**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**

**This part is to be filled with EDA officials only:**

|  |  |
| --- | --- |
| **Submission date (dd/mm/yyyy):** |  |
| **Submission Time (hh:mm):** |  |

**1.1. PRODUCT DETAILS**

* + 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. **Pharmaceutical form:**

**(Indicate the pharmaceutical form, for example, injectable solution, lyophilized powder for injectable suspension.)**

* + 1. **Physical description of the Pharmaceutical form:**

**(Indicate for example the tablets color)**

* + 1. **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 Unit Function Reference**

 **/ Volume /Monograph standard**

**Name of excipient(s)\* Quantity Unit Function Reference**

 **/volume /Monograph standard**

 **\* Details of any overages should not be included in the formulation columns but stated below:**

 **- Active substance(s):**

 **- Excipient(s):**

* + 1. **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. **Indications:**

* + 1. **Route(s) of administration**
		2. **Dose & dose regimen**
		3. **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:**

**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 Other Human Certificate of**

 **AS EX R susceptible to TSE animal origin origin 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. **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**

**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:**

 **[ ]  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:**

|  |
| --- |
|  |

**1.4 MANUFACTURERS**

**Note: ALLdata 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:**

**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 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:**

**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:**

 **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:**

**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):**