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

USER REQUIREMENT SPECIFICATION (URS)

PURIFIED WATER AND WATER FOR INJECTION SYSTEM FOR CEPHALOSPORINS PLANT

TABLE OF CONTENTS

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

2.0 INTRODUCTION

InspiraPharma Sdn. Bhd., Seri Iskandar (IPSB-SI) proposes to install a new Purified Water (PW) and Water for Injection (WFI) Generation System for the new Sterile Cephalosporins Plant. This URS covers the supply, installation, testing, and commissioning of Purified Water (PW) and Water for Injection (WFI) Generation System. The system shall include all necessary components for pretreatment, Reverse Osmosis (RO) purification, post-treatment Electrodeionization (EDI) processes and interconnection to the WFI generation system to achieve the required WFI quality. The system shall be fully automatic, skid-mounted, with integrated control and monitoring features. The system is critical to ensure continuous supply of pharmaceutical-grade water in compliance with GMP, FDA, and EU standards.

3.0 SCOPE & REQUIREMENTS

3.1 The PW and WFI systems shall be fully automated, controlled, and monitored via a Programmable Logic Controller (PLC) with Human–Machine Interface (HMI). The system shall be designed to minimize energy consumption and microbiological contamination and to ease the maintenance, operation, and cleaning.

3.2 All instruments i.e pH meter, conductivity, temperature sensor, flow meter, Total organic carbon(TOC) meter and etc. shall be GMP-compliant, calibrated, and suitable for sanitary/hygienic service.
System control shall include:

i. Automatic operation of valves, pumps, and sanitization sequences.
ii. Alarm management for deviation, equipment fault, or out-of-specification conditions.
iii. Data acquisition, trending, and secure storage in accordance with 21 CFR Part 11 and Annex 11 (electronic records and audit trails).
iv. Operator access shall be user-restricted (Administrator / Supervisor / Operator) with password protection.

3.3 All product-contact piping, fittings, valves, and tanks shall be fabricated from SUS 316L. No dead-legs shall be accepted. All tees shall be arranged to permit full drainage and continuous flow. Piping to be self-draining toward drains. Passivation and sanitization procedures shall be considered when selecting materials to avoid corrosive effects or damage to the distribution systems.

3.4 Provide aseptic sample ports and dedicated instrument taps (conductivity, temperature, TOC) at strategic locations. Sample points should be designed for easy aseptic sampling and full drainage.

3.5 All tanks and high points shall use 0.2 μm hydrophobic vent filters. Vents shall be piped for condensate/drain as applicable.

3.6 Design for continuous circulation, periodic sanitization cycles (automatic), and minimal storage time at user points to control the bioburden. The Purified Water (PW) system shall be installed within a room measuring 9 meters in length and 3 meters in width.

3.7 Purified Water (PW) System Capacity
- 3.7.1 Design Capacity: 1200 L/hr (continuous operation)
- 3.7.2 Operating Hours: 24hours
- 3.7.3 Feed Water Source: Supplied by the authority (Lembaga Air Perak) with the following water specifications: pH 6.5–8.5, Chloride 250 ppm (mg/L), and Sulfate 250 ppm (mg/L).

3.8 The System Process Flow Description begins with the feed water being pumped by a centrifugal pump through the Multimedia Filter.
- 3.8.1 Removes suspended solids, turbidity, and particulate matter.
- 3.8.2 Filtration through layers of graded sand, gravel, and anthracite media.
- 3.8.3 Automatic backwash and rinse cycle via PLC control.
- 3.8.4 Turbidity: ≤1 NTU.

3.9 Activated Carbon Filter
- 3.9.1 Removes free chlorine, organic compounds, color, and odor.
- 3.9.2 Prevents oxidation damage to RO membranes.
- 3.9.3 Equipped with automatic regeneration and backwash function.
- 3.9.4 Residual chlorine after ACF: <0.1 ppm.
- 3.9.5 ORP sensor installed downstream to verify chlorine removal.

3.10 Water Softener
- 3.10.1 Removes hardness (Ca^{2+}, Mg^{2+}) to prevent scaling on RO membranes.
- 3.10.2 Uses food-grade cationic resin with automatic regeneration using brine solution.
- 3.10.3 Outlet hardness: <5 ppm as $CaCO_3$.

3.11 5Micron Cartridge Filter
- 3.11.1 Protects RO membranes from fine particulates and resin carry-over.
- 3.11.2 Replaceable polypropylene cartridge type.

3.12 UV Sterilizer
- 3.12.1 To reduce microbial load before RO membranes and minimize biofouling potential.
- 3.12.2 Specification: UV intensity ≥ 30 mJ/cm², stainless steel 316L housing, quartz sleeve design with intensity monitors and alarm.

3.13 Reverse Osmosis Unit (RO)
- 3.13.1 Primary purification stage to remove 95–99% of dissolved salts, organic matter, bacteria, and pyrogens.

3.13.2 Equipped with high-pressure pump, RO membranes (polyamide thin-film composite), pressure gauges, conductivity sensors, and flow meters.
3.13.3 Automatic flushing before and after each operation.
3.13.4 RO recovery: 60–70%.
3.13.5 Conductivity: ≤1.3 µS/cm

3.14 Electrodeionization (EDI) Unit
3.14.1 Final polishing step to achieve pharmaceutical-grade purified water quality.
3.14.2 Removes residual ions using ion-exchange resins and electrical potential (no chemical regeneration).
3.14.3 Conductivity : ≤1.0 µS/cm (25°C).
3.14.4 TOC: ≤500 ppb.
3.14.5 Continuous operation with automatic alarm for conductivity deviation.
3.14.6 RO temperature prior to Product Water Storage Tank: 20-25°C.

3.15 Product Water Storage Tank
3.15.1 316L stainless steel, sanitary design with vent filter (0.2 µm hydrophobic).
3.15.2 Equipped with conductivity, temperature, and level sensors.
3.15.3 Spray ball for automatic hot water or chemical sanitization
3.15.4 Designed for feed to WFI generation system via transfer pump.

3.16 Transfer Pump
3.16.1 Provides constant pressure feed to **new WFI distiller** and **one unit of existing distiller** in IPSB-SI, located in the WFI room.
3.16.2 Equipped with variable frequency drive (VFD) and pressure control loop.
3.16.3 Pump head and seals: sanitary-grade SS316L, FDA-compliant.

3.17 System Interface with WFI Generation
3.17.1 WFI System : Design Capacity 800-900L/hr
3.17.2 Operating hours: 24 hours
3.17.3 PW system provides feed water to new and existing WFI distiller via dedicated transfer line.
3.17.4 The interface point shall be clearly identified in P&ID and validated during FAT/SAT.
3.17.5 Conductivity and temperature at the PW–WFI interface shall be continuously monitored.
3.17.6 Control interlocks:
3.17.6.1 Low PW tank level → inhibit WFI feed pump operation.
3.17.6.2 High conductivity alarm → signal to WFI PLC to prevent feed acceptance.
3.17.6.3 UV intensity alarm → inhibit feed line operation.
3.17.7 Communication between PW PLC and WFI PLC through Modbus TCP/IP or equivalent protocol.

3.17.8 The generated WFI will be connected to the existing 2000L tank located in the WFI room. The WFI supplied to the tank shall be fully compatible with the existing WFI system in terms of monitoring and system operation.

3.18 Control and Instrumentation Requirements

3.18.1 PLC-based automatic control with HMI interface.

3.18.2 Data logging for pH, Chlorine, Conductivity, TOC, Temperature, feed/circulation flow, pressure and operational status.

3.18.3 Alarm and interlock for pressure, conductivity, low feed flow, or abnormal system conditions.

3.18.4 Trending and report generation for audit trail (21 CFR Part 11 compliance preferred).

3.19 Construction and Materials

3.19.1 All product contact parts: SS 316L with sanitary weld and electro-polished finish (Ra ≤ 0.8 µm).

3.19.2 Piping: Orbital welded SS316L.

3.19.3 Skid frame: SS304.

3.19.4 Membrane housings: SS316L or FRP (for pretreatment).

3.19.5 Valves: Sanitary-grade diaphragm or ball valves.

3.19.6 Seals and gaskets: FDA-approved EPDM or PTFE.

3.20 Quality of Purified Water

3.20.1 The RO water shall comply with the following pharmacopoeia standards:

Parameter	Requirement	Reference
Conductivity	≤ 1.3 µS/cm @ 25°C	USP/EP
TOC	≤ 500 ppb	USP/EP
Microbial Count	≤ 100 CFU/mL	USP/EP
Nitrates	≤ 0.2 ppm	USP/EP
Heavy Metals	≤ 0.1 ppm	USP/EP
pH	5.0 – 7.0	USP/EP
Appearance	Clear, colourless, odourless	USP/EP
Temperature	Ambient (15–30°C)	-

3.20.2 The WFI shall comply with the following pharmacopoeia standards:

Parameter	Requirement	Reference
Conductivity	≤ 1.0 µS/cm @ 25°C	USP/EP
TOC	≤ 300 ppb	USP/EP
Microbial Count	0	USP/EP
Nitrates	≤ 0.2 ppm	USP/EP
Heavy Metals	≤ 0.1 ppm	USP/EP
Microbial limit	≤ 1 CFU/100ml	USP/EP
Bacterial Endotoxins	≤ 0.125 EU/ml	USP/EP
pH	5.0 – 7.0	USP/EP

Appearance	Clear, colourless, odourless	USP/EP
Temperature	80–85°C (Hot loop)	USP/EP

4.0 DOCUMENTATION REQUIREMENT

4.1 The system must comply with the following regulatory and design standards:
- 4.1.1 US FDA cGMP (21 CFR Part 210 & 211)
- 4.1.2 EU GMP (Annex 1 & Annex 15)
- 4.1.3 ISPE Baseline Guide – Water and Steam Systems
- 4.1.4 USP, EP Purified Water Specifications
- 4.1.5 ASME BPE for hygienic design
- 4.1.6 GAMP 5 for automation system

4.2 Vendor shall provide complete documentation package:
- 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 Installation Requirements
All equipment shall be installed, aligned, and interfaced with utilities:
- 4.3.1 Electrical power.
- 4.3.2 Compressed air.
- 4.3.3 Raw water supply.

4.4 The vendor shall be responsible for unloading at Malaysia port including insurance, delivery to site and unloading to secure storage area at site. The vendor shall prepare the HIRADC (covering the scope of installation of the PWS & WFI generation, storage, and distribution system) 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.

4.5 The system and all its ancillary items of equipment but excluding consumable parts must be guaranteed for 12 months from the time of on-site acceptance. The Vendor shall guarantee the availability of all spare parts for the equipment for at least 10 years from date of supply.

4.6 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.

4.7 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 3 months.

6.0 QUOTATION

6.1 The vendor shall provide quotation and rates for:

6.1.1 Purified water and water for injection system including the installation works.
6.1.2 FAT & SAT
6.1.3 Qualification & Training

7.0 REFERENCES

7.1 Chapter 3 – Premises & Equipment.
Guideline Good Manufacturing Practice for Medicinal Product Part I Aug 2023.
7.2 ISPE: Volume 4 – Water and Steam System 2nd edition.
7.3 Annex 2: WHO Good Manufacturing Practices: Water for Pharmaceutical Use.
7.4 US and EU Pharmacopeia.

8.0 VENDOR/SERVICE PROVIDER ACKNOWLEDGEMENT

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

Name: _____ Signature: _____

Position: _____ Date _____