World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Incepta Pharmaceuticals Ltd. (UNIT-10)**
Corporate address of the manufacturer	Incepta Pharmaceuticals Ltd. Corporate Head Office, 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208, Bangladesh
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Dhamrai unit Factory: Unit-10, Potent Drug Facility (PDF), Krishnapura, Sahabelishor, Dhamrai, Dhaka, Bangladesh
Unit/block/ workshop number	Unit-10: Medogen SubQ Injection (Uniject device) and Medogen Injection IM (depot) [Line 2]
Inspection details	
Dates of inspection	12-16 January 2025
Type of inspection	Initial inspection for Unit-10
Introduction	
Brief description of the manufacturing activities	The Dhamrai site comprises the following units and facilities respectively:

Unit	Facility
Unit-01	***Injectable Potent Drug (IPD)*** *and Oral Solid Dosage (OSD) Facility*
Unit-02	*Semi Solid preparation, BFS, Natural Products, AH Products*
Unit-03	*Oral Solid Dosage Production Facility for US Market*
Unit-04/15	*Central Utility Building-CUB 01 / CUB 02*
Unit-05/07	*Hygiene and Hospicare Production Facility 01 / 02*
Unit-06	*Animal Vaccine Production Facility*
Unit-08	*Swiss Bio-hygienic Equipment-SBE (a joint venture)*
Unit-09	*Sterile Production Facility*
Unit-10	***Potent Drug Facility (Injection, Solid and Semi-solid)***
Unit-11	*Multipurpose Production Facility (Planned)*
Unit-12	*Central Utility Building-CUB 04 (Planned)*
Unit-13	*Solvent Based Production Facility*
Unit-14	*New Production Facility Expansion (planned)*
Unit-16	*Technical Workshop*
Unit-17/18/19	*CUB 03 / Warehouse-IBS / Warehouse Central (Under Construction)*

	Other facilities include a quality control laboratory, microbiology laboratory, warehouse, engineering support, office, laundry and canteen, power generator and pump house, security gate, and wastewater treatment.
General information about the company and site	Incepta Pharmaceuticals Ltd was established in 1999 and started operations in January 2000. Incepta Pharmaceuticals Ltd is structured with two manufacturing sites: **1. Zirabo Facility:** Located at Savar, covering an area of about 12 acres, it manufactures pharmaceuticals, biosimilar products, and human vaccines. **2. Dhamrai Facility:** Located at Dhamrai, covering an area of about 104 acres and manufacturing pharmaceuticals, animal health products, herbal and Nutricare, hygiene and hospicare, Swiss Bio Equipment, and Incepta Chemicals. The site employed 193 employees dedicated to PDF and 43 for the common service-providing department at the time of inspection.
History	This was the first PQ inspection of Incepta, Unit-10. The last WHO inspection was conducted at Unit-1 from May 8 to 12, 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management system - Potent Drug Facility (PDF), Unit-10 (Medogen SubQ Injection (Uniject device) and Medogen Injection (IM) (Line 2). - Quality control laboratories - Utilities
Restrictions	The inspection was limited to Unit-10 for Medogen SubQ injection and Medogen Injection (IM) (Line 2
Out of scope	This inspection did not cover other units, areas, or products beyond the Medogen SubQ injection and Medogen Injection (IM) (Line 2).
WHO products covered by the inspection	Medroxyprogesterone acetate - Sterile Suspension for injection 104mg/0.65ml) (RH106) Medroxyprogesterone acetate - Sterile Suspension for injection 150mg/ml (RH084) [Line 2]
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring

FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	Summary of the findings and comments

1. Pharmaceutical quality system

A documented system for quality assurance was established, with procedures in place that cover key quality elements. The quality department was divided into QA and QC and separated from the production department. Operations were specified in written form, and critical GMP requirements were essentially met. The procedures reviewed and discussed during the inspection were generally acceptable; however, improvements were sought in some cases. The following PQS elements were reviewed:

Product quality review (PQR)
The SOP for PQR was reviewed, and it was noted that the QA department was responsible for performing PQR overall in support of other departments. The data were analyzed using Minitab software, and a graphical presentation was prepared. An Excel sheet would be used if fewer than 10 batches were manufactured. The process capability limit of not less than 1.33 was described in the procedure, and should the CpK be found to be below 1.00, a deviation would be raised and investigated. The procedure also stated that if 10-15 batches were manufactured, the CpK would not be performed; instead, a graphical presentation would be prepared. The PQR was prepared annually on a rolling basis, and the PQR for September 2023 and June 2024 was reviewed (approved dated 14/08/2024).

Change Control (CC)
SOP Change Control described managing changes related to materials, methods, processes, facilities, equipment, systems, and documents due to regulatory or business requirements. The scope of the SOP was applied to managing changes that have a direct or indirect impact on the PQS in all areas of the company. All changes were proposed through a CC form. The form included the change proposer, the scope, the department, the change control reference number, and the area to which the change was related, e.g., production, R&D/QA/QC/MB, supply chain, engineering, warehouse, cleaning procedures, and computer systems. The reason for the change was captured. Change Controls were classified as major and minor.

Quality risk management (QRM)
The SOP for QRM was discussed, which guided the performance of risk assessments. The risk assessments related to data integrity, contamination, cross-contamination, and others had been reviewed.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources, including adequate premises, equipment, and utilities, were provided to support the current operational level of Medogen subcutaneous injection (SQ) and Medogen Injection (IM) line 2 manufacturing activities. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. The manufacturing facility where Medogen SQ and Medogen Injection (IM) were produced was dedicated. The implementation of WHO guidelines on

good manufacturing practices for sterile pharmaceutical products (WHO TRS No. 1044, Annex 2) was discussed.
The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

3. Sanitation and hygiene

Clean areas were frequently disinfected per the defined process and procedure. More than one type of disinfecting agent was used. The disinfectants were sterilized before use in Grade A and B areas. The hygiene facilities established on the site appeared acceptable.

4. Qualification and validation

Validations and qualifications were performed according to the site policy and documented procedures. Necessary resources for production were provided, including qualified and trained personnel, adequate premises, equipment, and services, as well as appropriate materials, approved procedures and instructions, laboratories, and equipment for in-process and other controls. The validation master plan outlined requirements for performing validation related to processes, cleaning, analytical methods, media fill, and other areas.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

5. Complaints

The SOP Market Complaint Management was reviewed. The objective of the SOP was to manage market complaints, i.e., receiving, investigating, and providing feedback to the complainant. The procedure was implemented to ensure the identification of the root cause and implementation of the Corrective and Preventive Action (CAPA) for all complaints reported regarding products manufactured by Incepta Pharmaceuticals at both Zirabo and Dhamrai sites. The responsibilities were defined for Marketing, QA, Investigator/Cross-Functional (CFI) Team, Concerned Department Heads, and Head of Quality. The complaints were received by the Marketing Strategy Department, as defined in the SOP, through letters, phone calls, emails, faxes, or any other means of communication.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Product recalls

A system was in place to recall the product from the market, as described in the product recall management procedure.

7. Contract production, analysis, and other activities

It was noted that none of the production activities for Medogen injection and Medogen SubQ injection were contracted out. However, some of the analytical activities, such as leachables and extractables, were contracted out, in addition to calibration, qualification, and maintenance.

8. Self-inspection, quality audits and suppliers' audits and approval

The SOP for self-inspection described instructions for conducting self-inspections. The self-inspections were conducted once every year using a self-inspection checklist.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

9. Personnel

An organization chart was made available. The key personnel had appropriate education and qualifications to carry out their duties. Their job descriptions, duties, and responsibilities were documented. The finished products were released by the quality assurance department per the approved procedure.

10. Training

The training procedure was outlined and applied to all personnel. The training needs were identified by various departments and communicated to the training section. The training record for the cleaning and sanitization procedure of sterile product manufacturing was "read and understood,".

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

11. Personal hygiene

Instructions for entry and exit to the manufacturing areas were adequately described in a written procedure. A pictorial with instructions for gowning and de-gowning was included in the SOP. Before entering the production areas, the operators were required to remove their street shoes and place them inside demarcations in the stepover bench. The operator donned plant shoes and then entered another access-controlled change room. The pictorials were displayed to help people move from one change room to another. The requirements were clearly laid down regarding removing personal clothes and exchanging shoes utilizing the step-over bench. This was followed by washing and drying of hands.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

12. Premises

Entrance to the plant- Unit 10 was via an air curtain on the outside, activated when the entrance door opened. This provided access to a buffer space before entering the lobby via a second door. There were different pass boxes in the corridor. The pass box had a list attached of the materials that could be

transferred. The material entry had a dynamic pass box for media, seals, and rubber stoppers. The UV was on when the media was transferred to the area.

The utilities supplying unit 10 were assessed, which included Purified Water (PW), Water for Injection (WFI), HVAC, a Pure Steam Generator (PSG), Compressed air, and Nitrogen.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

13. Equipment

The manufacturing site was well-equipped both for Medogen SQ and Medogen IM (Line 2) with dedicated filling/sealing lines, autoclaves, sterilizers, ovens, tunnels, etc. The validation team conducted the calibration in-house and outsourced it when necessary.

14. Materials

The incoming materials were received, quarantined, and then sampled and tested before being released for use. The materials were stored under the appropriate conditions, as per the manufacturer's instructions, and procured from approved suppliers.

15. Documentation

Incepta Pharmaceuticals has a manual documentation system, and the quality assurance department was responsible for managing documents, including records.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.**16. Good practices in production**

The inspectors visited Unit 10, a new manufacturing unit for Medogen SubQ (SQ) and Medogen intramuscular (IM) injection. Unit 10 was spread across 10 floors, whereas secondary packaging was carried out at Level 1. Manufacturing of SQ and IM took place on Level 3, while Level 2 was dedicated to the warehouse, technical areas, excipient dispensing, and sampling. Level 4 housed the technical area and laundry, and Level 5 was reserved for solid and potent drug manufacturing. The inspectors visited the facility through the male changeroom instead of the visitor changeroom. The changeroom was supported by a toilet and handwashing facility, and gowning instructions were displayed on the walls. A cross-over bench was provided before advancing to the next changeroom. The changeroom was classified as Grade D. The gowning was changed twice weekly for Grade D, whereas Grade C and D gowning was meant for single use. The non-sterile part of manufacturing or compounding activity was carried out under UDAF with a Grade C background, and the sterile part of manufacturing or compounding, filling/sealing activity was carried out under UDAF with a Grade B background. Rubber stoppers and flip-off seals were received through the DPB before being transferred to the autoclave. The API was also obtained through a separate DPB transferred through the corridor to the isolator/hatch. The airlocks were interlocked, and BMS was used to record differential pressure digitally. Overall, the area was well-maintained, clean, and tidy during the inspection. At the time of inspection, Medogen Injection was being manufactured. This corridor had the material entry room.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

17. Good practices in quality control

The quality control laboratory served units 1 and 10 and was equipped with HPLC, GC, UV-VIS, FTIR, dissolution apparatus, liquid particle counter, and other instruments. The laboratory tested raw materials, finished products, stability, and validation samples, whereas another tested packaging materials within the same site. The laboratory maintained separate logbooks for the process validation samples, finished products, stability samples, etc. The incoming samples were required to be tested within 30 business days. The microbiology laboratory was located on Level 6 of Unit 10 and Level 2 of Unit 1~~serving Units 1 and 10~~. Before entering the controlled environment, the gowning procedure was in place, and 70% IPA was used to sanitize the hands. Separate change rooms for males and females were provided. The lab had two sterility testing rooms and other rooms used for bacterial endotoxin tests (BET), media preparation, autoclave, incubator, etc. A Grade B background was used for sterility testing under unidirectional laminar airflow, and mobile LAF was used to transport samples closer to the LAF bench.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Incepta Pharmaceuticals***, located at Potent Drug Facility (PDF), Unit-10 ***Krishnapura, Sahabelishor, Dhaka, Dhamrai, Bangladesh,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All the non-compliances observed during the inspection that were listed in the full report, as well as those reflected in the WHOPIR, were addressed by the manufacturer to a satisfactory level prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of WHO Guidelines referenced in the inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   untitled (digicollections.net)

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

6. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
   Short name: WHO TRS No. 937, Annex 4
   https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

7. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 961, 957), Annex 1
   https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.
Short name: WHO TRS No. 1044, Annex 2
TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
https://digicollections.net/medicinedocs/#d/s21438en

13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
Short name: WHO TRS No. 981, Annex 2
https://digicollections.net/medicinedocs/#d/s20177en/

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://digicollections.net/medicinedocs/#d/s20175en/

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
Essential Medicines and Health Products Information Portal (digicollections.net)

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10. ***Short name: WHO TRS No. 1010, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
9789240020900-eng.pdf (who.int)

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
9789240001824-eng.pdf (who.int)

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

28. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
https://www.who.int/publications-detail/978-92-4-000182-4