|  | **Medicine manufacturer Inspection and Law enforcement Lead executive office Of EFDA** | | | | **FORM- MMIE-LEO-062**  **SOP/MMIE-LEO PROC021**  **Revision No. 002** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Title | **SRA GMP Waiver Application form** | | | | | | | |
| **Part 1- Applicant information** | | | | | | | | |
| Date of Applications | | | |  | | | | |
| Name of Applicant | | | |  | | | | |
| Name of Product Registration Holder | | | |  | | | | |
| Name of Manufacturer | | | |  | | | | |
| Manufacturer Address | | | |  | | | | |
| Tel. No | | | |  | | | | |
| *Email* address | | | |  | | | | |
| Fax No | | | |  | | | | |
| **Part 2- Local agent information** | | | | | | | | |
| Name of local agent | | | |  | | | | |
| Address | | | |  | | | | |
| Tel.No | | | |  | | | | |
| *Email* address | | | |  | | | | |
| **Part C: Manufacturer Information** | | | | | | | | |
| *Manufacturer name* | | | |  | | | | |
| *Address* | | | |  | | | | |
| *Country* | | | |  | | | | |
| *Contact person of manufacturer* | | | | *Name:* | | | | |
| *Telephone:* | | | | |
| *Email:* | | | | |
| *Purpose of application* | | | | *New waiver application* | | | | |
| *Renewal waiver application* | | | | |
| ***Part 5: Scope of waiver application*** | | | | | | | | |
| *Select pharmaceutical dosage forms/ lines to be waived from GMP inspection ( tick the column in front of the dosage form)*  ***5.1. General Product production lines*** | | | | | | | | |
| *Small volume parental* | |  | *Granules ,powder, sachets* | | | | |  |
| *Large volume parental* | |  | *Non sterile External preparation (Cream, ointment, liquid, lotion)* | | | | |  |
| *Oral liquid* | |  | *Sterile (ointment, cream,)* | | | | |  |
| *Powder for oral suspension* | |  | *Eye drops* | | | | |  |
| *Tablet* | |  | *Nasal drops* | | | | |  |
| *Capsule (Soft gel, Hard gel)* | |  | *Ear drops* | | | | |  |
| *Powder, granules* | |  | *Others, specify:........................* | | | | |  |
| ***5.2. Penicilines production lines*** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| 5.3. **Cephalosporines production lines** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| **5.4. Penem Production lines** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| **5.6. Hormonal drugs production lines** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| 5.7. **Antineoplastic production lines** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| 5.8 **Biological medicinal products** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| 5.9. **Radiopharmaceuticals** | | | | | | | | |
| Small volume parental | |  | Granules ,powder, sachets | | | | |  |
| Large volume parental | |  | Non sterile External preparation (Cream, ointment, liquid, lotion) | | | | |  |
| Oral liquid | |  | Sterile (ointment, cream,) | | | | |  |
| Powder for oral suspension | |  | Eye drops | | | | |  |
| Tablet | |  | Nasal drops | | | | |  |
| Capsule (Soft gel, Hard gel) | |  | Ear drops | | | | |  |
| Powder, granules | |  | Others, specify:........................ | | | | |  |
| **Part 6-List of supporting documents** (please ensure that the following documents are attached together with this application | | | | | | | | |
|  | | | | | | Yes | NA | |
| Cover letter | | | | | |  |  | |
| Previous waiver cerificate ( if renewal) | | | | | |  |  | |
| Agency agreement with manufacturer or license holder | | | | | |  |  | |
| Manufacturer GMP certificate/ authenticated certificate | | | | | |  |  | |
| Site master file | | | | | |  |  | |
| Application form | | | | | |  |  | |
| Waiver Final payment | | | | | |  |  | |

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## Part D application declaration

1. I am here by authorized by the company to make this application
2. I have read and understood the content of GMP guidelines and registration guidelines of EFDA
3. I declare that the particulars given this application and the supporting documents are true or authentic or true copies and undertake to notify to EFDA within one week of any change in the particulars submitted in this application
4. I hereby confirm that I agree with any decision from EFDA regarding this application

Stamp

Full name…………..

Designation………………

Signature …………………