unit: Reception

BIOLOGICAL MEDICINAL PRODUCTS FOR HUMAN USE

APPLICATION FORM FOR RENEWAL PRODUCT SUBMISSION

This application form is to be used for the submission of a Biological medicinal product for Renewal & it should be filled and sent to the Egyptian Drug Authority together with the relevant data as described in Checklist

Please note that application fees are non-refundable in the event that you cannot meet requirements to enable the evaluation to proceed

<u>This part is to be filled with EDA officials only:</u>

Submission date (dd/mm/yyyy):	
Submission Time (hh:mm):	

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unit: Reception

1.1 PRODUCT DETAILS

1.1.1 Commercial or trade name.
(The name under which the product will be marketed and its strength.)

Commercial or trade name in the country of origin
(For imported products with different name in the country of origin than that proposed to Egypt)

1.1.2 Pharmaceutical form:
(Indicate the pharmaceutical form, for example, injectable solution, lyophilized powder for injectable suspension.)

1.1.3 Physical description of the Pharmaceutical form:
(Indicate for example the tablets color)

1.1.4 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s):
(Give full qualitative & quantitative composition in terms of active substances & Excipients, a note should be given as to which quantity the composition refers (e.g. 1 capsule), list the active substance(s) separately from the excipient(s))

Each contains:

Name of active substance(s)*	Quantity / Volume	Unit	Function	Reference /Monograph standard

Name of excipient(s)*	Quantity /volume	Unit	Function	Reference /Monograph standard

*** Details of any overages should not be included in the formulation columns but stated below:**
- Active substance(s):
- Excipient(s):

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unit: Reception

1.1.5 Commercial presentation (package) of the Product.
(Describe the package, indicate the package size & if it contains any additional accessories, for example whether the product is offered for sale in single or multiple doses presentation and whether it will be distributed in a single package or in a multi-unit package)

1.1.6 Therapeutic main group & Pharmacotherapeutic subgroup & indications
Therapeutic main Group:
Pharmacotherapeutic subgroup:
Indications:

1.1.7 Route(s) of administration

1.1.8 Dose & dose regimen

1.1.9 Container, closure and administration device(s) or accessories

1.1.9.1 Primary (Inner) pack (Which is in direct contact with the product dosage form)
1.1. 9.1.1 Description & the material from which it is made:

1.1. 9.2 Secondary (Outer) pack
1.1. 9.2.1 Description & the material from which it is made:

1.1. 9.3 Closure system
1.1. 9.3.1 Description & the material from which it is made:

1.1.9.4 Administration devices or accessories
1.1. 9.4.1 Description & the material from which it is made:

1.1. 9.5 proposed shelf life:

1.1. 9.6 proposed shelf life (after first opening container):

1.1. 9.7 proposed shelf life (after reconstitution or dilution):

1.1. 9.8 proposed storage conditions:
(Indicate the storage temperature for the product and any other storage conditions, for example: protect from light, do not freeze)

1.1. 9.9 proposed storage conditions after first opening:

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unit: Reception

1.2 TYPE OF APPLICATION

1.2.1 Proposed marketing status for the product

- ☐ For local market
- ☐ For exportation only

1.2.2 Type of license

- ☐ Local
- ☐ Toll
- ☐ Imported
- ☐ Under license
- ☐ Bulk

1.3 APPLICANT / MARKETING AUTHORISATION HOLDER / CONTACT PERSONS

1.3.1 Applicant company:
(Proposed marketing authorization holder legally responsible for placing the product on the Egyptian market)
(Company) Name:
Address:
Telephone:
Fax:
E-Mail:
Legal entity:

- ☐ Manufacturer of the final product
- ☐ Toll Company
- ☐ Packaging company (in case of bulk products)
- ☐ Scientific office
- ☐ Agent
- ☐ Distributor

1.3.2 Person authorized for communication on behalf of the applicant during the procedure:
Name:
Telephone:
Fax:
E-Mail:

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التـــلـيـــفـــــون: 0237484988

unit: Reception

Degree:
Position:

1.3.3 Market authorization holder in the country of origin (for imported products):
Name:
Address/country:
Telephone:
Fax:
E-Mail:

1.3.4 License holder in the country of origin (for imported products):
Name:
Address/country:
Telephone:
Fax:
E-Mail:

1.3.5 Qualified person for Pharmacovigilance
Name:
Degree :
Address:
Telephone:
Fax:
E-Mail:

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unit: Reception

1.4 MANUFACTURERS

Note: ALL-data mentioned throughout this section MUST be consistent regarding their names, detailed addresses and activities with CPP, Module 3 & Core file

1.4.1 Manufacturer(s) of the finished product and site(s) of manufacture:
Company name:
Address:
Country:
Telephone:
Fax:
E-Mail:

Brief description of functions performed:

Manufacturing authorisation number

Has the site been inspected for GMP Compliance by the regulatory authority?

❍ **No** ❍ **yes**

1.4.2 Manufacturer(s) involved in the production of accessories:
(Example for lyophilized products, mention the producer of the diluent)
Name:
Address/country:
Telephone:
Fax:
E-Mail:

Manufacturing authorisation number

Has the site been inspected for GMP Compliance by the regulatory authority?
❍ **No** ❍ **yes**

1.4.3 Packaging site(s)
(If different from the manufacturer of finished product or in case of bulk products, state the primary and secondary manufacturing site):
Name:
Address/country:

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التـــلـيـــفـــون: 0237484988

unit: Reception

Telephone:
Fax:
E-mail:

Brief description of functions performed:

Authorisation number

Has the site been inspected for GMP Compliance by the regulatory authority?
❍ No ❍Yes

1.4.4 Manufacturer(s) of the active substance(s) and site(s) of manufacture
(All manufacturing sites involved in the manufacturing process of each source of active substance. Brokers or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.
For each active substance specify:

Active Substance name:
Company name:
Address:
Country:
Telephone:
Fax:
E-Mail:

Brief description of manufacturing steps performed by manufacturing site:

Authorisation number

Has the site been inspected for GMP Compliance by the regulatory authority?
❍ No ❍ yes

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1.4.5 a) Authorized manufacturer(s) responsible for batch release of finished product

Company name:
Address:
Country:
Telephone:
Fax:
E-Mail:

Brief description of the functions & control tests carried out by the site:

Authorisation number:

b) Qualified Person responsible for batch release of finished product
(The person responsible for the release of the lots of the product)

Name:
Position:
Telephone:
Fax:
E-Mail:

1.4.6 Importer(s) of the finished product (for imported Products)

Name:
Address:
Telephone:
Fax:
E-Mail:
Authorisation number:

1.4.7 Storage sites of the finished product in Egypt

Name:
Address:
Telephone:
Fax:
E-Mail:
Authorisation number:

Has the site been inspected for GSP Compliance by the regulatory authority?

❍ **No** ❍ **yes**

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التـــلـيـــفـــــون: 0237484988

unit: Reception

1.4.8 Contact person for product defects and recalls

Name:
Address:
Telephone:
Fax:
E-Mail:

1.5 SCIENTIFIC REFERENCE

1.5 Scientific Reference:

Reference Name:
Edition / year:
Product name, composition, strength(s), pharmaceutical form(s) as mentioned the reference:
Manufacturer / Market authorization holder / license holder:

<u>For Imported products:</u>
Market authorisation number in the country of origin:
Date of issue of marketing authorisation:
Summary of the conditions under which the market authorization was granted by that regulatory authority:

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1.6 DECLARATIONS

In relation to this submission, I certify that to the best of my knowledge that:

***The data & information have been reviewed & are certified to be true & accurate**

***All existing data which are relevant to the quality, safety and efficacy of the Biological product will be supplied in the dossier, as appropriate**

***If the application is approved, I agree to comply with all applicable laws & regulations that apply to approved applications**

Signature of the Person authorized for communication on behalf of the applicant	**Typed name & title**	**Date**	**Official company stamp**
Signature of the head of registration department of the applicant company	**Typed name**	**Date**	

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