|  |
| --- |
| 1. **Product Information**
 |
| * 1. **Product name & Strength**
 |  |
| * 1. **Description/ Generic Name**
 |  |
| * 1. **Composition and concentration**
 |   |
| * 1. **Number of doses / Pack**
 |  |
| * 1. **Dosage form of the product:**
 |   |
| * 1. **Route of administration:**
 |  |
| * 1. **Commercial pack presentation:**
 |  |
| * 1. **Indication:**
 |  |
| * 1. **Country of Origin**
 |  |
| * 1. **International Accreditation**
 |  |
| * 1. **Reference**
 |  |
| * 1. **Approved / suggested Price**
 |  |
| * 1. **No. of Similar**
 |  |
| * 1. **Essential Drug List**
 |  |
| * 1. **Registration number/Date**
 |  |
| * 1. **Source of Active ingredient**
 |  |
| * 1. **Egyptian Immunization program (Mandatory).**
 |  |
| * 1. **Posology**
 |  |
| 1. **Manufacturers**
 |
| * 1. **Applicant company**
 |  |
| * 1. **License holder of the Product:**
 |  |
| * 1. **Manufacturer of the finished products :**
 |  |
| * 1. **Manufacturer of the Active substance:**
 |  |
| * 1. **Manufacturer responsible for packaging, Batch control & Batch release**
 |  |
| * 1. **Type of License:**
 |  |
| * 1. **Type of Marketing:**
 |  |
| 1. **Submission data**
 |
| * 1. **Decree of submission**
 |  |
| ***5*. Clinical Data (Attached)** |
| ***6.* Pre-Clinical Data (Attached)** |

**Scientific main appeal**

**Scientific summary report**

|  |
| --- |
| **Non- Clinical studies (Attached)** |
| **Clinical studies** |
|  |  |  |
|  | **t** |  |
|  |  |  |
|  |  |  |
|  **Clinical Data** |
| 1. **Title*:***

**Methodology*:*** |
| **Objectives** |  |
| **Study center(s)&duration** |  |
| **Dose** |  |
| **Route of Administration** |  |
| **Phase Type** |  |
| **Dose Regimen & Duration of Treatment** |  |
| **Patients / Healthy Volunteers (Subject criteria)** |  |
| **Evaluation criteria** |  |
| **Number of Subjects** |  |
| **Conclusion** |  |
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