Central Administration of Pharmaceutical Products
General Administration For Stability

Notice to applicant

File Content of Stability study dossier

Year 2026

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Table of Contents

• Scope:

This guidance is applied on submission data required for stability study dossier for local and imported pharmaceutical products. Ensuring that submissions are consistent, complete, and adhere to EDA standards, which ultimately facilitates quicker approvals and market access.

• Objective:

This guidance will help applicant company to prepare a well-organized dossier for submission to GA-Stab that eventually will benefit both the applicants and the regulatory evaluators. Using this standardized dossier format helps streamline the submission and evaluation process, ensuring that all essential information is presented clearly and efficiently, reducing misunderstandings and the need for additional clarifications, ultimately leading to a more efficient approval process for human pharmaceutical products.

Stability file Content for Human Pharmaceutical Products

Item	Document Name	Description and requirements (if applicable)	Re-registration	Variation	Registration License Requirements or post approval requirements
Regulatory Documents Folder					
	1.	**<u>Administrative Documents:</u>** - Registration license with its attachments (composition, finished product specifications, …) - Preliminary re-registration approval for expired registration license - (Electronic) Certificate of Pharmaceutical Product ((e)CPP) / free sale attached with Summary of product characteristics (SmPC) / Insert - Product's (all volumes / all pack sizes) packaging materials (primary, secondary (if functional)) supplier's certificate(s) of analysis / analyses.	√	√	√
	2.	**<u>EDA Reports:</u>** - Previous stability study / studies approval(s) with its attachment(s) - Recent variation approval(s) with its attachment(s) - Central administration of operations (CAO) report of submitted batch(es) - Central Administration of Drug Control (CADC) **detailed** final report of submitted batch(es) with its attachment(s) - Central Administration of Drug Control (CADC) **renewal certificate of the analysis file** for a registered pharmaceutical product with its	√	√	√

	attachment(s) - Drug product (P-Part) quality approval with its attachment(s)			
	3. <u>Applicant documents:</u> - A review of all changes carried out to the product, process & analytical method - A review of results of stability monitoring program - A list of validated analytical & manufacturing procedures & their revalidation dates	√	√	√
	4. <u>Applicant Commitments:</u> -Fill the required data in the form of **(Annex II)** N.B.: API(s) manufacturer should be the same as stated in CTD Section 3.2. S.2.1: Drug Substance Manufacturer(s) in case of products imported from reference countries or in products if quality module format is a requirement for registration)	√	√	√

	5. <u>Outsourcing Documents:</u> - **Stability performer EDA-license** - **Stability study contract** attached with: • Annex for product name, strength and dosage form, and performed test(s) • Both contract and annex must be legalized (bank signatures and EDA legal affairs) - **Microbiological testing contract**, submit one of the following options: **• Option 1:** - Valid, legalized and signed contract (bank signatures and / or EDA legal affairs) between the stability testing site and EDA-licensed microbiological testing organizations (St. centers, reference lab., ph. factories). - Contract shall clarify the type of microbiological tests. - Annex for product name, strength and dosage form, and performed test(s). **• Option 2:** - Valid, legalized and signed contract (bank signatures and / or EDA legal affairs) between the stability testing site and EDA-licensed microbiological testing organizations (St. centers, reference lab., ph. factories). - Contract shall clarify the type of microbiological tests. - Original stamped hard copies of microbiological tests certificates shall be handed to responsible administrator.		If local stability performer differs from local applicant or finished product manufacturer		
	6. <u>Fees:</u> - Payment code / Receipt copy		**In case of change in the following from last stability approval / reg. license):** 1- Shelf-life extension 2- Storage conditions 3- In-use duration / conditions		
Technical Documents Folder					
	Composition	-Refer to Annex I for full details	√	√	√

	Brand leaflet (i.e., Generic reference product SmPC (Summary of product characteristics)	Brand leaflet / SmPC in English with highlighted shelf life, storage conditions, in-use (after opening/after dilution/after reconstitution) shelf life and storage conditions, solvents used and their volume (if applicable), diluents used and their volume (if applicable)/package	√	√	√
	Post approval stability protocol and stability commitment	(**Annex IX**) • Commitment for continuing stability studies of: 1. Long term on same batches submitted for accelerated studies + proposed protocol 2.On-going stability studies+ proposed protocol 3.Declaration letter to inform stability general administration in case of OOS in ongoing stability & long term in case of variation	√	√	√
	Declaration letter	Declaration letter from License Holder stating the shelf life, storage conditions, pack and in use in case of missing information in CPP	√	√	√

Required stability Sections in quality module

(required in case of products imported from reference countries or in products in which the CTD format is a requirement for registration)

Required CTD module	**P-Part**	• 3.2.S Drug substance (or active pharmaceutical ingredient (API) • Section 3.2.S.2.1: Drug Substance Manufacturer(s) • Impurities S.3.2 if needed • 3.2.S.4.4 Batch analysis – If needed • Section 3.2.P.1: Description and Composition of the Drug Product • 3.2.P.2.6 Compatibility (name, dosage form) if needed • Section 3.2.P.3.3: Description of manufacturing process content (If needed) e.g. In case of mottling and holding time stability • Section 3.2.P.5.1: Drug Product Specification(s) • Section 3.2.P.5.2 Analytical procedure • Section 3.2.P.5.3 Validation of analytical procedure • Section 3.2.P.5.4: Batch Analyses • Section 3.2.P.5.5: Characteristics of impurities • Section 3.2.P.5.6: Justification of Specification(s) • Section 3.2.P.6 reference standard • Section 3.2.P.7: Container Closure System Section 3.2.P.8.1: Stability Summary and Conclusion (annex **VI**) • Section 3.2.P.8.2: Post-approval Stability Protocol and Stability Commitment (Annex **IX**) • Section 3.2.P.8.3: Stability Data	√	√	√

Note:
-The maximum holding time for bulk FPP (product prior to final packaging, e.g. tablets in HDPE drums) should be stated. The holding time should be supported by the submission of stability data, if longer than 30 days. For an aseptically processed FPP, sterile filtration of the bulk and filling into final containers should preferably be continuous; any holding time should be justified.
(Reference TRS 986 ANNEX 6)

-Any in-use period and associated storage conditions should be justified with experimental data, for example after opening, reconstitution and/or dilution of any sterile and/or multidose products or after first opening of FPPs packed in bulk multidose containers (e.g. bottles of 1000s). If applicable, the in-use period and storage conditions should be stated in the product information.
(Reference TRS 986 ANNEX 6)

	3.2.P.2.6 Compatibility	• 3.2.P.2.6 The compatibility of the FPP with reconstitution diluent(s) or dosage devices (e.g. precipitation of API in solution, sorption on injection vessels, stability) should be addressed to provide appropriate and supportive information for the labelling (if needed) • Where sterile, reconstituted products are to be further diluted, compatibility should be demonstrated with all diluents over the range of dilution proposed in the labelling. These studies should preferably be conducted on aged samples. (if needed) • Studies should cover the duration of storage reported in the labelling (e.g. 24 hours under controlled room temperature and 72 hours under refrigeration).			
	Finished product specifications (3.2.P.5.1)	**(Annex **III**) • should be presented by stability testing site signed and stamped • Should clearly include product name, dosage form, concentration (if applicable) • Should include list of tests, acceptance criteria and reference for both analytical procedures and acceptance criteria • Should include method of analysis for each mentioned test • <u>Should include the following:</u> ✓Physical analysis (Color, shape, size. Scoring, mottling (justification for mottling is required with detailed manufacturing process flow chart) for solid dosage form ✓(clarity, homogeneity, opalescence, color for liquid dosage form	√	√	√

		✓Chemical analysis; Should include assay of active ingredient(s), quantitation of impurities and related substances,and assay of preservative(s), stabilizers, chelating agents and/or antioxidant(s) (when applicable) antibiotics Microbiological analysis (when applicable) ✓Biological analysis (when applicable) e.g.: enzymes /Biocides. ✓Performance test: dissolution, viscosity, aerodynamic particle size for inhalers, granules, suspension, powder &antiseptic effectiveness test (antiseptic & disinfectant) Functionality test (administration-dependent functional performance characteristics) for packaging/devices in case of combination product (e.g. spray, inhalers, prefilled syringe…etc.) Additional consideration for combination product with a medical device Example of functionality test (dose delivery per actuation) Notes: • Any skip test should be mentioned as a footnote • Limit for any test should be specified as release and /or shelf specs (only) • Residual solvents should be included (if present in product formula) (release specifications) *(it should be the same as stated in CTD Section 3.2.P.5.1: Drug Product Specification(s) in case of products imported from reference countries or in products in which the CTD format is a requirement for registration)			

N.B:
The required tests for each dosage form should
*Comply with the "EDA Guidelines for technical assessment of finished pharmaceutical products for human use files".
Comply with TRS1010 Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical products".
ICHQ6A specifications: Test procedures and acceptance criteria for new drug substances and new drug products Chemical substances-scientific guidelines

	Method of analysis (3.2.P.5.2) For both finished product Specification and /or API	• Should be presented by stability testing site signed and stamped • Should include stability-indicating analytical-procedures used for physical, chemical and microbiological analysis • Should follow analytical procedurefound in a pharmacopoeia (if having pharmacopeial reference) **Notes:** ✓ Please attach and fill Annex (**IV**) in related analysis procedure if there's no pharmacopeial reference for product and ICH guidelines is being followed or CTD part characterization of impurities (P.5.5 and/or S.3.2) ✓ Justification should be submitted to clarify any deviation from the ICH limits. • Procedure for test done in stability studies only should be heighlighted &submitted in full details	√	√	√

	3-Method References + commitments	• Most updated monograph for finished product should be submitted. • Commitment from stability testing site that method of analysis submitted for assay/ related/anti-oxidant/chelating agent/stabilizer/preservative is the same method of analysis submitted and validated in CADC (last updated guidelines for file assessment for pharmaceutical products for human use). • If a test is done in stability only, all documents should be submitted (procedure/validation and results), and justification of adopting new methods.	√	√	√

Assay &Validation protocol & Charts Folder for both locally manufactured products & imported from non-reference countries	4-Assay chromatograms	• Should include product name, batch number and injection date/time • Should include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) chelating agent / stabilizer and/or antioxidant(s) (when applicable) &/or dissolution • Should include 3 injections for standard and test ateach time interval • System suitability charts should be included. • Should be stamped by stability testing site **Notes**: • Each time interval should be in a separate pdf	√	√	√
	5-Validation of analytical procedure	• Should include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content ofpreservative(s) stabilizer, chelating agent and/or antioxidant(s) (when applicable) &/or dissolution • Validation data in section P.5.3 in CTD /similar to that presented and approved by CADC • In case of new method applied in stability dossier differs than that in section p.5.3, complete method validation data should be submitted • In case of variation of composition (additional of excipients /change of amount of excipients /grade s) revalidation of method should be submitted • In case of site transfer in variation (apply method transfer requirements according to USP 1224)	√	√	√

		In Case of Full Validation Data • Complete validation of analytical procedures Should be conducted • the following validation characteristics should be submitted: specificity, precision, linearity, accuracy, ruggedness and robustness • Results for each validation parameter should be summarized in a tabulated form • In case of analytical procedure used, found in a pharmacopoeia, verification of analytical procedures Should be conducted in which the following validation characteristics should be considered including: specificity, precision and Accuracy (as required in USP 1226) For Quantitative test (e.g.: individual and total degradation products) it should be ensured that the actual numerical results are provided rather than range statement such as within the limit or conform. **<u>Notes:</u>** • Regarding stress conditions stability study, please apply conditions drastic enough to yield 10-30% degradation and fill Annex VII (TRS 929 annex 5) • Reference and scientific evidence should be submitted for products found to be stable in stress conditions stability study • If an officially recognized compendial method is used to control related substance that are not specified in the monograph, full validation of the method is expected with respect to those related substances. • If an officially recognized compendial standard is claimed and an in house method is used in lieu of the compendial method e.g.: for assay or related compounds), equivalency of in house and compendial method should demonstrated this could be accomplished by performing duplicated analysis one sample by both methods and providing the results for the study. In case of stability method change or addition of new sections; method equivalency should be provided			

	Validation chromatograms (3.2.P.5.3)	• Should 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)/dissolution • Should be stamped by stability testing site • <u>Should include the following:</u> ✓ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidationare required in addition to placebo and blank injections ✓ Minimum number of injections required for precision: 6 injections are required ✓ Minimum number of injections required for linearity: 5 concentrations are recommended with 1 injection required for each concentration ✓ Minimum number of injections required for accuracy: 3 concentrations are recommended with 3 injections requiredfor each concentration ✓ Minimum number of injections required for ruggedness: 3 injections are required for each random variation ✓ For robustness: 3 injections are required for each small variation in methodparameters **<u>Notes</u>**: • Each tested validation parameter should be in a separate pdf • Charts for stress conditions stability study (Should be for each API separately) should be with acceptable resolution showing peaks of active and degradation products • Chromatograms required for verification • Chromatograms required for method transfer	√	√	√
	3.2.P.6 Reference standards or materials (name, dosage form)	• Certificate of RS used in method of analysis (primary or secondary standard) As required in TRS 986/Annex 6 or as CTD assessment is sections S.5/P.6	√	√	√

	3.2.P.7 Container-closure system (name, dosage form)	• COA of primary packaging /device in case of combination products.			

	Stability study table(s)(3.2.P.8.3)	• Should be presented by stability testing site signed and stamped • Should clearly state product name, dosage form, concentration (if applicable), batch numberon which stability study was done, manufacturing and expiry date, date of starting stability study in case of being different than manufacturing date, study conditions, testing intervals and product pack in details batch size and batch type. • Should include results within shelf-life specifications • <u>Should include the following</u>: ✓ Physical analysis ✓ Chemical analysis: ✓ Microbiological analysis ✓ Biological analysis (when applicable) • <u>May include (when applicable):</u> In case of **<u>In-use stability study</u>** (A minimum of two batches, at least pilot scale batches, should be subjected to the test. At least one of the batches should be chosen towards the end of its shelf life.) • **<u>Antimicrobial preservative effectiveness</u>** test in case of presence of preservatives. • Bulk stability studies for bulk should be provided (if needed) • Comparative stability table in case of variation studies should be submitted (annex **VII**) • Long term stability studies including holding time (if present). • Statistical analysis data should be submitted if applicable • Justification of any significant should be submitted if applicable Multi container volume (Packaging Material) - In case of applying matrixing or bracketing; the design table, justification of the design, the design table data/ statistical analysis and data if applicable. (Annex **VIII**) In case of matrixing or bracketing of packaging submit with COA of supplies of packaging material of different containers including in the design • Summary of study should be submitted according	√	√	√

		to annex **VI** **Notes** • Dissolution results should be expressed as (average and range of individual results) for each individual time interval • Any out of specifications results should be scientifically justified • Any out of trend should be scientifically justified • Data should be presented either in tables, graphs or both. • Any significant change should be justified Any skipped test Should be scientifically justified			

Stability File Content for Veterinary, Herbal and Biocides Pharmaceutical Products

Folder name	Description and requirements (if applicable)	Veterinary	Herbal / complementary	Biocides
		Under-Registration Renewal / Re-registration Post approval (Var., License req., Stability approval)		
Regulatory documents				
Preliminary approval for Registration with attached composition "if applicable"	-	NA in case of variation / re-registration		
Naming Approval "if applicable"	(i.e. Herbal)	NA in case of variation / re-registration		
Approval for Re-registration and/ or transfer letter	-	--NA in case of under-registration -Applicable in case of re-registration - Applicable in case of variation if reg. license is non- valid		
Registration License and attached composition	-	NA in case of under-registration		
- Extension approval	(If needed)	Required in all cases (If needed)		
- CPP / free sale	with its attached SmPC (Summary of product characteristics) / Insert	Required in imported products		
- API COAs	Active Pharmaceutical Ingredient(s) (API(s)) supplier's certificate(s) of analysis / analyses	NA in case of variation / re-registration		

	(COAs)	
- Pack COAs	Product's (all volumes / all pack sizes) packaging materials (primary, secondary (if functional)) supplier's certificate(s) of analysis / analyses.	
EDA reports:	- Previous stability study / studies approval(s) with its attachment(s) - Recent variation approval(s) with its attachment(s) - Central administration of operations (CAO) report of submitted batch(es) - Central Administration of Drug Control (CADC) **detailed** final report of submitted batch(es) with its attachment(s) - Central Administration of Drug Control (CADC) **renewal certificate of the analysis file** for a registered pharmaceutical product with its attachment(s)	all available reports
Outsourcing Documents	- **Stability performer EDA-license** - **Stability study contract** attached with: • Annex for product name, strength and dosage form, and performed test(s) • Both contract and annex must be legalized (bank signatures and EDA legal affairs) - **Microbiological testing contract**, submit one of the following options: **• Option 1:** - Valid, legalized and signed contract (bank signatures and / or EDA legal affairs) between the stability testing site and EDA-licensed microbiological testing organizations (St. centers, reference lab., ph. factories). - Contract shall clarify the type of microbiological tests. - Annex for product name, strength and dosage form, and performed test(s). **• Option 2:** - Valid, legalized and signed contract (bank signatures and / or EDA legal affairs) between the stability testing site and EDA-licensed microbiological testing organizations (St. centers, reference lab., ph. factories). - Contract shall clarify the type of microbiological tests. - Original stamped hard copies of microbiological tests certificates shall be handed to responsible administrator.	If local stability performer differs from local applicant or finished product manufacturer

Fees	Payment code / Receipt copy	**In case of change in the following from last stability approval / reg. license):** 1- Shelf-life extension 2- Storage conditions 3- In-use duration / conditions
Commitments	Fill the required data in the form of **(Annex II)**	
Technical Documents		
Composition	(Annex **I**)	NA in case of biocides Herbal API: must to be written in details as the approved herbal registration) refer to annex I for more Details
Finished product specifications*	(Annex **III**)	Required • (In case of Vet: should comply with VICH GL39 specifications, test procedures and acceptance criteria for new veterinary drug substance and new medicinal products; chemical substances. • In case of herbal: 1- It should comply with EDA guidelines for Registration of herbal pharmaceuticals 2- EMA Guidelines of specifications test procedures and acceptance criteria for herbal substances, herbal preparations, and herbal medicinal products/ traditional herbal medicinal products scientific guidelines In Case of Biocides: (Biocides -Antiseptics-Disinfectants) references
Certificate of analysis	Recent COA of FPP	Required Antiseptic effectiveness test is required in case of antiseptic
Method of analysis	Detailed method with reference	Required
Stability study table(s)	(Annex **VI)**	Required
References + commitments	• Most updated monograph for finished product should be submitted “if present “ • Pharmacopeia references with highlighted limits (if applicable)	Required If applicable
Assay chromatograms	• Should include product name, batch number and injection date/time • Should include chromatograms of assay of active ingredient(s), quantitation of impurities and related substances, and content of preservative(s) chelating agent /	Required if applicable

	stabilizer and/or antioxidant(s) (when applicable) &/or dissolution • Should include 3 injections for standard and test ateach time interval • System suitability charts should be included. • Should be stamped by stability testing site **Notes**: Each time interval should be in a separate pdf	
Validation of analytical procedure	• Should include validation of analytical procedures for assay of active ingredient(s), quantitation of impurities and related substances, and content ofpreservative(s) stabilizer, chelating agent and/or antioxidant(s) (when applicable) &/or dissolution • Validation data similar to that presented and approved by CADC • In case of new method applied in stability dossier differs than that used in release complete method validation data should be submitted • In case of variation of composition (additional of excipients /change of amount of excipients /grade s) revalidation of method should be submitted • In case of site transfer in variation (apply method transfer requirements according to USP 1224)	Required if applicable -Declaration that these methods and their validations are the same submitted and approved by CADC if applicable
Validation chromatograms	• Should 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)/dissolution • Should be stamped by stability testing site • Should include the following: ✓ For specificity: injections for samples stored under relevant stress conditions: light, heat, humidity, acid/base hydrolysis and oxidationare required in addition to placebo and blank injections ✓ Minimum number of injections required for precision: 6 injections are required ✓ Minimum number of injections required for linearity: 5 concentrations	Required if applicable

	are recommended with 1 injection required for each concentration ✓ Minimum number of injections required for accuracy: 3 concentrations are recommended with 3 injections requiredfor each concentration ✓ Minimum number of injections required for ruggedness: 3 injections are required for each random variation ✓ For robustness: 3 injections are required for each small variation in method parameters **Notes**: • Each tested validation parameter should be in a separate pdf • Charts for stress conditions stability study (Should be for each API separately) should be with acceptable resolution showing peaks of active and degradation products • Chromatograms required for verification Chromatograms required for method transfer	
Reference standard certificate	• Certificate of RS used in method of analysis (primary or secondary standard) • Standard in case of herbal	Required
Calculation sheets	For all stability study intervals	Required in all cases
In-use stability study	(A minimum of two batches, at least pilot scale batches, should be subjected to the test. At least one of the batches should be chosen towards the end of its shelf life.)	If required
Bracketing & Matrixing	In case of applying matrixing or bracketing; the design table, justification of the design, the design table data/ statistical analysis and data if applicable. (Annex **VIII**) In case of matrixing or bracketing of packaging submit with COA of supplies of packaging material of different containers including in the design • Summary of study should be submitted according to annex **VI**	Required if applicable

Brand leaflet (i.e., Generic reference product SmPC (Summary of product characteristics)	Brand leaflet / SmPC in English with highlighted shelf life, storage conditions, in- use (after opening/after dilution/after reconstitution) shelf life and storage conditions, solvents used and their volume (if applicable), diluents used and their volume (if applicable)/package	If Applicable

References TRS 986 annex 6

- Technical Report series 1010 Annex 10,2018
- In-use stability testing EDAFAQ-2024
- Guidelines for technical assessment of finished pharmaceutical products for human use files-EDA.
- ICH Q6A Specifications
- References (ICH Q1A-D) bracketing and matrixing study designs
- ICH Q2&14 analytical procedures development
- TRS 992 annex 4 general guidance on hold time study
- TRS 928 annex 5 guidance for registration of fixed dose combination
- VICH QL3,GL4,QL5,G7,GL45,GL81,GL58
- Notes to applicant (Requirements for post approval stability studies submission (shelf life Extension/Change In-Use Study/Change in stability storage conditions2024)
- EDA FAQ on stability studies for veterinary products
- Egyptian guidelines for registration of herbal medicine 2021

Annexes

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Annex I

Composition Certificate

Trade Name & Dosage form	This section to be filled by the Applicant company

The description of the finished product included a physical description, the proposed strength and dosage form is submitted.

Composition of the dosage form: (p.3.1)

Ingredient(s)	Amount/ Unit	Percentage % w/w or % w/v	Function	Reference (Compendial or In-house)
API				
Excipient				
Total weight / Volume				

Applicant Company Signature, Date & Stamp:

Notes:

1- *This template should be copied and submitted on Applicant Company letterhead.*
2- *API (s), it's (their) hydrate(s) and salt form(s) with its (their) quantity (ies) per unit dose is (are) specified.*
3- *Grades of excipient should be mentioned beside excipient name.*
4- *Coat or Capsule Shell should be mentioned separate from the core or capsule content.*
5- *Weight of core tablet or content of capsule should be mentioned separately from total weight.*
6- *Solvents and Nitrogen Gas(its grade) used during manufacturing process: should be declared.*
7- *Composition of all components used as mixtures should be mentioned in details and submitted on supplier's Letterhead (e.g. Pellets, premixes, colorants, coatings, capsule shells and imprinting inks).*
8- *The Overage should be mentioned, and justification should be submitted on a separate document.*
9- *Reconstitution Solvents should be mentioned if present. (Not applicable for solvents with registration license).*
10- *In case of Pellets & Premix: composition on supplier letterhead should be attached. (template 4)*
11- *In case of presence of iso-tonicity agent, calculation for osmolality should be submitted*
12- *In Case of API equivalence (calculation of equivalence should be submitted)*
13- *In case of varying amount of API according to potency (equation for calculation should be stated in the footnote and the component which compensate change should be mentioned (template 4)*

- **Declaration states reference drug product used in developmental studies / BE approval**

Applicant Company:	This section to be filled by the Applicant company
Trade Name:	This section to be filled by the Applicant company
Generic Name(s) + Strength(s):	This section to be filled by the Applicant company
Dosage Form:	This section to be filled by the Applicant company

Reference Product Details:

Reference Drug Product	
Name, strength and dosage form of reference Product	This section to be filled by the Applicant company
Name of MAH, Manufacturer and Country of origin	This section to be filled by the Applicant company

Applicant Company Signature, Date & Stamp:

- **Calculation of Equivalent base of API/ Semi-Finished or Intermediate product -Quantity of pellets / Premix**

Applicant Company:	This section to be filled by the Applicant company
Trade Name:	This section to be filled by the Applicant company
Generic Name(s) + Strength(s):	This section to be filled by the Applicant company
Dosage Form:	This section to be filled by the Applicant company

Detailed Calculations should be provided:

Applicant Company Signature, Date & Stamp:

Annex II

Applicant Commitments

Header (Official Applicant's Document Template)

Finished Product	**Name**	.....	
	Concentration	.....	
	Dosage Form	.....	
	Batch No.	.....	
	Batch Type / Size	.....	
API(s)	**API Name**	**Manufacturer**	**Country of Origin**
	1.	.....	.....
	2.	.....	.....
	3.	.....	.....
Commitment of Responsibility-COR (*for local products only*)	**We commit the authenticity / accuracy of all submitted stability study data and are fully responsible for it.**	**Lab. Analyst signature**	.....
		Lab. Supervisor signature	.....
		Lab. Manager signature	.....
		Stability Performer Stamp	.....
Commitment of Authenticity (*for imported products only*)	**We commit the authenticity / accuracy of all submitted stability study data and are fully responsible for it.**		
Commitment of Storage Conditions (*for local / imported products*)	**We commit that the product will be stored at a temperature that does not exceed the approved temperatures specified in the stability study approval, and also obligates all distributors to do so in their warehouses and in their dealings with pharmacies that comply with these requirements.**		

Applicant's Authorized Person **Signature & Date** Applicant's **Stamp**

Footer (Official Applicant's Document Template)

Annex III

Finished Product Specifications:

Product name, Conc. (if applicable) & Dosage form					
Test/	**Method**	**Acceptance criteria**		**Reference**	
		Release specification	**Shelf Specification**	**Analytical procedure**	**Acceptance criteria**
Description					
Identification					
Impurities					
Assay					
etc.					

***in case of difference between release and shelf specification, justification needed.**

Annex IV

Impurities ICH calculations

Maximum daily dose for "API"	**<x mg/day>**		
	Parameter	**ICH threshold or concentration limit**	**Observed results**
Each Degradation product	Reporting Threshold		
	Identification Threshold		
	Qualification Threshold		

Maximum daily dose (i.e. the amount of API administered per day) for the API, corresponding ICH Reporting/Identification/Qualification Thresholds for the degradation products in the FPP

Annex V

Stress conditions stability study results

Stress Type	Conditions /parameters used	Duration	Degradation %
Acidic			
Alkaline			
Oxidative			
Heating			
Light			
Photostability			
Others (Freeze/Thaw) cycles			

Annex VI

Stability Summary Table

STABILITY ANALYTICAL RECORD

Sample Name:
Lot#:
Study #:
Protocol #:
Study Start Date:
Study Purpose:

Manufacturing Date:
Manufacturing Site:
Expiration Date:
Testing Site:
Packaging Site:

Storage condition:
Sample Orientation (if applicable):
Packaging Information:
Packaging Date:

Test Name	Method	Acceptance Criteria	Time Zero	1 Mo	2 Mo	3 Mo	6 Mo	9 Mo	12 Mo
Pull Date									
Test Date									
Appearance									
Assay									
Impurities Individual Total									
Dissolution Average % RSD Range									
Moisture									
Completed By:						Date:			
Reviewed By:						Date:			
Approved By:						Date:			

*If OSS or trend in data is present a scientific justification should be submitted

Annex VII

Comparative stability table

Comparative Stability Data Sheet (Template)

Parameter / Specification	Old Specification & Method	New Specification & Method	Comparative Stability Data	Conclusion
Assay (API content)	Spec: _____ Method: _____	Spec: _____ Method: _____	Long-term (30°C/65% RH): _____ Accelerated (40°C/75% RH): _____	_____
Impurities	Spec: _____ Method: _____	Spec: _____ Method: _____	Comparative impurity profile: _____	_____ _____
Dissolution	Spec: _____ Method: _____	Spec: _____ Method: _____	Results: _____	_____
Other Quality Attributes (e.g., water content, hardness, friability, pH)	Spec: _____ Method: _____	Spec: _____ Method: _____	Comparative results: _____	_____
Packaging-related stability (if applicable)	Spec: _____ Method: _____	Spec: _____ Method: _____	Comparative data under storage conditions: _____	_____

Annex VIII

Bracketing & Matrixing

Bracketing is defined as the design of a stability schedule such that only samples on the extremes of certain design factors, e.g., strength, package size, are tested at all-time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. Where a range of strengths is to be tested, bracketing is applicable if the strengths are identical or very closely related in composition (e.g., for a tablet range made with different compression weights of a similar basic granulation, or a capsule range made by filling different plug fill weights of the same basic composition into different size capsule shells). Bracketing can be applied to different container sizes or different fills in the same container closure system

Design Example										
Table: Example of a bracketing Design								**Total=27** **Tested=12**		
Strength		**50mg**			**75 mg**			**100 mg**		
Batch		**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
Container Size	**15ml**	**T**	**T**	**T**				**T**	**T**	**T**
	100 ml									
	500 ml	**T**	**T**	**T**				**T**	**T**	**T**
Key: T=Sample Tested										

Matrixing is defined as the design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations is tested at a specified time point. At a subsequent time, point, another subset of samples for all factor combinations is tested. The design assumes that the stability of each subset of samples tested represents the stability of all samples at a given time point. The differences in the samples for the same drug product should be identified as, for example, covering different batches, different strengths, different sizes of the same container closure system, and, possibly in some cases, different container closure systems. *In case of bracketing and Matrixing study design and tables should be included.

Design Example

Table: Example of a Matrixing Design "One Third Reduction"									**Total=48 1/3=16 Reduced=10**
Time Point (months)			**0**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Strength	**S1**	**Batch 1**	**T**	**T**		**T**	**T**		**T**	**T**
		Batch 2	**T**	**T**	**T**		**T**	**T**		**T**
		Batch 3	**T**		**T**	**T**	**T**	**T**	**T**	**T**
	S2	**Batch 1**	**T**		**T**	**T**	**T**	**T**	**T**	**T**
		Batch 2	**T**	**T**		**T**	**T**		**T**	**T**
		Batch 3	**T**	**T**	**T**		**T**	**T**		**T**

Key: T=Sample Tested

Design Example

Table: Example of a Matrixing Design "One Third Reduction"									**Total=48 1/3=16 Reduced=10**
Time Point (months)			**0**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Strength	**S1**	**Batch 1**	**T**	**T**		**T**	**T**		**T**	**T**
		Batch 2	**T**	**T**	**T**		**T**	**T**		**T**
		Batch 3	**T**		**T**	**T**	**T**	**T**	**T**	**T**
	S2	**Batch 1**	**T**		**T**	**T**	**T**	**T**	**T**	**T**
		Batch 2	**T**	**T**		**T**	**T**		**T**	**T**
		Batch 3	**T**	**T**	**T**		**T**	**T**		**T**

Key: T=Sample Tested

Annex IX

Stability Commitment

Post-approval Stability Protocol and Stability Commitment

For presentation to concerned authorities of the Arab Republic of Egypt

We **(Applicant)** as Marketing Authorization Holder of **(Product name)**, that is to be registered and marketed in Egypt, confirm the following recommended shelf life, storage conditions and container closure system for this product, based on the present knowledge confirmed by updated long-term stability studies:

Packaging material	Shelf-life	Storage conditions

We commit to ----------

- The application of Stability Studies on Commercial scale Production batches and ongoing Stability studies following the same protocol used in primary batches stability concerning test items, acceptance criteria& frequency of testing**.**
- To complete the ongoing stability study for the product after finishing the long-term stability study of production batches
- To complete shelf study (12 and/ or 24 months) on the submitted pilot batches

Annex x

تعهد

بالنسبة للمستحضر التي :

نتعهد نحن شركة /مكتب علمي ..... بالإبلاغ عند حدوث أي حيود في دراسات الثبات الخاصة بالمستحضرات في

Ongoing stability & long term in case of variation

History of Change:

Versions (Effective Date)	Updated Sections	Summary of changes
21/8/2024(new issue)		
6/8/2026	Documentation and fulfilment requirements	-Change of title of notice to applicant -Clarification of required CTD module for stability evaluation in case of local & imported drugs -Updating Annexes -Adding Annexes (II,VI,VII,IX,X) -Removal of (requirements of human under registration – 3.2.S Drug substance or API - Certificate of analysis of stability batches for API/Intermediate due to one submission requirement) -Updating the regulatory & technical document in case of herbal ,veterinary & biocides pharmaceutical products.