

INSTRUCTION TO BIDDERS

This Instruction to Bidders applies to all non-trade procurement opportunities issued by Pharmaniaga Berhad and all its subsidiaries (*Hereinafter referred to as Pharmaniaga*), including but not limited to Requests for Quotation (RFQ), Requests for Proposal (RFP), Closed Tenders, and Open Tenders. By participating in any of these procurement exercises, bidders acknowledge and agree to the following terms and conditions:

1. Confidentiality & Integrity

- All documents, information, and communications related to this procurement exercise must be treated as confidential. Any breach of confidentiality may result in disqualification.
- Bidders must act with integrity and disclose any actual or potential conflict of interest. Pharmaniaga reserves the right to reject any bidder found in violation of ethical standards.
- Pharmaniaga is committed to the highest standards of integrity and transparency in procurement processes and adheres to the ISO 37001:2016 Anti-Bribery Management System (ABMS). Bidders are expected to comply with all applicable anti-bribery and corruption laws and regulations.

2. No Obligation to Award

- This procurement process does not constitute an offer to enter into any agreement, and Pharmaniaga is under no obligation to award any contract.
- Pharmaniaga reserves the right to amend, suspend, terminate, extend, or re-issue the procurement process at its sole discretion without liability.

3. Eligibility & Registration

- Bidders must meet all relevant registration and regulatory requirements.
- All vendors must be registered with Pharmaniaga before any award can be finalized. However, new vendors are allowed to participate but must complete the registration process at the earliest opportunity.

4. Pricing & Validity

- Prices must be detailed, including a clear breakdown of costs and applicable taxes.
- All prices must be quoted in Malaysian Ringgit (RM). However, foreign manufacturers may submit pricing in other currencies, subject to conversion at the prevailing exchange rate.
- Bidders must ensure that their quotations or proposals remain valid for a minimum of **60 days** from the closing date.

5. Submission & Deadline Compliance

- All required documents must be submitted in accordance with the instructions provided in the procurement notice.
- The bidders must follow the instructions carefully. If the requirement is soft copy, submission is via email to the email mentioned in the notice. If the requirement is hard copy, submission shall be inserted into the tender box.
- Submissions must be received **before the stipulated date and time**. **LATE SUBMISSIONS WILL NOT BE ACCEPTED** and will be rejected outright.

6. Award Notification & Decision Discretion

- Pharmaniaga will inform the successful bidder via email or telephone.
- The company reserves the right to appoint the winning bidder at its discretion and is **not** bound to accept the lowest-priced offer.
- If no notification is received within **180 days** from the closing date, bidders may consider their submission as unsuccessful.

By submitting a bid, bidders agree to comply with all the above terms. Non-compliance may result in disqualification from the procurement process.

ARAHAN KEPADA PEMBIDA

Arahan kepada Pembida ini terpakai kepada semua tawaran perolehan yang dikeluarkan oleh Pharmaniaga Berhad dan termasuk semua anak syarikatnya (*selepas ini dirujuk sebagai Pharmaniaga*), yang merangkumi Tawaran Sebut Harga, Tender Terhad, dan Tender Terbuka. Dengan penyertaan ke atas mana-mana proses perolehan ini, pembida mengakui dan bersetuju dengan terma dan syarat berikut:

1. Kerahsiaan & Integriti

- Semua dokumen, maklumat, dan komunikasi berkaitan dengan proses perolehan ini hendaklah dianggap sebagai sulit. Sebarang pelanggaran kerahsiaan boleh menyebabkan pembida dikeluarkan daripada proses perolehan.
- Pembida hendaklah bertindak dengan penuh integriti dan mendedahkan sebarang konflik kepentingan. Pharmaniaga berhak untuk menolak mana-mana pembida yang melanggar standard etika.
- Pharmaniaga komited dengan standard integriti dan ketelusan tertinggi dalam proses perolehan serta mematuhi Sistem Pengurusan Anti-Rasuah ISO 37001:2016 (ABMS). Pembida dikehendaki mematuhi semua undang-undang dan peraturan anti-rasuah serta anti-korupsi yang berkaitan.

2. Tiada Kewajipan untuk Pemberian Kontrak

- Proses perolehan ini bukan merupakan tawaran untuk memasuki sebarang perjanjian, dan Pharmaniaga tidak mempunyai kewajipan untuk memberi sebarang kontrak.
- Pharmaniaga berhak untuk meminda, menggantung, menamatkan, melanjutkan, atau mengeluarkan semula proses perolehan ini mengikut budi bicara mutlaknya tanpa sebarang liabiliti.

3. Kelayakan & Pendaftaran

- Pembida hendaklah memenuhi semua syarat pendaftaran dan peraturan yang berkaitan.
- Vendor hendaklah berdaftar dengan Pharmaniaga sebelum sebarang tawaran kontrak diberikan. Vendor baharu dibenarkan untuk menyertai tetapi hendaklah melengkapkan proses pendaftaran secepat mungkin.

4. Harga & Tempoh Sah Laku

- Harga yang ditawarkan mesti mempunyai butiran lengkap, termasuk pecahan kos dan cukai yang berkaitan.
- Semua harga mesti dinyatakan dalam Ringgit Malaysia (RM). Walau bagaimanapun, pengeluar asing boleh membida dalam mata wang lain, tertakluk kepada kadar pertukaran semasa.
- Pembida mesti memastikan bahawa sebut harga atau cadangan mereka kekal sah sekurang-kurangnya 60 hari dari tarikh tutup.

5. Penyerahan & Pematuhan Tarikh Akhir

- Semua dokumen yang diperlukan hendaklah dikemukakan mengikut arahan dalam notis perolehan.
- Pembida hendaklah mematuhi arahan dengan teliti. Sekiranya keperluan adalah salinan digital, penghantaran hendaklah dibuat melalui e-mel ke alamat e-mel yang dinyatakan dalam notis. Sekiranya keperluan adalah salinan cetak, penghantaran hendaklah dimasukkan ke dalam peti tender.
- Semua penyerahan mesti diterima **sebelum tarikh dan masa yang ditetapkan**. Penyerahan **LEWAT TIDAK AKAN DITERIMA** dan akan ditolak.

6. Pemakluman Pembida yang Berjaya & Hak Keputusan

- Pharmaniaga akan memaklumkan pembida yang berjaya melalui e-mel atau panggilan telefon.
- Pharmaniaga berhak untuk melantik pembida yang berjaya mengikut budi bicaranya dan tidak terikat untuk menerima tawaran harga terendah.
- Sekiranya tiada sebarang pemakluman diterima dalam tempoh 180 hari dari tarikh tutup, pembida boleh menganggap penyertaan mereka sebagai tidak berjaya.

Dengan penghantaran tawaran bidaan, pembida bersetuju untuk mematuhi semua terma di atas. Kegagalan mematuhi mana-mana syarat boleh mengakibatkan penyingkiran daripada proses perolehan.

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	1 of 10

USER REQUIREMENT SPECIFICATION (URS)

PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS

TABLE OF CONTENTS

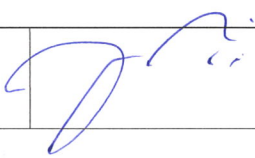




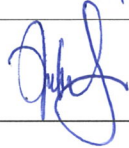
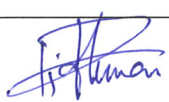
NO	CONTENT	PAGE
1.0	APPROVAL	2
2.0	INTRODUCTION	3
3.0	SCOPE	3
4.0	REQUIREMENT	3-7
5.0	DOCUMENTATION REQUIREMENT	8
6.0	PROJECT LIFE CYCLE	8
7.0	QUOTATION	8
8.0	REFERENCES	8
9.0	VENDOR / SUPPLIER APPROVAL	8

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	2 of 10

1.0 APPROVAL

The following approvals indicate that User Requirement Specification (URS) has been reviewed and approved for execution.

Responsible Person	Name:	Signature:	Date:
Prepared by:			
Assistant Manager Engineering	Saiful Azrin Bin Jamaludin		25 Nov 2025
Reviewed by:			
Head of Engineering	Muhammad Hafizi Bin Zainal Abidin		25 Nov 2025
Head of Production	Muhammad Syafiq Bin Che Abdullah		27 Nov 2025
Head of Technical Service	Fadhlina Hani Binti Shahaldin		27 Nov 2025
Head of Quality Control	Nur Afiza Binti Abu Bakar		04 Dec 2025
Head of Quality Assurance	Hashahrul Izam Bin Mat Sarif		05 Dec 2025
Approved by:			
Head of Plant	Mohd Ridhwan Bin Kalantar Mastan		24 Dec 2025

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	3 of 10

2.0 INTRODUCTION

- 2.1 InspiraPharma Sdn. Bhd., Seri Iskandar (IPSB-SI) proposes to renovate and reconfigure the existing Penicillin Sterile Plant to support the transfer and production of Sterile Cephalosporin products, ensuring full compliance with cGMP standards, effective process segregation, and efficient facility operation tailored to the new product requirements.

3.0 SCOPE & REQUIREMENT

- 3.1 Heating, Ventilation and Air Conditioning (HVAC) system.

Requirements:

- i. To supply and replace all primary, secondary and HEPA filter for AHU1 to AHU4 and PAHU.
- ii. To supply and replace all flexible ducts.
- iii. To connect the new flexible ducts (supply and return) from/to the main duct to the newly designated rooms in accordance with the approved design layout.
- iv. To inspect all instruments and equipment associated with the HVAC system and replace any defective components where necessary.
- v. The HVAC system shall be designed to control and maintain the **relative humidity (RH), temperature (T), and differential pressure (DP)** within the Cephalosporins area according to the following parameters:
 - a. $RH \leq 55\%$
 - b. $18^{\circ}\text{C} \leq T \leq 24^{\circ}\text{C}$
 - c. DP: same grade more than 5Pa, different grade more than 10Pa (more than 15Pa for Airlock).

- 3.2 Cephalosporins plant

General Requirements:

- i. The renovation works shall be conducted in a manner that does not interrupt the operations of the Non-Sterile Penicillin plant, including but not limited to material movement, disposal bin placement, and contamination risk.
- ii. Dismantling of the polyurethane (PU) panel walls and ceiling, vial washer, tunnel, and vial filling machine, and transferring them to the Engineering Store. The newly installed PU panel ceiling shall be at a height of 3 m from the finished floor level.
- iii. The flooring in Grade D, C, B and Secondary Packing cleanroom areas shall be finished with a self-levelling epoxy system, and any renovated or affected areas shall be repaired and made good to ensure a seamless surface.
- iv. All existing brick walls (including change room for Secondary Packing and Airlock) shall be covered with polyurethane (PU) panels, complete with mortar or aluminum coving as required.
- v. All existing supply and return grilles shall be cleaned and polished and made free from stains and surface roughness. Powder coating shall be applied where

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	4 of 10

necessary to restore the surface finish and appearance. Replacement with new supply and return grilles shall be carried out if required.

- vi. The contractor shall supply and replace all switch socket outlets.
- vii. The contractor shall supply and replace all door closer units.
- viii. The contractor shall recommend and identify appropriate pest control points for the newly constructed Microbiology Laboratory areas located in the vacant area.
- ix. The contractor shall supply and replace Relative Humidity (RH), Temperature (T), and Pressure transmitters, including rewiring work if required. All supplied and installed instruments shall be calibrated, with valid calibration certificates and corresponding calibration stickers provided.
- x. The contractor shall design and install the fire safety system for the renovated rooms and microbiology laboratory and shall be fully responsible for obtaining the Certificate of Completion and Compliance (CCC) as well as securing the required fire certification and approvals from Jabatan Bomba dan Penyelamat Malaysia (JBPM).

3.3 Renovation of existing rooms/areas:

Scope of rooms:

- i. Secondary packing
- ii. Male change room
- iii. Female change room
- iv. Air lock
- v. Inspection room
- vi. Vial filling
- vii. Corridor Grade B
- viii. Sterile preparation room
- ix. Preparation area
- x. Vial washing
- xi. Filter Integrity Test (FIT) room
- xii. Media preparation
- xiii. Cleaned equipment
- xiv. C Degown
- xv. Sterile office

Requirements:

The above rooms shall be renovated and upgraded in accordance with the new facility layout (refer attachment for existing plant layout and proposed new facility layout) and design intent to meet GMP and functional requirements.

3.4 PU Panel Dismantling and Area Reconfiguration

- i. Airlock
- ii. Male & Female Change Room (including dismantling of sink and three cubicles)
- iii. Inspection

Requirements:

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	5 of 10

- i. The areas listed shall be dismantled and reconfigured to accommodate the new layout for **Secondary Packing, Coding Room, Packaging Material Staging, WIP Staging, Airlock 5, Inspection, and IPQC Room.**
- ii. The system shall include the installation of new PU panels wall, single/double leaf PU panel doors, and electrical power sockets (**3 points** in Coding Room, **3 points** in Packaging Material Staging, **4 points** with stainless steel trunking installed at the center of the Secondary Packing area, **8 points** in Inspection Room, **4 points** in IPQC Room, **3 points** at vacant space adjacent to Inspection room).
- iii. Installation of new PU panel ceiling to replace suspended ceiling to create dedicated room listed above. Application of self-levelling epoxy flooring to replace the existing vinyl floor and epoxy floor.
- iv. Each newly configured room shall be equipped with dedicated air diffusers, return louvers, lighting, and pressure/RH/temperature transmitters/manometer as per the approved design layout.
- v. Existing or new electrical sockets, Central Vacuum (CV), CDA points of use, water supply piping, sink, lighting fixtures, diffusers, and return grilles shall be relocated/dismantled as necessary to suit the new configuration.
- vi. A new PU panel wall and double-leaf door shall be installed at the airlock connecting the Secondary Packing and Capping Station rooms, complete with an interlock system. The airlock floor shall be of self-levelling epoxy type, and the ceiling shall be constructed of PU panel.

3.5 Change Room Reconfiguration

Requirements:

- i. The existing Female Change Room shall be reconfigured into two separate change room areas for Male and Female personnel. Each change room shall include two gowning cubicles.
- ii. Installation of new PU panel ceiling and wall. Installation of a new PU panel entrance door at the Male Changing Room. Each new changing room shall include dedicated diffusers, return grilles, lighting, and pressure transmitters/manometer as per design.
- iii. The water supply piping shall be relocated, and new piping installed according to the approved design. Each change room shall be equipped with a stainless steel sink fitted with one faucet, a soap dispenser, a hand dryer, and a crossover bench.
- iv. Existing or new electrical power sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA points of use, lighting, diffusers, and return grilles shall be relocated where necessary.
- v. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

3.6 Sterile office

Requirements:

- i. The existing vinyl floor shall be replaced with a self-levelling epoxy finish complete with mortar/aluminium coving. The existing gypsum board ceiling shall be replaced with PU panel.
- ii. The existing static passbox shall be dismantled and will be installed at Microb Lab. Any structural poles inside the office shall be enclosed with PU panel.

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	6 of 10

- iii. Defective PU panel walls shall be replaced. The existing PU panel door shall be relocated as required.
- iv. Dedicated diffusers, return grilles, and lighting shall be installed as per the design layout. Electrical power sockets shall be relocated where necessary.

3.7 Capping Station room

Requirements:

- i. Dismantling of PU panels/door, electrical points, central vacuum points, CDA points, and transmitters (RH, T, P), air supply and return grilles (including flexible duct).
- ii. Reconfigure the rooms size by installation of new PU panel wall, ceiling, air supply and return grilles (including new flexible duct). Installation of a new PU panel double-leaf door.
- iii. Existing or new electrical sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA POU's, lighting, diffusers, and return grilles shall be installed or relocated as required.
- iv. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

3.8 Vial Filling

Requirements:

- i. The PU panel wall shall be relocated and replaced with a new one according to the revised layout. The air return duct shall be relocated accordingly.
- ii. Reconfigure the rooms size by installation of new PU panel wall (with 2 viewing glass from Vial Filling to Capping Room and Vial Washing room), ceiling, air supply and return grilles (including new flexible duct).
- iii. To supply and replace the softwall curtain. The material used shall be chemically resistant and suitable for cleanroom applications.
- iv. All Fan Filter Units (FFU) (2 ft × 4 ft – 18 units; 2 ft × 2 ft – 1 unit) above the ceiling shall be replaced with new units.
- v. To supply and replace the FFU for the **three** Dynamic Pass Boxes.
- vi. Existing or new electrical sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA POU's, lighting, diffusers, and return grilles shall be installed or relocated as required.
- vii. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

3.9 Corridor, B Gown and B Degown.

Requirements:

- i. The Janitor, return duct and associated PU panel shall be dismantled and relocated per the design layout. A new **L-shape Dynamic Passbox** shall be installed to connect Corridor 2W21 and Corridor 2W07.
- ii. A new cross-over bench shall be installed in each B Gown and B Degown Room. The bench shall be constructed from SUS304, with dimensions of 1500 mm (L) × 300 mm (W) × 300 mm (H), and shall be of floor-mounted type with no gap between the bench and the floor.
- iii. Existing or new electrical sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA POU's, lighting, diffusers, and return grilles shall be installed or relocated as required.
- iv. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	7 of 10

3.10 Sterile Preparation Area, Vial Washing and Preparation Area

Requirements:

- i. The PU panel wall between Sterile Preparation Area, Vial Washing and Preparation Area shall be dismantled to allow reconfiguration of the Vial Washing Room. Reconfigure the rooms size by installation of new PU panel wall (with 3 viewing glass from Vial Washing to Sterile Preparation Area/Preparation Area and Corridor to Preparation Area)
- ii. The dynamic passbox in Sterile Preparation Area shall be relocated to the Preparation Area.
- iii. Another dynamic passbox shall be dismantled and relocated adjacent to the sterilizer unloading area, along with the relocation of the return air grille.
- iv. The PU panel double-leaf door of the Vial Washing Room shall be relocated accordingly. Defective PU panel walls or ceiling shall be replaced.
- v. Four units of FFU (2 ft × 4 ft) shall be supplied and installed at the Dynamic Passbox and Sterilizer locations.
- vi. To supply and replace the softwall curtain. The material used shall be chemically resistant and suitable for cleanroom applications.
- vii. Existing or new electrical sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA POU's, lighting, diffusers, and return grilles shall be installed or relocated as required.
- viii. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

3.11 FIT, Media preparation, Cleaned Equipment and C Degown room.

Requirements:

- i. The room sizes for FIT, Media Preparation, and Cleaned Equipment Rooms shall be reconfigured due to PU panel wall adjustments. The static passbox shall be dismantled and will be installed at Microb Lab. Defective PU panel walls or ceiling shall be replaced.
- ii. The C Degown Room shall be reconfigured to include a new dedicated Sterile Garment Room.
- iii. Existing or new electrical sockets, pressure transmitter, RH/T transmitter, Central Vacuum (CV), CDA POU's, lighting, diffusers, and return grilles shall be installed or relocated as required.
- iv. Relocation of the air return grill including the floor mounted bump rail at the corridor due to reconfiguration of room size.
- v. Application of self-levelling epoxy flooring to replace the existing epoxy floor.

3.12 Microbiology Laboratory Facility

Requirements:

- i. The laboratory design shall comply with GMP Grade B for critical operations and Controlled Unclassified as per design layout except for waste room area.
- ii. The laboratory shall have control access door to prevent unauthorized personnel from accessing the laboratory.
- iii. Construction materials for ceilings and walls shall be PU panels with non-shedding, smooth, easy-to-clean surfaces that are resistant to disinfectants and chemicals. Application of self-levelling epoxy flooring, with coving provided at the wall-to-floor junctions.

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	8 of 10

- iv. Each area should have independent lighting, air distribution, and differential pressure control.
- v. The HVAC system shall maintain **temperature, humidity, and pressure differential** as per classification.
- vi. Door interlock systems shall be provided for all airlocks to maintain pressure integrity.
- vii. Sliding door frame with half-glass with accessories and easy to clean features shall be provided to related 6 rooms as per approved layout. Installation of PU panels with viewing glass at three locations (Instrument Area, between the Microbiology Office and the Preparation Area, and the Autoclave Room).
- viii. Safety systems (sprinkler, fire alarm, exhaust hood, fire extinguisher) shall be installed as required.
- ix. To supply and install **two new Dynamic Pass Boxes** and reinstall two **existing Static Pass Box** from the Production Department ensuring installation is carried out in accordance with the approved layout.
- x. To install new standard electrical sockets (UK 13A and 15A plug) as required which can accommodate electrical current requirements with an additional 20-40% capacity with GENSET availability. The quantity of plug required is as below:
 - a. Plug 15A: 5 pcs
 - b. Plug 15A with GENSET availability: 2 pcs
 - c. Plug 13A: 30 pcs
 - d. Plug 13 A with GENSET availability: 14 pcs.
- xi. Circuit breakers should be located outside the lab, but not in rated corridors. In the event of an emergency, the laboratory may be unsafe to enter. Hence, the circuit breakers for key electrical appliances should be located outside the laboratory.
- xii. New piping installed according to the approved design. Piping required as listed below:
 - a. Change Room 1: Sink fitted with one faucet with drainage system, a soap dispenser, a hand dryer, and a crossover bench.
 - b. Preparation area: Sink fitted with one faucet with drainage system.
 - c. Instrument room: Installation of 2 floor trap systems for condensation produced from operated incubators.
 - d. Autoclave room and decontamination room: Installation of one heat-resistant floor trap in each room for the discharge of hot water and steam condensate. Installation of a drainage system for sink installation in the decontamination room.
 - e. Waste room: Installation of one raw water tap and one floor trap system for cleaning purposes.
- xiii. Dedicated HVAC system serving only the Microlab. Shall maintain required temperature, humidity, and pressure cascade across rooms. Continuous monitoring of differential pressure, temperature, and RH. The specification of temperature and RH as below:

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	9 of 10

No	Area	Grade	Temperature (°C)	Relative Humidity (%)	Differential Pressure
			Operating range	Operating range	
1	Microbiology area that consists of: a. Autoclave room b. Office c. Preparation area d. Decontamination room e. Corridor f. Instrument area g. Testing area h. Air Lock 1 i. Air Lock 2 j. Change Room 1	CNC	19-23	50-60%	
2	Change room 2	D			
3	Change room 3	C			
4	Change room 4	B			
5	Sterility room	B			
6	Door from unclean area to air lock				>20
7	Door from air lock to Grade CNC area				>15
8	Door from Grade CNC to Grade CNC				>5
9	Door from Grade CNC to Grade D				>20
10	Door from Grade D to Grade C				>15
11	Door from Grade C to Grade B				>15
12	Door from Grade B to Grade B				>5

xiv. Sterility Room

- a. Classified as **Grade B** cleanroom.
- b. Dedicated supply and return air diffusers with HEPA filtration.
- c. Surfaces shall be smooth, non-porous, and disinfectant-resistant.
- d. Equipped with dynamic passbox for material transfer.

3.13 Inbound G

Requirements:

- i. The Inbound G area shall be reconfigured to accommodate the installation of the new Purified Water System (PWS).
- ii. A new room shall be constructed with the following specifications:
 - a. Double-leaf PU panel door
 - b. Brick wall construction
 - c. Room size: 9 m (L) × 3 m (W)
- iii. The existing waste cage shall be relocated to an area adjacent to the Airlock 1 door.

3.14 HVAC balancing and Cleanroom Performance Test (CPT) to meet Cleanroom Pharmaceutical Grade specifications.

3.15 Vendor:

INSPIRAPHARMA SDN. BHD.

USER REQUIREMENT SPECIFICATIONS PLANT RENOVATION FOR CEPHALOSPORINS PRODUCTS	Document No.	ENG/URS-0114
	Revision No.	00
	Page No	10 of 10

- i. Conduct a site visit to obtain actual measurements of the rooms.
- ii. Complete the project within three months.

4.0 DOCUMENTATION REQUIREMENT

- 4.1 The vendor shall provide detailed specifications for the ducting including primary/secondary/HEPA filter, PU panel, coving, epoxy self levelling, PU panel door, HVAC system for Microlab, return/inlet grilles along with the workflow and materials used, including their specifications.
- 4.2 Vendor shall provide complete documentation package for Microlab Facility and HVAC:
 - 4.2.1 Design Qualification (DQ)
 - 4.2.2 Installation Qualification (IQ)
 - 4.2.3 Operational Qualification (OQ)
 - 4.2.4 Piping & Instrumentation Diagram (P&ID)
 - 4.2.5 Material Certificates (MOC)
 - 4.2.6 FAT & SAT Protocols and Reports
- 4.3 The vendor shall prepare HIRADC (covering the scope of dismantle/installation of the panel/ceiling/return & supply grill, HVAC ducting, electrical works and etc) in accordance with the workflow and submit it to IPSB-SI for review and approval. The HIRADC shall identify all risks and hazards and propose comprehensive control measures.
- 4.4 All foreign workers involved in this project must have valid permits and passports. They shall be supervised to ensure compliance with the rules and regulations of IPSB-SI. Working hours for the workers shall comply as per Employment Act in Malaysia.

5.0 PROJECT LIFE CYCLE

- 5.1 The vendor shall complete the project within **three months**.

6.0 QUOTATION

- 6.1 The vendor shall provide quotation and rates for:
 - 6.1.1 Plant renovation.
 - 6.1.2 Microbiology Laboratory Facility

7.0 REFERENCES

- 7.1 Chapter 3 – Premises & Equipment.
Guideline Good Manufacturing Practice for Medicinal Product Part I Aug 2023.
- 7.2 ISO 14644-1 Cleanroom Classification.
- 7.3 ISPE: Temperature & Humidity Requirements in Pharmaceutical Facilities Oct 2021.

8.0 VENDOR/SERVICE PROVIDER ACKNOWLEDGEMENT

This document has been reviewed and acknowledged by the Vendor/Service Provider.

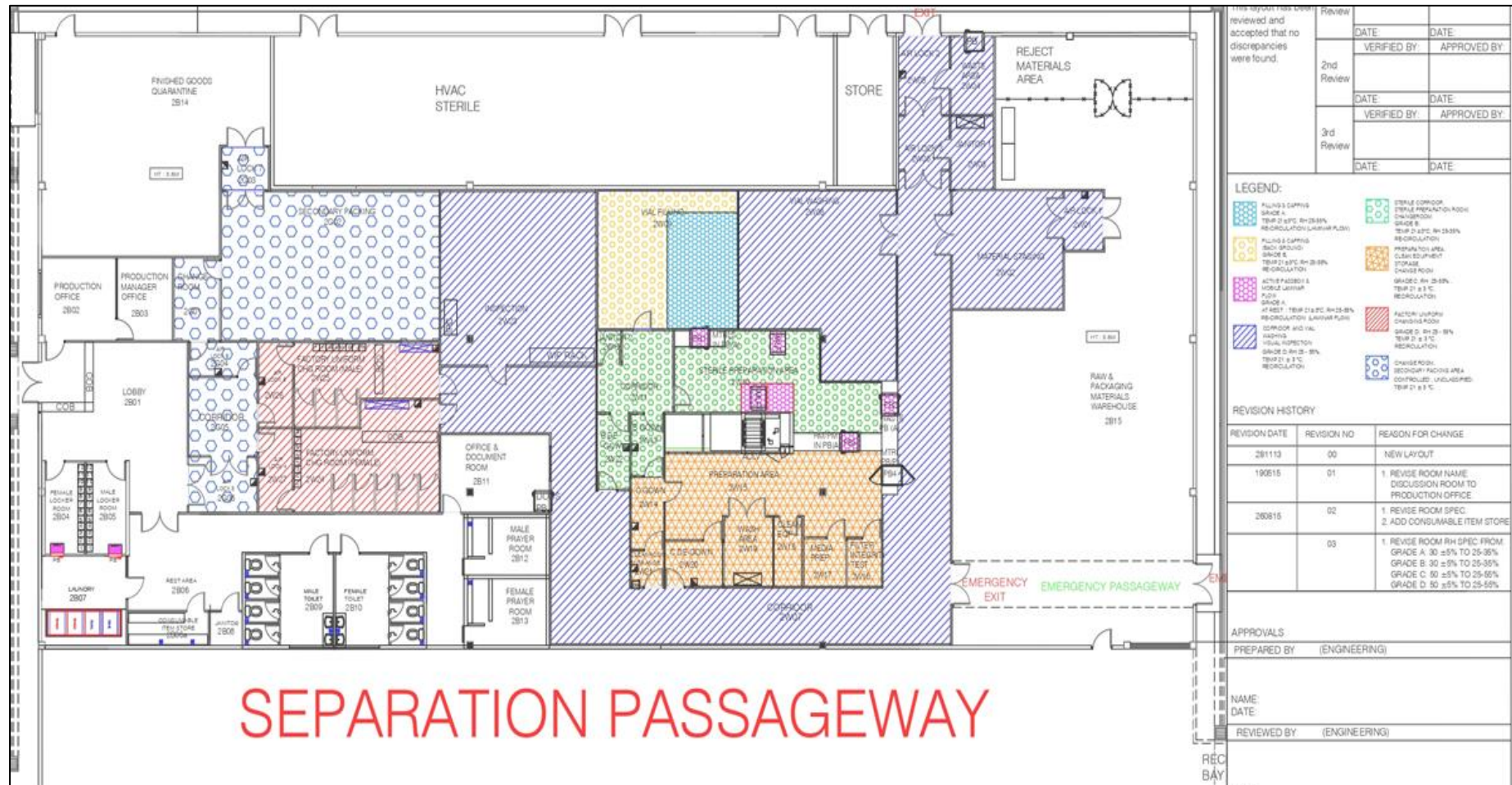
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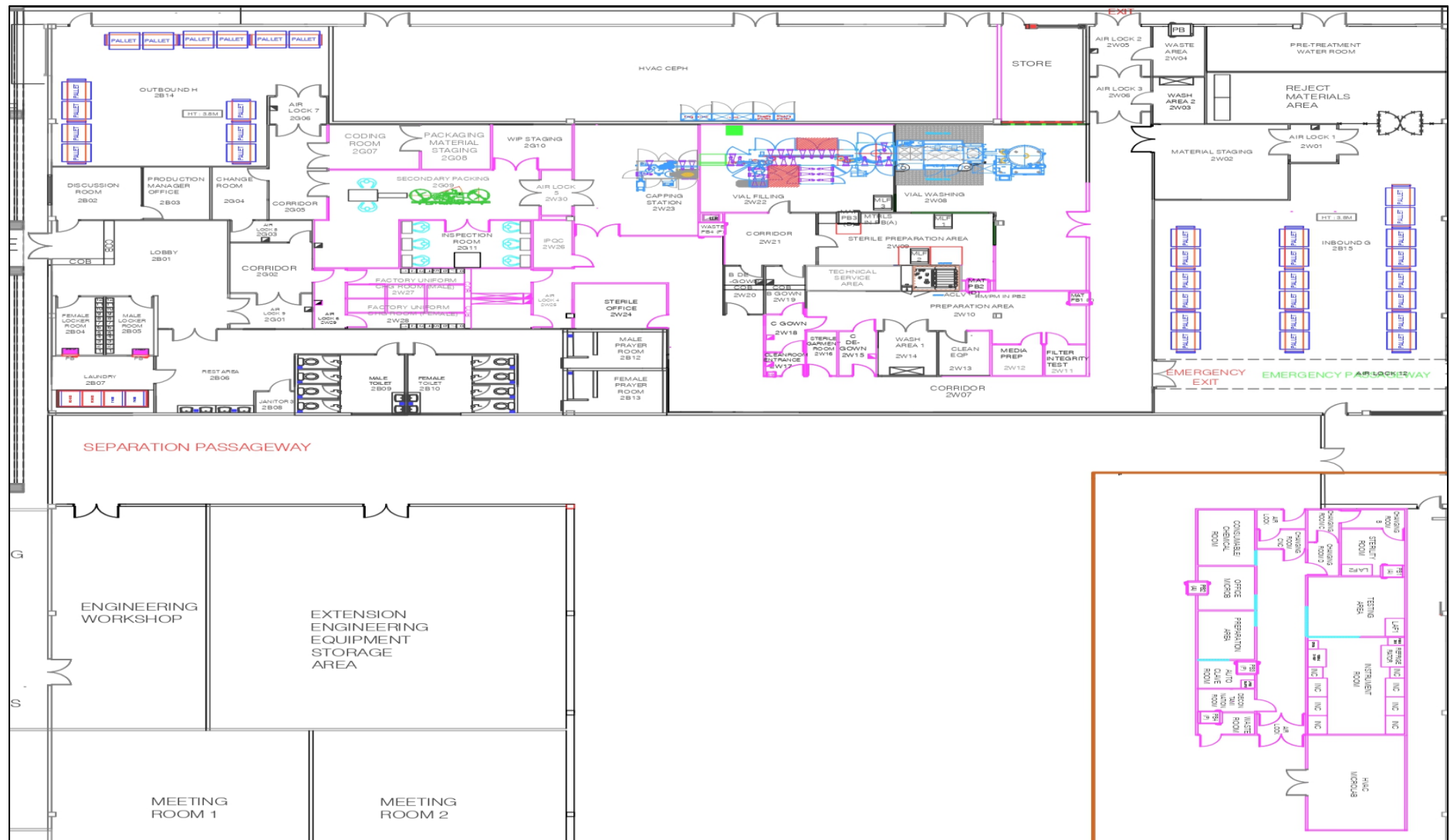
Position: _____

Date _____

Annexure 2: Existing Room Specifications



Annexure 3: New Plant Layout



Annexure 4: New Room Specifications

