BIOLOGICAL MEDICINAL PRODUCTS FOR HUMAN USE

APPLICATION FORM

This application form is to be used for an application for a marketing authorization of a Biological medicinal product for human use & it should be filled and sent to the Central administration of Pharmaceutical affaires, 21 Abdel Aziz Al Soud – El Manial together with the relevant data as described in the Application Guidelines for Registration of Human Medicinal Products

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

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

Application number:	
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.)

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

NONE ☐

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

*** 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)**

1.1.11 Is a certificate for a Plasma Master File (PMF) being used for this MAA?

❍ **No** ❍ **yes**

If yes,

- **Substance referring to PMF:**

Function*		
AS	EX	R
❍	❍	❍

- Name of the PMF Certificate Holder/ PMF Applicant:

- PMF Certificate 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)**

1.1.12 Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) ?

❍ **No** ❍ **Yes**

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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

1.2.3 This application concerns:

- ☐ Brand product
- ☐ Biosimilar product

Difference(s) compared to the Brand product:

- ☐ None
- ☐ Change(s) in the raw material(s)
- ☐ Change(s) in the manufacturing process(es)
- ☐ Change in therapeutic indication(s)
- ☐ Change in pharmaceutical form(s)
- ☐ Change in strength (quantitative change to the active substance(s))
- ☐ Change in route of administration(s)
- ☐ Other

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1.3APPLICANT / MARKETING AUTHORISATION HOLDER / CONTACT PERSONS

1.3.1 Applicant company:
(Proposed marketing authorisation 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:
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:

1.4 MANUFACTURERS

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

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 Other manufacturer(s) involved in the production of the Product:
(In the event that some parts of the manufacturing process are performed by a different company)
Name:
Address/country:
Telephone:
Fax:
E-Mail:
Fax:

Brief description of functions performed:

Manufacturing authorisation number

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

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1.4.3 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

1.4.4 Packaging site(s)
(If different from the manufacturer of finished product or in case of bulk products):
Name:
Address/country:
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

1.4.5 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, including quality control / in-process testing sites should be listed. 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. Only one manufacturer should be specified for each active ingredient)

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**

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

❍ **No** ❍ **yes**

If yes,
- Substance:
- Reference number:

Is an EMEA certificate for a Vaccine Antigen Master File (VAMF) being used for this MAA?

❍ **No** ❍ **yes**

If yes,
- Substance name:
- Name of the VAMF Certificate Holder/ VAMF Applicant:
- Reference number of Application/ Certificate:

1.4.6 a) Authorized manufacturer(s) (or importer(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:

1.4.6 b) Official batch release for Blood Products and Vaccines:

(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:
Telephone:
Fax:
E-Mail:

1.4.6 c) 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:

1.4.7 Batch control Testing arrangements

(Site(s) where batch control testing takes place)
Company name:
Address:
Country:
Telephone:
Fax:
E-Mail:
Brief description of control tests carried out by the laboratory (ies) concerned:

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1.4.8 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**

1.4.9 Contact person for product defects and recalls

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

1.4.10 Contract companies used for clinical trial(s) on bioavailability or used for the validation of blood product manufacturing processes.

For each contract company, state where analytical tests are performed and where clinical data are collected and give:

Title of the study:
Protocol code:
Name of the company:
Address:
Country:
Telephone:
Fax:
Email:
Duty performed according to contract:

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1.5 REFERENCE

1.5.1 Reference (The reference text book):

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

For Imported products:
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 LIST OF COUNTRIES WHERE THE PRODUCT HAS ALREADY BEEN LICENSED AND SUMMARY OF APPROVAL CONDITIONS

The list of countries where the product (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same company)is registered at the time the application for registration is submitted or, if there are none, the countries where registration is being processed.)

Country:
Product Name:
Date of authorization:
Authorisation number:

1.7 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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1.8 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 medicinal 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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1.9 LIST OF SUGGESTED NAMES OF THE PRODUCT

Application No.:……..

Date:.....

Generic Name(S):…….

Dosage Form:…… ……

Company Name:……..

No	To be Filled by Company		To be Filled by CAPA		
	English name	Arabic name	Reasons for Refusal	Checked by	Revised by
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

The Final Name after Revision:……..
Note: The names must be arranged by the company priority.

Declaration:

The Company acknowledges that the chosen name from the names provided above is the final name and not subject to amendment.

stamp

Applicant Signature
……..

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