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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Incepta Pharmaceuticals Ltd
Corporate address of manufacturer	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	Krishnapura, Sahabelishor, Dhamrai, Dhaka, Bangladesh.
Unit / block / workshop number	Injectable Potent Drug Facility (IPD, Unit-1)
Inspection details	
Dates of inspection	8-12 May 2023
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	Manufacturing and quality control of Finished pharmaceutical products, including OSD and IPD at Unit-1.
General information about the company and site	Incepta Pharmaceuticals Ltd was established in 1999 and started operations January 2000. Incepta Pharmaceuticals Ltd is structured with two manufacturing sites. Among the two sites, the Dhamrai Facility, in the inspection scope, manufactured pharmaceuticals, animal vaccines, herbal, nutricare, hygiene and hospicare etc. The site employed 190 employees dedicated to IPD and a further 43 in the common services department providing support to IPD at the time of inspection.
History	The current inspection was the second routine inspection since the product dossier submission was accepted by the WHO medicines PQ programme. A WHO pre-inspection was held 24 to 28 July 2017 to support a rolling submission for the DMPA Injection. The last on site WHO inspection was held 15 -16 March 2020; it was closed earlier than planned due to developing travel restrictions early in the COVID-19 pandemic. Several sections as mentioned in that report were not covered in that inspection due to the inspection being shortened The sterile DMPA injection manufactured in Unit 1 has not been

	inspected by any other international inspectorate. The site was inspected by the domestic Bangladesh Authority, Directorate General of Drug Administration, Bangladesh (DGDA) on 12 December 2021 and 9 April 2022.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality management system • Injectable Potent Drug Facility (IPD, Unit-1) and support utilities • Quality control laboratory • Warehouses
Restrictions	The inspection was restricted to the production of the product listed in the inspection scope.
Out of scope	All other products and the production facility on the site were outside the inspection scope and were not visited.
WHO product numbers covered by the inspection	RH084 Medroxy progesterone Intramuscular Injection 150 mg/ml (suspension) DMPA Injection
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 packaging record
BSC	Bio-safety cabinet
CC	Change control
CCS	Contamination control strategy
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
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
LAF	Laminar air flow

MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
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
SAP	Systems, Applications & Products in Data Processing
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 covering all key quality elements in place. The quality department was divided into QA and QC and was organizationally separate from the production department. Operations were specified in written form and critical GMP requirements were essentially being met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard.

Product quality review (PQR)

The SOP for PQR management was reviewed.

APQR for DMPA injection (WHO grade) approved on 25/11/2022 was reviewed. The change control, OOS, batch release, PV, stability study and CPPs etc. were reviewed in the APQR. No market complaints were reported.

Quality Risk Management

Quality risk management and risk assessment were handled and performed according to documented policies and procedures. Several assessments were reviewed including those related to the implementation of the new sterile annex gap finding audit. Some of the tools specified in the QRM included basic risk management facilitation methods (flowcharts, check sheets etc.), Failure Mode Effects Analysis (FMEA), Ishikawa (Fishbone) Analysis, and Risk ranking and filtering. For the assessments reviewed, those seen were prepared using the FMEA tool.

A documented Contamination Control Strategy (CCS) was in place, and discussed.

Management review (MR)

Management review followed a documented procedure which required MR to be performed regularly with attendance of senior management. The MR meeting reports for IPD Unit held in December 2022 and in March 2023 were checked and discussed.

Change control

Change control was managed according to a documented procedure. A major change in increasing the batch size of DMPA Injection was reviewed and discussed. The change of process was generally well managed.

Deviation management

Deviation was managed according to the SOP. Deviations were reported in the QMS system. Deviations were classified into critical, major, and minor based on the impact analysis. Deviations in respect of DMPA product were reviewed and discussed.

Out of specifications (OOS)

A procedure for handling of OOS was reviewed. The OOE (Out of expectation) procedure was also used for QC lab testing which was discussed.

CAPA management

The company had a procedure for management of deviations, OOS and non-compliance established and recorded in the appropriate register for IPD products. The review was focused on DMPA injection.

Product release

The product release of FPP followed a documented procedure, which was reviewed. The personnel responsible for final release and batch certification were specified.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources with adequate premises, equipment and utilities were provided for the current operational level of DMPA injection manufacturing activities. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. The manufacturing facility where DMPA injection was produced was a dedicated facility. The implementation of WHO guideline on good manufacturing practices for sterile pharmaceutical products (WHO TRS No. 1044, Annex 2) e.g., CCS, barrier technology and PUPSIT were discussed.

3. Sanitation and hygiene

Disinfection of clean areas was performed frequently in accordance with the SOP. More than one type of disinfecting agent was used. The disinfectants were sterilized before used in Grade A & B areas. The facilities for hygiene 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 in production were provided, including qualified and trained personnel, adequate premises, equipment and services, appropriate materials, approved procedures and instructions, laboratories and equipment for in-process and other controls.

Process validation

Process validation had been identified what validation and qualification activities were required. Equipment requalification and process revalidation followed standard operating procedures. The key elements of a qualification and validation programme were defined. The CCS and process validation were checked.

Aseptic process simulations APS (media fills)

The SOPs for APS, performance and summary records of media simulation studies were reviewed. The company had no positives observed in any APS performed to date. The APS protocol for the most recent simulation was reviewed. There were no positive units in the three studies performed. The protocols followed and reporting were broadly acceptable.

Steriliser qualification and validation

Procedures and the reports for the most recent revalidation of the sterilizers used for stopper and fill equipment steam sterilization were reviewed. The results were broadly acceptable.

Hot air sterilizing tunnel validation

The validation of the Depyrogenation tunnel was reviewed and found generally acceptable.

Smoke studies

The smoke studies were performed in the machine enclosure of the filling RABs and at the entrance and egress points of the aseptic rooms. The available studies viewed appeared to show adequate flow patterns for these locations.

Cleaning validation

The production line was dedicated to DMPA injections in different quality specifications with different API sources. The cleaning validation of the DMPA production line was not reviewed during this inspection due to time constraints.

Computer System (CS) validation

Computerized systems were used in the warehouse for material management and logistic administration, as well as in the QC laboratory for material and product testing and data management. Computerised system validation and qualification were not reviewed in detail due to time constraints.

5. Complaints

Market complaints were managed according to a documented procedure which was reviewed. It was the responsibility of QA to investigate complaints and instigate CAPA if necessary. No complaints on WHO grade DMPA injections were received since the last WHO inspection.

6. Product recalls

The product recalls were handled according to a documented procedure which was reviewed. The product recalls were classified into three levels. Mock recall was required to be performed for Class I recall once every two years if no real recall occurred. No batches of WHO grade DMPA injections were recalled.

7. Contract production, analysis and other activities

There was no contract production outsourced for WHO DMPA injections.

The testing for API impurities was performed by the external laboratory used by the API manufacturer located in Italy.

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

Self-inspection

A self-inspection plan and SOP was in place. This was not reviewed in detail.

Suppliers' audits

Suppliers' audits procedure for starting materials was in place. The approved vendor list was available which included API, excipients and packaging materials and was managed in the corporate SAP system. The API manufacturer was audited (on site re-audit) in 2023. A quality agreement with rubber stopper supplier signed in 2022 was reviewed and discussed.

9. Personnel

There was an adequate number of personnel suitably qualified by education and training to perform and supervise the manufacture of FPPs. The personnel met during the inspection appeared to be knowledgeable about GMP. An organization chart was available. Key personnel responsibilities were required to be defined in job descriptions. There were appropriate controls over personnel entering clean rooms.

10. Training

Training was required to be conducted on an initial and ongoing basis. Re-training was required in the event of personnel errors, resulting in a CAPA event. QA was responsible for training. Training programme was not reviewed in detail in this inspection, other than the effectiveness of aseptic training which was evaluated by direct observation during the inspection e.g., filling machine set up etc.

11. Personal hygiene

Changing and washing before entry to production areas followed written procedures. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials. The protective clothing washing, and sterilization operations followed standard operating procedures.

12. Premises

Exposed surfaces of production areas were generally smooth, impervious, and unbroken to minimize the shedding or accumulation of particles or microorganisms.

Production

The injection production line dedicated to DMPA injection was in the North Side of Unit 1 block. An OSD facility was in the South Side. These two production areas were separated. The existing production facilities were noted to be well maintained and in a good state of housekeeping.

The clean rooms for DPMA injection were surrounded by a CNC corridor that gave good visibility to some processing rooms and excellent views of the fill area. Changing rooms were designed as airlocks and used to provide physical separation of the different stages of changing. Changing rooms were flushed with filtered air and equipped with mirrors.

QC laboratories

QC laboratories for microbiological and chemical testing were separated from production areas. Entering QC was access controlled. The QC laboratory was well designed and with enough space for the various activities. The dedicated secondary controlled area for the handling of DMPA required entering through changing room with gowning procedure, with appropriate pictorials.

Warehouses

There were warehouse areas for raw materials, primary packaging materials, secondary packaging materials and finished DMPA injections located in Unit 1. Sampling rooms were available in the raw material warehouse. A locked area for rejected material and products were in place. The area were visited and appeared clean and well organized.

Utilities

The HVAC system provided filtered air to the cleanrooms. The PQ protocol and report for HVAC and clean room system performed in February 2023 were reviewed and discussed.

Water system

The bore well water was used as source water to produce demineralized (DM) water and purified water (PW). Pure steam and WFI were produced from PW. WFI was produced by distillation method. The procedure for sampling and testing of water for pharmaceutical purposes and

microbiological sampling and testing result for PW and WFI in 2022 were reviewed. Steam testing methodology and results were spot checked and discussed.

Nitrogen

Nitrogen used in the aseptic filling process was supplied from cylinders through a gas distribution line. The P & ID document, nitrogen sampling and testing were reviewed and discussed.

13. Equipment

The equipment installed in Unit 1 was dedicated for manufacturing DMPA drug product. Equipment used for manufacture of the drug substance and finished product generally appeared to be of appropriate design and capacity, and suitably located for its intended purpose. Labels attached to the equipment clearly indicated equipment identification numbers, clean status, qualification status and due date. Equipment maintenance and cleaning were performed according to written procedures.

14. Materials

Incoming materials and finished products were quarantined after receipt until they were released for use or distribution. Starting materials and packaging materials in the scope were purchased from approved suppliers. Materials and products were stored under the specified conditions.

Starting material, and packaging material for FPP were stored in different warehouse rooms under controlled temperature conditions. The storage rooms for raw materials, packaging materials and finished Goods were visited and appeared clean and acceptable. Procedures for raw and packaging materials receiving and storing in warehouse and for ERP process for inventory management were reviewed. The PQ Standard DMPA finished products were stored in the dedicated production block prior to shipment to the procurement organisation.

15. Documentation

The documentation system was both electronic and paper based which were controlled by the QA department. In general, documentation was designed, prepared, reviewed and distributed according to a documented procedure. Approved, signed, and dated testing procedures and specifications were available for starting and packaging materials and for finished products.

A Batch numbering system followed the batch document management procedure which was reviewed. Batch numbers were generated by the SAP system. Batch manufacturing records (BMRs) were retained for each batch processed.

Master BMRs for WHO grade DMPA injections, SOPs and logbooks in production were available for review. A DMPA BMR and the operating procedure of the filter integrity tester were reviewed and discussed.

16. Good practices in production

The manufacturing process of WHO grade DMPA injections was generally well designed and executed. The process of dispensing and filling were checked and discussed. The company performs manual visual inspection. Reprocessing and reworking were not allowed for sterile products as specified in SMF.

17. Good practices in quality control

QC laboratories, including the microbiological laboratory, were separated from production areas. The microbiology laboratory was segregated from the chemistry laboratory. Overall, enough space was available to avoid mix-ups and cross-contamination. Adequate storage space was provided for samples, reference standards, solvents, reagents, and records.

Physico-chemical and microbiology:

The areas for sample receiving and distribution, volumetric testing, packaging material testing, media preparation, bioburden testing, sterility testing, incubation rooms, etc., were spot-checked.
All media used for testing and environmental monitoring were obtained as preprepared media for preparation and pouring of liquid media in house. Each delivery of a batch was tested for growth promotion with the required strains and in-house isolates. Sterility testing was performed in an isolator placed under Grade A/B room conditions.

Testing of starting materials and finished products

QC testing was specified in the relevant specifications and conducted according to documented test methods. The procedure for sampling of raw materials, the sampling register for raw material and testing records were checked. Samples for testing were kept in a designated area. The sample receiving, and distribution logbook, as well as the testing and release of Medroxy progesterone API were checked and discussed.

The computer access control, authorization of the functions and audit trials in HPLC analysis were spot checked during the inspection.

EM Monitoring programme

The EM monitoring programme was reviewed together with trend results. Data seen was generally satisfactory.

Stability monitoring of FPPs.

Stability study data was reviewed in APQR, for the increased batch size, 12-month data was in place.

Reserve/retention samples

The storage areas for reserve samples and stability testing were visited and found to be under a satisfactory level of control.

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 Ltd,*** located at ***Krishnapura, Sahabelishor, Dhamrai, Dhaka, 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 GMP 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-eight 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://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

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. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

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***
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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 artemisinin 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***
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22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties 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**
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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**
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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***
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