



ETHIOPIAN FOOD AND DRUG AUTHORITY

Guideline on Reliance for cGMP Inspection

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Abbreviations

cGMP	Current Good Manufacturing Practice
CoA	Certificate of Analysis
DART	Developmental and Reproductive Toxicology
DP	Drug Product
DS	Drug Substance
EC	European Commission
EMA	European Medicine Agency
eRIS	Electronic Regulatory Information System
GMP	Good Manufacturing Practice
ICH	International Council for Harmonization
MFID	Medicine Facility Inspection Directorate
NGO	Non-Governmental Organization
NRA	National Regulatory Authority
PPQ	Process performance Qualification
SAE	Serious Adverse Event
SMF	Site Master File
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
TGA	Therapeutic Good Administration
WHO	World Health Organization
WLA	WHO Listed Authorities



1. Background

National medicines regulatory authorities have the responsibility to improve access to safe, effective and quality assured medicines for public use. Developing and implementing various initiatives, including devising risk-based approaches in regulatory activities such as GMP inspections and marketing authorization of medicines is one of the mechanisms being employed by the majority of the national medicine regulatory authorities (NMRAs) across the globe. The current global practices show that the majority of the regulatory authorities use risk-based strategies to respond to such public needs. Reliance on the work of other regulators is the wise way of making decisions as it enables regulatory bodies' economical use of the available resources and expertise. Reliance and recognition of decisions of other NMRAs will not only improve access to quality assured medical products but also give the chance to focus on other value-added regulatory activities that cannot be undertaken by other authorities. Reliance facilitates timely access to safe, effective, quality-assured medical products and can support regulatory preparedness and response, particularly during public health emergencies.

In Ethiopia, despite several progress made by the Authority to improve access to quality assured medicines, unprecedented shortages of critical and essential medicines, limited number of registered medicines and relatively long waiting time for registration are still continued to be the challenges of the Authority.

To address these challenges, the Authority has introduced a risk based approach while regulating medicines throughout the lifecycle. This is also reflected in the national Food and medicines regulation proclamation (Pro. No. 1112/2019) as "The rigor of regulatory assessment of medicine and medical devices shall be commensurate with the product's type, nature and potential risk to human health" as indicated in article 19 (1). In addition, article 5(18) of regulation 531/2023 gives the authority the power to adopt and implement, as appropriate, criteria, standard, methods, pharmacopeia, criteria adopted or activity undertaken by stringent regulatory authorities.

The Authority has been implementing risk based medical product regulation which includes reliance on stringent regulatory authorities for medicine registration and inspection of good manufacturing practices (GMP) since 2014. For this purpose, the Authority has identified some reliable medicine regulatory authorities and recognized them as stringent regulatory authorities (SRA). As indicated in the Expediting Medicine Marketing Authorization Strategy, 2017, implementation of risk-based inspection approach is one of the GMP inspection strategic directions for assuring manufacturers compliance with cGMP requirements. This strategic direction mainly focuses on implementation of

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abridged procedures for scrutinizing cGMP compliance of pharmaceutical manufacturers that have been granted cGMP certificate by regulatory authorities recognized by EFDA as SRAs, when they submit application for marketing authorization of Medicines.

This guideline is, therefore, developed to further standardize the procedure to be followed for the exemption of on-site GMP inspections by implementing reliance and recognition schemes. It will guide the listing of regulatory authorities recognized as SRAs and assist the authority to ensure transparency in receiving, reviewing and approving of GMP inspection waivers. Implementation of the guideline will not only accelerate the approval of medicines and improve access to quality assured products but also saves resource.

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2. Definition

Abridged regulatory pathways: Abridged regulatory pathways are regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or partially based on the application of reliance. The expectation is that the use of reliance would save resources and shorten the timelines compared to the standard pathways while ensuring that the standards for regulatory oversight are maintained.

Authority means Food and Drug Authority of Ethiopia

Desktop review is the review of information such as history of the manufacturing facilities, GMP compliance status by regulatory authorities (including NMRA) and other sources to gain assurance that GMP compliance has been established remotely.

Manufacturer is any entity which is engaged in the formulation, production, preparation, propagation, compounding, conversion or processing of medicines from raw materials (active pharmaceutical ingredients and inactive ingredients). The entity could also engage in the packaging, repackaging, labeling, relabeling, or distribution of medicines.

Recognition is the acceptance of the regulatory decision of another regulator or other trusted institution. It is a special and more complete form of reliance whereby one regulatory authority relies on the decisions of another regulatory authority, system or institution, obviating the need for additional regulatory assessment in reaching its own decision. Recognition usually requires formal and enabling legal provisions. It may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Reference regulatory authority is a national or regional authority or a trusted institution (such as WHO prequalification, SRA and others) being relied upon by another regulatory authority.

Reliance is the act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

Remote (Virtual) Inspection is a type of GMP inspection designed to assess GMP compliance of pharmaceutical manufacturers at a distance/virtually using real-time document sharing and live video interaction with key personnel of pharmaceutical manufacturers.

Risk based approach is a process that allows the regulatory Authority to classify or categorize medicines based on the risk they impose to the end user.

Stringent Regulatory Authority is regulatory authorities which are recognized and listed as stringent by the Authority.

Waiver of Inspection is the exemption of physical onsite inspection of pharmaceutical manufacturers.

3. Scope

This guideline is applicable for categorization of national medicine regulatory authorities for the purpose of reliance and recognition of cGMP inspection of pharmaceutical manufacturers. The list of reference regulatory authorities is also applicable for applications submitted for marketing authorization to be approved by SRAs procedure.

4. Purpose

The purpose of this guideline is to introduce transparent procedures and set requirements (criteria's) for listing regulatory authorities to be considered for reliance.

5. Reliance and Recognition approaches

The concept of reliance and recognition for regulatory oversight of medical products should be applied across the full life cycle of medical products and GMP inspection. While reliance and recognition approaches are widely used for the initial approval of waiver of physical GMP inspection of pharmaceutical manufacturing sites, it is equally important to consider the use of reliance and recognition on other approval of GMP compliance the manufacturing site renewal and post-approval changes following the product marketing authorization.

The Authority also uses risk-based factors to reliance and recognition include the type & complexity of products manufactured at site, the strength of regulatory system of national regulatory authority, regulatory compliance history of the manufacturing facility, the level of resources and expertise available in the Authority, the public health needs and priorities of the country, and opportunities for reliance.

The approaches to ensure reliance procedure followed by the Authority for an abbreviated procedure for cGMP inspection include:

- 1 Reliance
- 2 Unilateral recognition
- 3 Mutual recognition
- 4 Regional Reliance

5.1. Reliance

GMP inspection reliance approach is an alternative /non-routine application approval pathway used by the Authority in its regulatory decisions regarding GMP inspection. This approach aims at reducing time and other resources for ensuring cGMP compliance through conducting on-site inspection and to speed up access to medicines. EFDA may rely on GMP inspection reports and other authoritative information of reference regulatory authorities and institutions. EFDA may follow this approach when there is a mechanism in place to get the inspection reports from the reference regulatory authority.

5.2. Unilateral Recognition

This approach is another form of alternative /non-routine application approval pathway used by the Authority in its regulatory decisions based on other regulatory authorities or trusted agencies decisions regarding GMP inspection. The authority will rely on decisions of reference regulatory authorities with regard to cGMP compliance of pharmaceutical manufacturing sites and accept their cGMP certificates or granted in the form of letter. The requirements for recognition through this approach may vary depending on the category of the NMRAs or trusted agencies as indicated in annex I, II & III.

5.3. Mutual Recognition

Mutual recognition may be seen as a special and more formalized approach to reliance, whereby EFDA recognizes the decisions of other regulatory authorities or trusted agencies based on mutual legally binding agreement. This binding mutual agreements or treaties may need to be negotiated at the level of governments.

5.4. Regional Reliance

This approach is applicable for cGMP complying manufacturers based on joint inspection with the regional organizations that share information on GMP inspections of manufacturers of medicines located outside the participating countries' NMRs and the manufacturer should be

willing to organize joint inspections of manufacturing sites of common interest. GMP inspections of manufacturing facilities in third countries conducted by a regulatory authority of either party may voluntarily be accepted.

For this procedure, signed mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of good manufacturing practice (GMP) inspections of medicine manufacturers and batch certification in case of vaccines is required.

As a member of a regional organization, EFDA may accept or reject the abbreviated joint inspection report and decisions.

6. Reference Regulatory Authority Listing Criteria

The Authority may rely on evaluation reports or cGMP certificates of other NRAs recognized as reference regulatory authority, those listed in Annex I to III, if the criteria listed below are fulfilled. NMRAs are classified in to three categories based on their cGMP approval types and stringency as indicated below.

- Category A is the reference authority or trusted agency that issues globally acceptable product specific GMP certificate for reliance of GMP inspection. US FDA and WHO PQ are under this category
- Category B countries are indicated in annex II of this document and valid GMP certificate shall be used as a base for approval of the manufacturing site as the base of reliance.
- Category C countries are indicated in annex III of this document and both valid GMP & MA certificates shall be used as a base for approval of the manufacturing site as the base of reliance.
- Category B and C reference regulatory authorities' issues production line specific GMP certificate. The selection criteria shall include:
 - a) The authority believes that the NRA is well functioning and trusted globally
 - b) The NRA is leading in the development and implementation of the requirements and principles of cGMP, quality management system and risk management guidelines used as reference by other regulators
 - c) cGMP inspections conducted by the NRA are accepted by globally trusted agencies such as WHO or by majority of the regulatory bodies in developing countries.

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In addition to the above general criteria (a to c), category A reference regulatory agencies should meet.

1. Medicinal products included in the WHO PQ medicines list. or
2. The founding member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and conducting product specific GMP certificate namely US.FDA.

Category B reference regulatory authorities should meet the below criteria as additional to the criteria indicated above (a to c), to be considered for recognition.

1. Some of the founding members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) including Japan Health Authority, Western EU members.
2. NRA is ICH observer member (as being the European Free Trade Association) as represented by Swissmedic, and Health Canada
3. Previous review or inspection findings of the EFDA proves that regulatory compliance history of the manufacturing facilities granted cGMP by this NMRAs is reliable
4. A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Norway, MHRA of UK. Or
5. The manufacturer GMP certificate (for applied dosage form facility) is available on EUDRA-GMDP website, or officially authenticated

Category C reference regulatory authorities should fulfill the below criteria as an additional to the above listed general criteria (a to c), to be considered for recognition under this category.

1. Some of founding member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) such as Eastern Europe
2. If the cGMP is granted by the reference regulatory authority for manufacturing facilities located outside Europe, USA and Canada such as Asia, Middle East, Africa, South America etc the product must be approved in the country of the reference regulatory authorities (RRA).

3. The manufacturer GMP certificate (for applied dosage form facility) is available on EUDRA-GMDP website, or officially authenticated
4. The product registered or granted marketing authorization in any of reference regulatory authorities

Note 1: The authority consider the review of previous inspection findings of manufacturing facilities to cGMP compliance and post marketing quality compliance history as a basis for reliance to categorise NMRAs into category B and C.

Note 2: the authority will accept GMP certificates of manufacturing facilities based on the inspection conducted jointly by the authority and regional communities (Such as IGAD & AMA) or by other NMRs in the region or the continent based on legally binding and signed mutual recognition agreement.

7. Application submission and review

7.1. Application submission

Applicants shall submit for reliance on-site GMP inspection of the manufacturing sites as per the process or platform described by the Authority. The application should fulfill requirements of this guideline and submit documents indicated below while applying for waiver for on-site GMP Inspection:

- a) Cover letter with official header and signed by the responsible person. The cover letter should indicate the name and address of the manufacturing facility(ies) under consideration.
- b) Filled application form through the eRIS. The application form indicated in the Annex IV of this guidance to facilitate the application process. The application form should be signed by the authorized person.
- c) Updated Site Master file (SMF).
- d) Copy of the valid GMP certificate(s) from the reference SRA under consideration
- e) Copy of valid GMP certificates and/or manufacturing authorization issued by the local authority.
- f) Evidence that the product registration (market authorization) by the indicated SRA for at least one product per line shall also be included for those regulatory considerations by reliance.

- g) For those products which are WHO prequalified, a final acceptance letter and a copy of the WHO detailed GMP report shall be submitted.
- h) Declaration by an applicant to certify that all the information in the application and all accompanying documentation is correct
- i) Evidence of payments made by the applicant as per the current Rate of Service Fees of the Authority.

7.2. Application Review Procedure

- 1) Evaluation of application for reliance of GMP inspection shall be executed in accordance with the laid down standard procedure for application review (SOP/MFID-PROC021) to ensure appropriateness and completeness of the assessment findings and conclusions.
- 2) The Authority shall evaluate and verify the sameness of the production lines approved by the NRA recognized as SRA and the production lines requested for waiver by the applicant.
- 3) Validity and authenticity of the GMP report will be verified from reliable, easily accessible and traceable resources including Edura GMP website <http://eudragmdp.ema.europa.eu/inspections/logonGeneralPublic.do> and official site of the reference SRA regulatory authority. As applicable, officially requesting the reference SRA regulatory authority may be essential.
- 4) Once screening and evaluation of application for on-site GMP inspection waiver is completed, applicants will be notified to settle the fee as indicated in the recent Service fee regulation of the Authority.
- 5) Approval of waiver of on-site cGMP inspection of the manufacturing site and issues of the GMP waiver certificate/letter will be made by the Authority following the confirmation of payments made by the applicant.
- 6) The review process of GMP waiver applications with reliance and recognition may be supplemented by:
 - a) Conducting remote inspection,
 - b) Conducting desk review,
 - c) Conducting joint inspection

- d) Waive physical inspection based the decision of reference NRA
- 7) Despite the waiver from physical inspection based on reliance procedure indicated in this guideline, the Authority reserves the right to conclude to conduct on-site GMP inspection on pharmaceutical manufacturing facilities when found to be necessary on the basis of benefit-risk analysis.

8. Decisions

The Authority applies a risk-based approach when considering reliance of cGMP inspection results conducted by other regulatory bodies, which includes factors such as the type and source of products under consideration, the level of resources and expertise available in the authority, the public health needs and priorities of the country, and opportunities for reliance. Considering the above principles, the Authority shall follow the conditions for reliance of cGMP assessment results for decision making.

- a) For a manufacturer granted cGMP certificate by a regulatory authority listed as Reference regulatory authority or trusted agency by EFDA, is application shall be accepted if all manufacturing process (manufacturing, laboratory testing, and packaging) accomplished in the same country and same facility unless the approval by the recognized SRA shows that it undertakes different process at different facilities.
- b) Applicants shall indicate the facilities/countries where the critical manufacturing operations are undertaken. The manufacturer should undertake all manufacturing activities end to end (from dispensing of raw material to packaging) at the facility(ies) that(those) is(are) approved by the SRA.
- c) Pharmaceutical bulk production should be fully accomplished at one site and the firm should possess a laboratory that has testing capacity for the products manufactured at the site. Packaging of finished pharmaceutical products which may be undertaken at other facilities could be acceptable but the applicant must specify the batch certification site.
- d) Reliance practice by the authority is an independent decision, the authority may choose when to use reliance procedures for onsite cGMP inspection waiver and on which NRAs to rely based on realistic evidence. The basis for relying on a specific regulatory authority is basically based on the competence of the NRA and

fulfillment of EFDA's criteria for recognition as reference regulatory authority or SRA.

- e) Reliance procedure is equally applicable for all products/practices in the same predetermined category provided that it is approved by NRAs recognized as SRA by the Authority. The authority may fully or partially accept or totally reject the other NRAs assessment reports based on the documents submitted by applicants.
- f) The authority retains a list of NRAs recognized as SRAs and updates the list on a regular basis (annually). NRAs those fail to maintain competencies and performance and hence do not consistently meet EFDA's criteria, based on the review of assessment reports submitted by applicants for cGMP approval by the authority, may be excluded from the list.

9. Verification and quality assurance mechanism

9.1. Gathering information

If a new GMP certificate has been issued by the reference NMRA, the applicant shall submit this document to EFDA or it should be notify the authority if it is accessible online such as from a central repository (e.g. EudraGMP). If the reference NRA does not issue GMP certificates, the inspection report from the most recent inspection of the manufacturing site by the reference NRA shall be submitted by the applicant. The authority may request additional information from the reference regulatory authority (RRA) or the applicant if necessary. The information may include:

- Detail Information relating to the latest inspection by the reference NRA. For example: dates on site, inspection scope and outcome, inspection report, company response/corrective and preventative action (CAPA) plan, and planned re-inspection date (if known).
- Post inspection information provided by the NRA on justified request
- Information relating to inspections by other regulatory authorities in a defined time period (e.g. previous 2 years or since the previous inspection by the regulatory authority performing the assessment). For example: name of regulatory authority, dates on site, inspection scope and outcome

Based on the result of the gathered information the authority may undertake one of the following actions

9.2. cGMP compliance Desktop Review

Confirming GMP compliance through desktop review on the facilities involved in the manufacture of medicines without undertaking an onsite inspection to efficiently improve the available resources. The scope of the desktop review will vary on the complexity of the manufacturing processes, the nature of the product, the number of manufacturing lines.

9.3. Virtual cGMP inspection

In such cases, the Authority shall take evidence of inspection (inspection report and the decision) made by the reference regulatory authority considered for reliance. In addition, the evidence indicated above, performing inspections remotely or virtually on facilities may be considered by the Authority. However, not all inspections are well-suitable to be conducted remotely; in this case, the Authority may consider other types of abridged inspection types.

9.4. Onsite cGMP inspection

The Authority may conduct on-site inspection of the manufacturing site which is already granted a waiver for cGMP inspection by the Authority where found to be necessary on a case by case basis. Furthermore, the Authority will conduct inspection on 10% of the manufacturing site exempted onsite inspection through waiver procedure annually.

The following factors will be taken into account when considering for on-site GMP inspection on facilities approved by authorities recognized as SRA:

- a) when the product(s) meant for the Ethiopian market is (are) not registered in the SRA countries
- b) when evidences from reputable sources show that the manufacturer's products have history of quality defects, and the number and the significance of known quality defects encountered call for scrutiny;
- c) When the submitted documents have some doubtful information that needs to be verified by onsite inspection
- d) When there are major changes made to, the buildings, equipment, processes, key personnel;

- e) When the manufacturing site has limited experience with manufacturing and testing of a product (less than two years)
- f) Repeatable quality defects of different medicines manufactured by the specific manufacturing site during consignment and PMS testing.

10. SRAs list and periodic Review

Based on the criteria indicated in this guideline, the Authority retains and regularly updates the list of the NRAs recognized as SRAs for both reliance and recognition procedures. Such a list may be categorized into two based on the type of product and whether to follow reliance or recognition procedure based on the status of the SRA. For Example, in the case of EU, the mandate for approval of new vaccines lies with EMA and therefore only EMA is relevant from the EU authorities in the above list

The current list of NRAs (countries) which are considered for category B by the Authority are listed in annex I and those countries for category C are indicated in annex II of this guidance document. The list will be regularly updated every 5 years.

The list of national regulatory authorities for recognition schemes will be posted on the Authority website and updated on a regular basis based on day-to-day practices, international trend, on the agreements between the NRA and EFDA and other scientific evidence.

Reference:

1. Food and Medicines Administration Proclamation, Proclamation No. 1112/2019, Federal Negarit Gazette of the Federal Democratic Republic of Ethiopia.
2. Expediting Medicine Marketing Authorization Strategy ,Ethiopian Food and Drug Authority (former EFMHACA), Oct, 2018, Addis Ababa, Ethiopia
3. FDA Reliance Policy. Doc. No. FDA/GEN/POL-02, 2 January, 2019, Food and Drugs Authority of Ghana
4. Good reliance practices in regulatory decision-making: high-level principles and considerations, Draft working document for comment, Working document QAS/20.851/Rev.1, August, 2020, WHO.
5. Press release: PIC/S meetings in Geneva (Switzerland), From 8 to 10 April 2019, the following meetings took place in Geneva (Switzerland): PIC/S Committee and PIC/S Executive Bureau.
6. GMP Inspection, at Tanzania Medicines and Medical Devices Authority (TMDA) at <https://www.tmda.go.tz/pages/gmp-inspection>
7. Product eligibility under the COVAX Facility at WHO website: https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf
8. Guidelines on Reliance for Regulatory Decision Making, Rwanda Food and Drugs Authority, October 2022.

Annex

Annex I: List of regulatory agencies considered as Reference regulatory authority for Category A type of GMP Reliance

1. US FDA approved (United State of America)	2. WHO Pre-Qualified
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Annex II: List of countries considered as Reference regulatory authority for Category B type of GMP Reliance

1. Australia	2. Ireland	3. Austria
4. Italy	5. Belgium	6. Japan
7. Canada	8. Netherlands	9. Denmark
10. Norway	11. EMEA	12. Switzerland
13. Finland	14. United Kingdom	15. France
16. Germany		

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Annex III: List of countries considered as Reference regulatory authority for Category C type of GMP Reliance


1. Poland	2. Greece	3. Portugal
4. Bulgaria	5. Hungary	6. Romania
7. Croatia	8. Slovakia	9. Cyprus
10. Slovenia	11. Czech Republic	12. Latvia
13. Spain	14. Lithuania	15. Sweden
16. Estonia	17. Luxembourg	18. Malta
19. Iceland	20. Liechtenstein	

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Annex IV: Application form

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	Medicine Facility Inspection Directorate of EFDA	FORM- MIFID-062.001
Title	SRA GMP 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 <input type="checkbox"/>	
	Renewal waiver application <input type="checkbox"/>	

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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. Penicillines 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,)	

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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)	

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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

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Cover letter		
Previous waiver certificate (if renewal)		
Agency agreement with manufacturer or license holder		
Manufacturer GMP certificate/ authenticated certificate		
Site master file		
Application form		
Waiver Final payment		

Part D application declaration

- I am here by authorized by the company to make this application
- I have read and understood the content of GMP guidelines and registration guidelines of EFDA
- 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
- I hereby confirm that I agree with any decision from EFDA regarding this application

Full name.....

Designation.....

Signature

<p>Stamp</p>

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