Guideline for Authorization and Establishment of Manufacturing Facility for Medicinal Products

MPD-G-LI

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1. Introduction

The Medicines Act of the Kingdom of Bhutan 2003 empowers the Medical Product Division (MPD) of the Bhutan Food and Drug Authority (BFDA) to regulate medicinal products, ensuring they meet the required standards of safety, quality and efficacy/effectiveness. In line with this mandate, the MPD is also responsible for regulating facilities involved in the manufacturing of medicinal products.

With this, it is crucial to provide a guidance document that outlines the policies, procedures and conditions for applicants wishing to manufacture medicinal products in the country. While international Good Manufacturing Practices (GMP) standards exist, it is equally important to incorporate country-specific regulatory requirements to foster a better understanding between applicants and the Authority.

The guidance document outlines the procedures to streamline the approval process, thereby enhancing transparency and consistency in regulatory decisions. The document is intended to serve as a guiding tool for applicants, helping them to understand and comply with the technical and regulatory requirements to establish a manufacturing firm.

2. Scope

2.1. This guideline shall apply to the following category of medicinal products which are intended to be manufactured in the country:

- 2.1.1. Finished pharmaceutical formulation
- 2.1.2. Active Pharmaceutical Ingredients
- 2.1.3. Traditional medicinal products
- 2.1.4. Herbal medicinal products
- 2.1.5. Medical devices
- 2.1.6. Medical gases
- 2.1.7. Supplements
- 2.1.8. Vaccines and biologics

2.2. This guidance does not cover the following types of products:

- 2.2.1. Human tissues intended for transplantation
- 2.2.2. Blood and Blood Products

3. Objectives

3.1. To provide guidance on the establishment of manufacturing facilities for medicinal products in the country aligning with international best practices.

3.2. To guide the Authority in the assessment of applications for the authorization of manufacturing facilities for medicinal products, ensuring fair, consistent and effective enforcement of regulatory requirements.

3.3. To guide the applicants in preparing project proposal and meeting the technical and regulatory requirements required for establishing a manufacturing facility for medicinal products

4. Normative Reference

4.1. The Medicines Act of the Kingdom of Bhutan 2003

4.2. Bhutan Medicines Rule and Regulation 2025

4.3. Guideline for Good Reliance Practice 2025

5. Definition

5.1. **Active Pharmaceutical Ingredient:** It refers to any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

5.2. **Authority:** It refers to Bhutan Food and Drug Authority.

5.3. **Competent Person:** It refers refers to any person who possesses the requisite qualifications and practical experience prescribed by the Board and is approved to undertake:

- 5.3.1. manufacturing of medicinal products;
- 5.3.2. dispensing of medicinal products;
- 5.3.3. retail sale of medicinal products; or
- 5.3.4. distribution of medicinal products.

5.4. **Cleanroom:** It refers to a room or area with defined environmental control of

particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

5.5. **Contamination:** It refers to the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API during production, sampling, packaging or repackaging, storage or transport.

5.6. **Cross-contamination:** It refers to contamination of a starting material, intermediate product, or finished product with another starting material or product during production.

5.7. **Dedicated Facility**: It refers to the facility within the same building with no common access and with separate HVAC and having common Utilities and Waste treatment. It may be on the same floor or may be on a different floor.

5.8. **Good Manufacturing Practices (GMP):** It refers to a system for ensuring that products are consistently produced and controlled according to quality standards (*WHO*).

5.9. **Technical Authorization for Manufacture (TAM):** It refers to the final authorization issued to establishments responsible for manufacture of medicinal products.

5.10. **Medical Device:** It refers to all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- 5.10.1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
- 5.10.2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- 5.10.3. investigation, replacement, modification, or support of the anatomy or of a physiological process;
- 5.10.4. supporting or sustaining life;
- 5.10.5. control of conception;
- 5.10.6. disinfection of medical devices; or
- 5.10.7. providing information by means of in-vitro examination of specimens derived from the human or animal body.

5.11. **Medicinal Product: It refers to:**

- 5.11.1. All substances intended for internal or external use of human beings or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals;
- 5.11.2. Such substances intended to affect the functioning of any structure found in the human and animal body; andAny other substance or device declared by the Board to be a medicinal product or a medicine or a drug and this may belong either to modern (allopathic) or traditional systems of

5.12. **Plant layout** refers to the most effective physical arrangement, either existing or in plans of industrial facilities i.e. arrangement of machines, processing

equipment and service departments to achieve greatest co-ordination and efficiency of 4 M's (Men, Materials, Machines and Methods) in a plant.

5.13. **Production:** It refers to all operations involved in the preparation of a pharmaceutical product, from receipt of the starting materials, through processing and packaging, to completion of the finished product

5.14. **Provisional Technical Authorization for Manufacture (PAM):** It refers to the authorization for setting up a manufacturing plant until it becomes fully operational.

5.15. **Quality System or Quality Management System (QMS):** It refers to a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives (it actually refers to the entirety of the system).

5.16. **Reference Regulatory Authority (RRA):** It refers to a national or regional authority or a trusted institution whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions. (Refer to the Guideline for Good Reliance Practice for considerations regarding RRAs)

6. Acronyms

6.1. AHU: Air Handling Unit
6.2. API: Active Pharmaceutical Ingredient
6.3. ASEAN: Association of Southeast Asian Nations
6.4. BMRR: Medicines Rules and Regulation
6.5. FDI: Foreign Direct Investment
6.6. GMP: Good Manufacturing Practice
6.7. HVAC: Heating Ventilation & Air Conditioning
6.8. ICH: International Council for Harmonisation
6.9. PIC/S: Pharmaceutical Inspection Convention/Co-operation Scheme
6.10. QMS: Quality Management System
6.11. RRA: Reference Regulatory Authority
6.12. TAM: Technical Authorization for Manufacture
6.13. WHO: World Health Organization
6.14. WOAH: World Organisation for Animal Health

PART I: GENERAL REQUIREMENTS AND CONDITIONS FOR THE ESTABLISHMENT OF MANUFACTURING FACILITIES FOR MEDICINAL PRODUCTS

7. The applicants intending to manufacture any medicinal products should adhere to the following general requirements and conditions.
8. Notwithstanding the above, the general requirements and conditions should be applicable based on the scope and risk classification of the medicinal product intended for manufacture.

9. Authorization

9.1. The Authorization from the Authority shall be a prerequisite for obtaining a license from the relevant agency for manufacturing any medicinal products.

9.2. The Authorization for manufacture shall involve two stages of approval:

9.2.1.1. Provisional Technical Authorization for Manufacture (PAM); and

9.2.1.2. FTechnical Authorization for Manufacture (TAM).

9.3. Compendial medicinal products including API will be permitted for manufacture.

9.4. The following compendium may be adopted for manufacturing of any medicinal product:

9.4.1. Indian Pharmacopoeia;

9.4.2. British Pharmacopoeia;

9.4.3. US Pharmacopoeia; and

9.4.4. any other standards as determined by the Authority.

9.5. For manufacturing of medicinal products including API with In-house specifications, the applicant shall furnish product approval from at least one Reference Regulatory Authority (RRA) provided that the sameness of the product is established.

10. Type of Quality System

10.1. **Pharmaceuticals and Active Pharmaceutical Ingredients (APIs):** Manufacturing should comply with Good Manufacturing Practice (GMP) standards that are equivalent to those established by WHO, PIC/S or ICH.

10.2. **Vaccines and Biologics:** Manufacturing should adhere to WHO GMP for biological products, ASEAN GMP guidelines for veterinary vaccines, or other internationally recognized standards such as PIC/S or those issued by the World Organisation for Animal Health (WOAH).

10.3. **Medical Devices:** Manufacturing should adhere to quality systems such as ISO 13485:2016 or other internationally recognized standards.

10.4. **Traditional and Herbal Medicinal Products:** Standards must align with WHO Guidelines on GMP for Herbal Medicines or the ASEAN Guidelines for the Quality, Safety and Efficacy of Traditional Medicines.

10.5. **Medical Gases:** Compliance should be based on pharmacopoeial standards or GMP requirements equivalent to WHO GMP for medicinal gases.

10.6. **Supplements:** Standards must conform to or be equivalent to the ASEAN Guidelines for Health Supplements.

11. Location of the Facility

11.1. The applicant must obtain necessary clearance from the relevant authorities/agency prior to the application.

11.2. Location of the proposed facility should be without any risk of potential contamination from and/to the immediate environment and other manufacturing activities on the site.

11.3. The proposed location should have easy accessibility to road, water, undisturbed electricity and waste management system.

12. Building

12.1. Facility buildings should be structurally sound to prevent rodents, insects and dust. Ceilings, walls and floors must be smooth, free of cracks and crevices, easy to clean and resistant to dust accumulation.

12.2. There should be effective hygiene and sanitation measures in place.

12.3. The entry to the facility should be controlled to prevent unauthorized access.

12.4. Ancillary areas shall be clearly separated from production and quality control areas to prevent cross-contamination and ensure operational integrity.

12.5. Areas housing animals for experimental tests shall be isolated from other areas.

12.6. There should be a dedicated warehouse for the storage of raw materials supplies, semi-finished products and end products and should be separated from the manufacturing areas.

12.7. The facility must be equipped with a suitably designed HVAC/AHU system, and cleanroom classifications shall be established and maintained in compliance with product-specific requirements.

12.8. The manufacturing facility should have its own full-fledged testing laboratory and instrument room with appropriate testing equipment.

12.9. There should be a water purification system and waste water treatment plant in the facility.

12.10. First aid facilities shall be readily accessible in all operational areas where flammable or hazardous raw materials are handled, to enable prompt medical response in the event of an incident.

12.11. An emergency exit must be provided to ensure safe and rapid evacuation in case of emergencies.

13. Plant layout and design

13.1. The manufacturing site and buildings should be described in sufficient detail (by means of plans and written explanations) in the plant layouts to ensure that the designation and conditions of use of all the rooms are correctly shown.

13.2. Manufacturing area should be demarcated in line with process steps and flow and should be sufficient to carry out the intended process(s).

13.3. The following plant layouts shall be developed, but not limited to:

13.3.1. **Overall Location Layout** depicting the geographical location of the manufacturing facility and its relation to the surrounding environment.

13.3.2. **Site and building Layout** providing a comprehensive view of the site, showing all buildings, their purpose and spatial relationship.

13.3.3. **Functional Layout** detailing the specific activity assigned to each room or area, including room dimensions and designated usage.

13.3.4. **HVAC/AHU Classification and Zoning Layout** indicating the cleanroom classification (e.g ISO Class or Grade A-D), zoning and the configuration of the HVAC/AHU system.

13.3.5. **Differential Pressure Zoning Layout** showing the design and maintenance of pressure cascades between rooms to prevent cross-contamination.

13.3.6. **Personnel and Material Flow Layout** illustrating movement patterns of personnel and materials to ensure unidirectional flow and segregation of clean and dirty paths.

13.4. The detailed plant layout shall be prepared by a relevant firm or personnel.

13.5. All plant layouts must be developed in accordance with current applicable GMP/quality standards.

13.6. The facility should be constructed in accordance with the approved layout. Any deviations from the approved design must be formally documented, justified and submitted for review and approval by the Authority prior to implementation.

14. Stages of Manufacture;

14.1. All stages of manufacture may be approved subject to the demonstration of adequacy of the facility, equipment and personnel involved.

14.2. In cases where the manufacturer intends to carry out only packaging activities, approval will be considered only if a clear and justifiable rationale is provided for limiting operations to the packaging process.

15. Manufacturing area

15.1. The entry to the manufacturing area should be restricted to only authorized personnel

15.2. Production, processing and packaging areas should be completely separated from offices, reception rooms, quality control laboratories, restaurants and their associated lavatories; the use of asbestos shall be avoided.

15.3. Operational area should be clearly delineated according to its formulation or nature of the product.

15.4. There should be dedicated rooms or areas for different stages involved in the manufacturing process.

15.5. Facilities for the manufacture of different types of medicinal products must be physically separated and should not operate within the same building.

15.6. For manufacture of steroid, sex hormone, cytotoxic and immunosuppressant groups of medicinal products, there should be a dedicated facility with separate air handling unit systems, containment measures and dedicated equipment.

15.7. A separate building including independent air handling unit systems and dedicated equipment should be required for production of beta lactam products. The distance between the facility manufacturing beta lactam and other classes of medicinal products should be maintained at an adequate distance to prevent risk

of cross contamination.

15.8. For sterile product manufacturing, preparation, filling, and sterilization processes must be conducted in distinct, separate zones within the designated clean area to minimize the risk of cross-contamination.

15.9. There should be facilities for the treatment of dust and powder, wastewater, hazardous wastes, toxic containers, hazardous gases, biological components and other hazardous components or materials.

16. Personnel

16.1. The key personnel overseeing the Production and Quality Control Units with qualifications and experience as prescribed in the BMRR should be registered with the Authority as Competent Person.

16.2. The manufacturer must ensure that an adequate number of appropriately trained personnel are employed, in proportion to the workload.

16.3. An organogram depicting the top management and various units of the manufacturing should be available.

17. Equipment

17.1. Equipment used in the manufacturing, processing, packaging or storage must be of appropriate design, adequate capacity and properly positioned to support efficient operation, cleaning and maintenance in line with its intended use.

17.2. All applicable equipment should undergo Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) to verify and document that it is installed correctly, operates as intended and performs consistently within specified parameters.

17.3. A calibration program should be established for critical instruments and equipment used for measuring, weighing, recording and process control at defined intervals to ensure accuracy and reliability.

17.4. A preventive maintenance program must be established and implemented for all equipment to ensure sustained performance, minimize downtime and prevent operational failures.

18. Waste Management

18.1. Designated storage facilities shall be established for hazardous waste materials and toxic containers. These materials and containers must be safely decomposed or disposed of in accordance with relevant guidelines and environmental safety standards.

18.2. For wastewater management, effective treatment methods such as acidification, alkalization, neutralization, activated carbon adsorption or other validated processes should be employed to break down or eliminate toxic substances. The discharge of treated wastewater must fully comply with established environmental standards.

19. Outsourced Services

19.1. Outsourcing of any type of the services related to manufacture of the medicinal products may be allowed provided it is scientifically or logically justifiable.

19.2. There should be a defined mechanism for monitoring of outsourced services and such activities should be properly documented.

20. Technology Transfer

20.1. For proposals involving Foreign Direct Investment (FDI), it shall be mandatory for the applicant to establish a technical collaboration with a recognized and established manufacturer of comparable products. These products must be duly registered with the National Regulatory Authority (NRA) of the country of origin.

20.2. Additionally, the manufacturer must ensure full compliance with the WHO Guidelines on Technology Transfer or equivalent standards. The technology transfer process should include comprehensive documentation, training programs, knowledge sharing, and support for implementation to guarantee sustainable local capacity development.

PART II: SPECIFIC REQUIREMENTS FOR THE MEDICINAL PRODUCTS

21. In addition to the requirements specified in Part I, the following standards, or their equivalent, shall also apply where relevant:

SN	Type of medicinal Product		Reference standard
1	Finished Pharmaceuticals Products		*1. TRS 986 - Annex 2: WHO good manufacturing practices for pharmaceutical products: Main principles* *2. TRS 1060 - Annex 2: WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products* *3. TRS 957 - Annex 3: WHO good manufacturing practices for pharmaceutical products containing hazardous substances* *4. TRS 1010 - Annex 8: Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products* *5. TRS 1019 - Annex 2: WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines* *6. TRS 1019 - Annex 3: Good manufacturing practices: guidelines on validation* *7. TRS 902 - Annex 9: Guidelines on packaging for pharmaceutical products*
	1.1	Sterile Pharmaceuticals Products	*1. TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products*
	1.2	Active Pharmaceuticals Ingredients	*1. TRS 957 - Annex 2: WHO good manufacturing practices for active pharmaceutical ingredients (bulk drug substances)*
	1.3	Water for Pharmaceutical use	*1. TRS 1033 - Annex 3: Good manufacturing practices: water for pharmaceutical use*
	1.4	Non-Sterile Pharmaceuticals	*1. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products* *2. WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines*

	1.5	Pharmaceutical products containing hazardous substances	1. TRS 957 - Annex 3: WHO good manufacturing practices for pharmaceutical products containing hazardous substances
	1.6	Water for injection	*1. TRS 1025 - Annex 3: Production of water for injection by means other than distillation*
	1.7	Excipients for Pharmaceutical use	*1. TRS 1060 - Annex 3: WHO good manufacturing practices for excipients used in pharmaceutical products*
2	Traditional Medicines		*1. WHO good manufacturing practices for the manufacture of herbal medicines*
3	Herbal medicines		*1. TRS 1010 - Annex 1: WHO good manufacturing practices for the manufacture of herbal medicines* *2. TRS 1010 - Annex 2: WHO good manufacturing practices for the manufacture of herbal medicines* *3. ANNEX VIII - ASEAN guideline on good manufacturing practice for traditional medicines*
4	Supplements		*1. Annex VIII-ASEAN guideline on good manufacturing practice for health supplements*
6	Vaccines and Biologicals		*1. TRS 996 - Annex 3: WHO good manufacturing practices for biological products (jointly with the Expert Committee on Biological Standardization)*
7	Medical Gases		*1. TRS 1044 - Annex 5: WHO good manufacturing practices for medicinal gases* *2. BFDA Guidelines for Good Manufacturing Practices of Medical Gases*
8	Medical Devices		*1. ISO 13485-Medical devices Quality Management System* *2. ISO 14971- Medical devices-Application of risk management to medical devices* *3. Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices, IMDRF*

PART III: APPLICATION PROCESS FOR TECHNICAL AUTHORIZATION FOR MANUFACTURE

22. Provisional Technical Authorization for Manufacture (PAM)

22.1. The Applicant shall apply to the Authority using the form *BMRR II-PAM and* pay the fee as prescribed under BMRR along with following documents:

22.1.1. Project proposal; and

22.1.2. Plant layout of the manufacturing facility.

22.2. The project proposal should contain the information as per *Annexure I.*

22.3. The Authority should conduct assessment and review of the detailed project proposal and plant layout and communicate to the applicant on any missing details/information.

22.4. The Authority should then issue the PAM in the prescribed format or otherwise inform the applicant about its rejection within 90 calendar days from date of receipt of application using the stop clock principle.

22.5. Provisional Authorization for Manufacture is valid for a period of 2 years.

22.6. The Authority shall conduct periodic inspection of the plant during the PAM stage to monitor the compliance as per the approved design.

22.7. The applicant may request Authority for inspection when key stages in the technology transfer are completed.

23. Technical Authorization for Manufacture (TAM)

23.1. The manufacturer should ensure that the key personnel is identified and registered as the Competent Person with the Authority before applying for TAM.

23.2. Once the plant set up is complete, the applicant should apply to the Authority for Technical Authorization for Manufacture using the form *BMRR III-FAM* and pay the fees as prescribed under BMRR along with following documents:

23.2.1. Site Master File;

23.2.2. Standard Operating Procedures; and

23.2.3. Any other documents as deemed necessary by the Authority

23.3. The Authority should conduct authorization inspection of the facility.

23.4. The Authority shall issue the TAM in a prescribed format within 45 calendar days from the date of receipt of application using stop clock principle.

23.5. The validity of TAM shall be five years from the date of issuance.

23.6. In case of the application considered deficient, the Authority shall provide the reasons in writing including the grounds for refusal and direction for improvements, if any.

24. Renewal of PAM and TAM

24.1. The application for renewal of Provisional and Technical Authorization for Manufacture shall be submitted in the form *BMRR II-PAM and BMRR III-TAM* respectively with the fee as prescribed

24.2. The manufacturing firm must be GMP certified at the time of renewal of TAM.

24.3. Application for renewal should be submitted within 90 calendar days before the expiry date of the authorization.

24.4. After the expiry of the Authorization, a grace period of 30 calendar days should be granted after which the renewal shall be done with a daily fine of minimum wage for maximum 30 calendar days.
24.5. Non-renewal of certificate within the period provided should be cancelled.
24.6. In the event of non-completion of the construction of the facility within the valid period, PAM can be renewed only for two times after which it shall be considered as a new application.
24.7. Irrespective of the date of renewal, the validity of the renewed certificate should be considered from the actual date of expiry of the last certificate or at par with the validity for the certificate issued by the relevant certification bodies, where applicable.
24.8. The Authority should issue renewed PAM/TAM within 7 working days from the date of receipt of application.

25. Post Approval Variation

25.1. The applicant shall apply for Post Approval Variation (PAV) for any deviation from the initial proposal or SMF submitted to the Authority in form BMRR IV-PAV TAM and pay the fees as prescribed under BMRR.
25.2. The PAV will be applicable only for the following deviations:
25.2.1. Addition of medicinal products in the approved categories and list;
25.2.2. changes on the layout of the premises;
25.2.3. Change in the ownership; and
25.2.4. Or any other changes as deemed minor by the authority
25.3. If the changes are not falling conditions stated above, the changes shall be considered as major and the applicant shall apply for new authorization.
25.4. The Authority shall approve post approval variation within 15 working days using stop clock principle.

26. Suspension or cancellation of Provisional or Technical Authorization for Manufacture

26.1. The Provisional or Technical Authorization for Manufacture may be suspended when:
26.1.1. any conditions of the Authorisation has been contravened;
26.1.2. repeated deviations from good manufacture practices standards or quality system requirements posing high risk to the consumers as determined by the Authority;
26.1.3. any minor changes carried out without prior approval from the Authority;
26.1.4. absence of Competent Person for supervision of the production and/or quality unit; or
26.1.5. any other conditions as deemed necessary by the Authority.

26.2. The Provisional or Technical Authorization for Manufacture may be canceled when:
26.2.1. any major changes carried without prior approval from the Authority;
26.2.2. failure to fulfil the requirement for upliftment of suspension within stipulated timeline;
26.2.3. non-renewal of authorizations within the stipulated timeline; or

26.2.4. any other conditions as deemed necessary by the Authority.

26.3. Technical Authorization Holder for manufacture shall not operate the business during the suspension period and shall not engage in any activities under the Act and BMRR

27. References

27.1. The Medicines Act of the kingdom of Bhutan 2003

27.2. The Bhutan Medicines Rule and Regulation 2025

27.3. TRS 986 - Annex 2: WHO good manufacturing practices for pharmaceutical products: Main principles

27.4. WHO guidelines on Production (TRS)

27.5. Pharmaceutical Manufacturer Licensing Procedure - National Health Regulatory Authority (NHRA), Bahrain.

27.6. Standards for the Establishment of Pharmaceutical Factories

27.7. Requirements and deadlines for applications for company authorization - Danish Medicines Agency.

27.8. Guidelines on applications for authorisation to manufacture and import medicines and intermediates - Danish Medicines Agency.

Annexure I: Format for Project Proposal

A. Details of the firm

1. Name of the proponent:
2. Name of the firm:
3. Physical Address:
4. Telephone number:
5. Email:

B. Details on the manufacturing project

Sl.no	Details	Description
1	Introduction of the project	● Introduce the manufacturing project by outlining scope and goals. ● Clearly define the scope of activities to be undertaken such as product, quality control, packaging. ● Highlight the purpose of setting up the facility
2	Medicinal Products to be manufactured	● Provide the list of all medicinal products intended for production with therapeutic category (e.g., antibiotics, antivirals, antihypertensives, etc.) risk classification. ● Indicate whether these products adhere to pharmacopeial/compendial standards (USP, BP, IP etc.). ● For non-compendial products, submit evidence of regulatory approval from a recognized Reference Regulatory Authority. ● Include information on dosage forms (tablets, injectables, syrups, etc.), strength of the medicinal products.
3	Cost of project	Provide an estimated cost of the project
4	Objectives of the project	Clearly define the primary and secondary objectives (if applicable) of the project.
5	Source of raw materials	List the countries from which Active Pharmaceutical Ingredients (APIs), excipients, packaging materials and other raw materials will be sourced.

6	Targeted Market	List the primary and secondary markets (countries) where the products will be sold, specifying whether they are domestic, regional or international.
7	Project timeline	Provide a detailed timeline for major activities such as planned start date for construction, the schedule for equipment installation, and the expected date for completion of construction activities
8	Details of promoters	Provide complete details of the promoters or founders of the project, including the fo 1. Names 2. Residential or business addresses 3. Contact numbers 4. Email addresses. Mention their professional background, experience in the pharmaceutical industry, and any other relevant ventures they have been involved in.
9	FDI (If applicable)	● If the project involves Foreign Direct Investment, provide details of the technical collaborators, especially if they are established manufacturers of similar pharmaceutical products. ● Include the following details of the collaborator: 1. Name 2. Nationality 3. Technical capabilities 4. Nature of the partnership
10	Quality System	Briefly describe the type of quality system that would be implemented. (A quality system in accordance with standards such as cGMP, ISO or similar recognized standard may be implemented)
11	Location	● Provide details about the facility's location, including information on any nearby industrial activities and the surrounding natural environment. ● The description should also include whether the factory is situated in a sanitary area, adequately distanced from other factories that may pose risks of contamination, fire, or other safety hazards, and whether appropriate safety measures are in place.
12	Building	● Provide details of the proposed construction, including the total number of buildings and

		whether it will be a single integrated facility or multiple separate buildings. Specify the intended use of each block. **Other information** ● If beta-lactam products are to be manufactured, describe how a dedicated facility will be maintained including the distance between this facility and others producing different classes of medicinal products. ● For the production of steroids, sex hormones, cytotoxic and immunosuppressant medicinal products, explain how a dedicated and self-contained facility will be established to ensure proper segregation and safety.
	Stages of Manufacture	● Provide a comprehensive overview of all the manufacturing processes and operations that will be carried out. ● Detail out the activities in sequence
	Personnel	● Provide detailed information regarding the project management structure including top-level management and the organizational chart. ● Provide detail on the Intended size of the employees
	Equipment	● Provide a comprehensive list of all manufacturing equipment to be acquired. ● Elaborate on the engineering and maintenance services that will be performed. ● Describe the procedures and methods that will be used to carry out calibration
	Waste Management	A comprehensive waste management plan addressing all types of waste that may be generated
	Outsourced services	Provide a detailed description of all services to be outsourced and explain how their management will be handled
	Technology Transfer (If applicable	A comprehensive proposal outlining the process for technology transfer. This should include the key steps, timelines and responsibilities involved to ensure a smooth and effective transition.
	Other	Any other additional information

C. Plant Layouts

Sl.No.	*Plant Layout Requirements*	*Status/ Remarks*
1	Overall description	Description of the manufacturing site and buildings in detail to ensure that the designation and conditions of use of all the rooms are correctly shown.
2	Biodata of the personnel/firm	Is the plant layout prepared and signed by a qualified and competent firm or personnel? Bio data of the qualified and competent firm or personnel.
3	Overall Location Layout	This layout should depict the geographical location of the manufacturing facility and its relation to the surrounding environment.
	Site and building Layout	This layout should provide a comprehensive view of the site, showing all buildings, their purpose and spatial relationship.
	Functional Layout	This layout should detail the specific activity assigned to each room or area, including room dimensions and designated usage.
	HVAC/AHU Classification and Zoning Layout	This layout should indicate the cleanroom classification (e.g ISO Class or Grade A-D), zoning and the configuration of the HVAC/AHU system.
	Differential Pressure Zoning Layout	This layout should show the design and maintenance of pressure cascades between rooms to prevent cross-contamination.
4	Personnel and Material Flow Layout	This layout should illustrate movement patterns of personnel and materials to ensure unidirectional flow and segregation of clean and dirty paths.
5	Others	Any other additional layouts

Quality Policy of Medical Product Division

"We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers'

satisfaction and confidence"

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