|  |  |
| --- | --- |
| 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**

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| --- | --- | --- | --- | --- |
| **Non- Clinical studies (Attached)** | | | | |
| **Clinical studies** | | | | |
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|  |  |  | | |
| **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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