BIOLOGICAL MEDICINAL PRODUCTS FOR HUMAN USE

APPLICATION FORM FOR NEW PRODUCT SUBMISSION

This application form is to be used for submission of a Biological medicinal product to registration process & 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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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):

1.1.5 Commercial presentation (package) of the Product.

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(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 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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List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

NONE ☐

Name	Function* AS	EX	R	Animal origin susceptible to TSE	Other animal origin	Human origin	Certificate of suitability for TSE (Available Not Available)
1.	❍	❍	❍	❍	❍	❍	❍
2.	❍	❍	❍	❍	❍	❍	❍
3.	❍	❍	❍	❍	❍	❍	❍
4.	❍	❍	❍	❍	❍	❍	❍

(If available, State number)

*** AS=active substance, EX=excipient (incl. Starting materials used in the manufacture of the active substance/excipient),**
R=reagent/culture medium (incl. Those used in the preparation of master and working cell banks)

1.1.10 Is a certificate for a Plasma Master File (PMF) being used for this MAA? (* in case of blood products or

❍ **No** ❍ **yes**

If yes,
- **Substance referring to PMF:**

Function* AS	EX	R
❍	❍	❍

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1.2. TYPE OF APPLICATION

1.2.1 Proposed marketing status for the product

- ☐ **For local market**

1.2.2 Type of license

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

1.2.4 Comply decree number

- ☐ **343 for 2021**
- ☐ **820 for 2016:** **- EMA & FDA** **- EMA** **- FDA** **- CTD**

1.2.5 Application comply

- ☐ **Normal Track Guidelines**
- ☐ **Fast Track Guidelines**
- ☐ **Biosimilar Guidelines**
- ☐ **Second Brand Guidelines**

1.2.5 WHO Pre-qualification

- ☐ **Pre-qualified**
- ☐ **Not Pre-qualified**

1.3APPLICANT / 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:
E-Mail:
Legal entity:

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- ☐ **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:
E-Mail:

1.3.3 Market authorization holder in the country of origin (for imported products):
Name:
Address/country:

1.3.4 License holder in the country of origin (for imported products):
Name:
Address/country:

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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:
Brief description of functions performed:

1.4.2 Manufacturer(s) involved in the production of accessories:
(Example for lyophilized products, mention the producer of the diluent)
Name:
Address/country:
Brief description of functions performed:

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:
Brief description of functions performed:

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 preparation & manufacturing of master and working cell bank)
For each active substance specify:
Active Substance name:
Company name:
Address:
Country:
Brief description of manufacturing steps performed by manufacturing site:
Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):
❍ **No** ❍ **yes**
If yes,
- Substance:
- Reference number:

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

Company name:
Address:
Country:

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

1.4.5 b) Official batch release for <u>Blood Products and Vaccines</u>:

(Details of the Official Medicines Control Laboratory or laboratory designated for the purpose of official batch release in the country of origin in case of imported products)
Laboratory name:
Address:
Country:

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

Name:
Address:
Telephone:
E-Mail:

1.4.7 Storage sites of the finished product in Egypt

Name:
Address:
Telephone:

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:

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Summary of the conditions under which the market authorization was granted by that regulatory authority:

1.6 DOES THE SAME APPLICANT HOLD OTHER MARKETING AUTHORISATION(S) FOR A MEDICINAL PRODUCT(S) CONTAINING THE SAME ACTIVE SUBSTANCE(S) IN EGYPT?

❍ **No**

❍ **Yes**

- **Product name, strength, pharmaceutical form:**
- **Manufacturer / Market authorisation holder:**
- **Marketing authorisation number(s):**

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