registration)	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or Free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder,

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

	storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Declaration letter stating manufacturer of active pharmaceutical ingredient(s)	• Declaration letter shall be presented from License Holder Shall state product name, its strength, formulation, name of active pharmaceutical ingredient(s) and its/their manufacturer

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Stability data	Finished product specification(s)	• Shall include test, specification and reference for

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

		specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis Biological analysis (when applicable)
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) ▪ Shall include results within shelf-life specifications
	Analytical Procedures	• Shall include stability-indicating analytical

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

		procedure used for physical, chemical and microbiological analysis
	Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation

Dossier content for stability study submitted for herbal medicine products imported from non-reference countries non-CTD (new registration, registration or variation)

		are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for biocides imported from reference and non-reference countries (new registration, re-registration or variation)

EDA Approvals	Biocides Committee Approval and attached composition	
	Registration License and attached composition (note: in case of re-registration)	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or free sale and attached label (when applicable)	The certificate or free sale shall establish up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and formulation • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Shelf life, storage conditions, in-use shelf life (if applicable), and in-use storage conditions (if applicable) • Pack in details The certificate or free sale shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate should be submitted
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or pack (in details) (if not stated in CPP or free sale or attached label or if updated	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability

Dossier content for stability study submitted for biocides imported from reference and non-reference countries (new registration, re-registration or variation)

	than those mentioned in registration license)	General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, applicant company shall submit commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Declaration letter stating manufacturer of active pharmaceutical ingredient(s)	• Declaration letter shall be presented from License Holder • Shall state product name, its strength, formulation, name of active pharmaceutical ingredient(s) and its/their manufacturer
	Certificate of analysis	• For any batch of product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s)
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Presented by applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Presented by applicant company signed and stamped
	Cover letter for scope of variation (in case of variation)	

Dossier content for stability study submitted for biocides imported from reference and non-reference countries (new registration, re-registration or variation)

	Payment receipt	Required when stability study is submitted for the purpose of shelf-life/in-use shelf-life extension or change of storage conditions/in-use storage conditions
Stability Data	Finished product specification(s)	Shall include the following: • Physical Analysis • Chemical Analysis
	Stability study summary and protocol	Shall include batch(es) number, batch(es) scale, manufacturing and expiry date(s), storage conditions, duration, and testing frequency
	Stability study table(s)	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis • May include (when applicable): ▪ In-use stability study
	Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical and chemical • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered

Dossier content for stability study submitted for biocides imported from reference and non-reference countries (new registration, re-registration or variation)

		including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Assay chromatograms annexes	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country Shall include chromatograms of assay of active ingredient(s) and quantitation of impurities and related substances • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required

Dossier content for stability study submitted for biocides imported from reference and non-reference countries (new registration, re-registration or variation)

		▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation • For robustness: 3 injections are required for each small variation in method parameters

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

EDA Approvals	Box Approval	Shall state that the dossier shall be submitted as full Common Technical Dossier CTD (i.e.: Both drug substance and drug product) (note: required in case of ministerial decree 820/2016 and 645/2018)
	Naming Approval	
Product Documents	Certificate of Pharmaceutical Product (CPP) and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate shall establish up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (when applicable) and in-use storage conditions (when applicable) • Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

	updated than those mentioned in registration license)	General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, applicant company shall submit commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized composition shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, applicant company shall submit commitment for legalization of declaration letter within 6 months according to EDA Chairman decision
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

		▪ Biological analysis (when applicable) • Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data submitted	(Template 2) Shall be presented by applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by applicant company signed and stamped
Required CTD Sections for Drug Product	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Manufacturer(s)	
	Section 3.2.P.5.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Section 3.2.P.5.2: Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

		• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3: Validation of Analytical Procedures	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	
	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

		substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters
Required CTD Sections for Drug Substance (note: required in case of ministerial decree 820/2016 and 645/2018)	In case of availability of valid Certificate of Suitability of the European Pharmacopoeia (CEP): *CEP specifying a retest period that is the same as or longer than that proposed by the applicant, and storage conditions are the same or at a higher temperature and humidity than those proposed by the applicant, the applicant is waived from submission of CTD Sections for Drug Substance OR *CEP stating a container closure system while not stating a retest period and storage condition, the applicant is waived from submission of analytical procedure and validation of analytical procedure	
	Section 3.2.S.2.1: Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.S.3.2: Impurities	
	Section 3.2.S.4.1: Specification(s)	• Shall include test, specification and reference for specification • Shall include the following:

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

		▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable) ▪ Biological analysis (when applicable)
	Section 3.2.S.4.2: Analytical Procedures	• Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis • Shall submit reference if analytical procedure used found in a pharmacopoeia
	Section 3.2.S.4.3: Validation of Analytical Procedures	• Shall include validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness • In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.S.4.4: Batch analyses	
	Section 3.2.S.4.5: Justification of Specification(s)	
	Section 3.2.S.6: Container Closure System	

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

	Section 3.2.S.7.1: Stability Summary and Conclusions	
	Section 3.2.S.7.2: Post-approval Stability Protocol Commitment	
	Section 3.2.S.7.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s) and quantitation of impurities and related substances ▪ Microbiological analysis (when applicable) ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • Shall include results within shelf-life specifications
	Assay chromatograms annexes	• Shall include chromatograms of assay of active ingredient(s) and quantitation of impurities and related substances • Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s) and quantitation of impurities and related substances • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration

Common Technical Dossier content for stability study submitted for Human pharmaceutical products imported from reference or non-reference countries (new registration)

		▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation ▪ For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

EDA Approvals	-Transfer Letter and attached composition (in case of 296/2009) -Preliminary Re-registration Approval (in case of 425/2015)	
	Registration License and attached composition	
	EDA Labs composition (in case composition is not attached to registration license or variation approval for changing composition) (note: in case of 425/2015)	In case the composition is not inferred by EDA Labs, Stability General Administration accredits the composition
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate shall be submitted

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or free sale or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Legalized composition (if not stated in CPP, free sale or if not attached registration license, no EDA Labs composition or variation approval for changing composition)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
Required CTD Sections	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Drug Product Manufacturer(s)	

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

	Section 3.2.S.2.1: Drug Substance Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.P.5.1: Drug Product Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Section 3.2.P.5.2 Analytical Procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3 Validation of analytical procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable)

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

		• Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

		▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required

Dossier content for stability study submitted for human pharmaceutical products in CTD format Imported from reference and non-reference countries (re-registration)

		▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

EDA Approvals	Veterinary Committee Approval	
	Transfer Letter (in case of re-registration) and attached composition	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate shall be submitted
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

	(if not stated in CPP or free sale or attached SmPC or PIL or if updated than those mentioned in registration license)	• Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data	(Template 2)

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

	Submitted	Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Required CTD Sections	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Drug Product Manufacturer(s)	
	Section 3.2.S.2.1: Drug Substance Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.P.5.1: Drug Product Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

	Section 3.2.P.5.2 Analytical Procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3 Validation of analytical procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval

Dossier content for stability study submitted for Veterinary Products in CTD format Imported from reference and non-reference countries (New Registration, Re-registration or variation)

	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

EDA Approvals	Variation Committee Approval (if applicable)	
	Valid Registration License and attached composition	Is a must in case of shelf-life extension or storage condition change
	Evidence for submission of product for re-registration (in case of invalid Registration License)	
	EDA Labs composition (if not attached to Registration License or variation approval for changing composition)	
Product Documents	Certificate of Pharmaceutical Product (CPP) and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (when applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate
	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage	• Is a must in case of shelf life extension or storage condition change

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

	conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped
	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Required CTD Sections	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Drug Product Manufacturer(s)	
	Section 3.2.S.2.1: Drug Substance Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.P.5.1: Drug Product Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

		identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)
	Section 3.2.P.5.2 Analytical Procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3 Validation of analytical procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	
	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) Shall include 3 injections for standard and test at each time interval
	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation

Dossier content for stability study submitted for human pharmaceutical products in CTD format imported from reference non-reference countries (variation)

		For robustness: 3 injections are required for each small variation in method parameters

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

EDA Approvals	Herbal Medicine Committee Approval and attached composition	
	Name Approval (in case of new registration)	
	Registration License (in case of re-registration) and attached composition	
	Any other EDA approvals and/or decisions (e.g.: variation approval…)	In case of any approvals or decisions issued for the product and not reflected in the last released registration license
Product Documents	Certificate of Pharmaceutical Product (CPP) or free sale and attached Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) (if applicable)	The certificate establishes up to date status and data of the product in the exporting country or region at the time of issuing of certificate. This data may include (when applicable): • Product Trade name in Egypt, its strength and dosage form • Complete composition of the product • License Holder, Manufacturer and Packager of the product • Summary of Product Characteristics (SmPC) or Product Information Leaflet (PIL) • Shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) Container closure system in details The certificate shall be legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate shall be submitted

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Legalized declaration letter stating shelf life, storage conditions, in-use shelf life (if applicable), in-use storage conditions (if applicable) and/or container closure system (in details) (if not stated in CPP or free sale or attached SmPC or PIL or if updated than those mentioned in registration license)	• Declaration letter for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original legalized declaration letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted
	Legalized composition (if not stated in CPP or free sale)	• Composition for the product shall be presented from License Holder and legalized by Health Authority in country of License Holder, Chamber of Commerce, and Egyptian Embassy or Consulate • Original composition letter shall be submitted by the applicant company to Stability General Administration once stability dossier is accepted • In case of legalization is not available at time of submission due to current situation, Applicant Commitment for legalization of declaration letter within 6 months according to EDA Chairman decision shall be submitted

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Declaration letter stating Manufacturer of Active Pharmaceutical Ingredient	• Shall be Presented by license holder In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Certificate of analysis	• For any batch of finished product • Shall state product name, batch number, manufacturing and expiry date • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) Shall include results within release specifications
Applicant Commitments	Stability summary sheet	(Template 1) Shall be presented by applicant company in two formats: • Word format • PDF format (signed and stamped)
	Commitment for authenticity of data Submitted	(Template 2) Shall be presented by Applicant company signed and stamped

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Commitment for storage (in case of proposed storage conditions at temperature not exceeding 25°C)	(Template 3) Shall be presented by Applicant company signed and stamped
	Cover Letter for scope of variation (in case of variation)	
	Payment Receipt (in case of variation of shelf-life, storage conditions, in-use shelf-life or in-use storage conditions)	
Required CTD Sections	Section 3.2.P.1: Description and Composition of the Drug Product	
	Section 3.2.P.3.1: Drug Product Manufacturer(s)	
	Section 3.2.S.2.1: Drug Substance Manufacturer(s)	In case of more than one manufacturer for an active ingredient(s), declaration letter from License Holder mentioning manufacturer(s) of active pharmaceutical ingredient(s) for each batch submitted
	Section 3.2.P.5.1: Drug Product Specification(s)	• Shall include test, specification and reference for specification • Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include identification and assay of active ingredient(s), quantitation of impurities and related substances, and identification and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable)

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Section 3.2.P.5.2 Analytical Procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include stability-indicating analytical procedure used for physical, chemical and microbiological analysis
	Section 3.2.P.5.3 Validation of analytical procedure	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Complete validation of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision, linearity, accuracy, ruggedness and robustness In case of analytical procedure used found in a pharmacopoeia, verification of analytical procedures shall be conducted in which the following validation characteristics should be considered including: specificity, precision and accuracy
	Section 3.2.P.5.6: Justification of Specification(s)	
	Section 3.2.P.5.4: Batch Analyses	
	Section 3.2.P.7: Container Closure System	
	Section 3.2.P.8.1: Stability Summary and Conclusion	

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment	
	Section 3.2.P.8.3: Stability Data	• Shall include the following: ▪ Physical analysis ▪ Chemical analysis Shall include assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) ▪ Microbiological analysis ▪ Biological analysis (when applicable) • Any skipped test shall by scientifically justified • May include (when applicable): ▪ In-use stability study ▪ Photo stability study ▪ Hold time stability study (for Bulk Products) • Shall include results within shelf-life specifications
	Assay chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference country • Shall include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include 3 injections for standard and test at each time interval

Dossier content for stability study submitted for herbal medicine in CTD format imported from reference and non-reference countries (new registration, re-registration or variation)

	Validation chromatograms annex	• Required only for imported products from non-reference countries or when stability testing site is in non-reference countries • Shall include chromatograms of validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and assay of preservative(s) and/or antioxidant(s) (when applicable) • Shall include the following: ▪ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidation are required in addition to placebo and blank injections ▪ For precision: 6 injections are required ▪ For linearity: 5 concentrations are recommended with 3 injections required for each concentration ▪ For accuracy: 3 concentrations are recommended with 3 injections required for each concentration ▪ For ruggedness: 3 injections are required for each random variation For robustness: 3 injections are required for each small variation in method parameters

Template 1

Stability Summary Sheet

Type of Registration	**New Registration**		**Re Registration**		**Variation**			
Type of Product	**Human**		**Veterinary**		**Herbal Medicine / Dietary Supplement**		**Biocide**	
Applicant Name								
Manufacturer								
License Holder								
Packager								
Stability performed by								
Trade Name								
Active Ingredient(s) & Strength(s)								
Dosage Form								
Physical Characters								
Proposed shelf life / In-use shelf life (when applicable)	**Proposed storage conditions and / or in-use storage conditions should be mentioned in details and general terms such as "Ambient conditions" OR "Room temperature" should be avoided**							
Proposed storage conditions / In-use storage conditions (when applicable)								
Pack	**Pack should be mentioned in details**							

Note: All items of the sheet should be fulfilled

Summary of Stability Study:

(Type of study, duration, conditions and batches number)

Template 2

Commitment for authenticity of data submitted

تعهد

نتعهد نحن شركة / مكتب علمي ..... بأن جميع البيانات و االمستندات المقدمة لملف دراسة الثبات الخاص بمستحضر ..... صحيحة و على مسئولية الشركة / المكتب العلمي

مدير التسجيل

Template 3

Commitment for storage conditions

تعهد بظروف التخزين المقترحة

بالنسبة للمستحضر الآتى:

نتعهد نحن شركة / مكتب علمي ..... بتخزين المستحضر عند درجة حرارة لا تزيد عن 25 درجة مئوية وكذلك الزام جميع الموزعين بذلك فى مخازنهم وفى تعاملهم مع الصيدليات التى تراعى هذه الاشتراطات .

رئيس مجلس ادارة الشركة / مدير المكتب العلمي

شهادة

يشهد مصنع..... بأنه قام بعمل دراسة الثبات الخاصة بمستحضر..... و مسئول عنها مسئولية كاملة و هذه الدراسة مقدمه على

Batch number	Type of batch	Type of study

التى تمت بعرفة فريق العمل المكون من:

Performed by (Q.C. analyst): ……

Checked by (Q.C. Head): …….

Authorized by (Q. assurance Head):……

Stamp: ……