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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	**Mepro Pharmaceuticals Pvt. Ltd (Unit-II)**
Corporate address of the manufacturer	Mepro Pharmaceuticals Pvt. Ltd Address: 3rd Floor, The International Building, 16 Maharshi Karve Road, Churchgate, Mumbai – 400 020
Name & address of inspected manufacturing site if different from that given above	Unit-II, Q Road, Phase-IV, G.I.D.C, Wadhwan –363 035, Dist: Surendranagar, Gujarat, India GPS details of the manufacturing site: GPRS: 22.724296/71.665387
Unit / block / workshop number	Tablet section
Dates of inspection	14-17 March 2023
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Mepro Pharmaceuticals Pvt. Ltd., Unit II, is located on an independent plot of land in Wadhwan City, Dist. - Surendranagar, Gujarat, India. The factory is 3.5 km from the Surendranagar Railway Station, 120 km from the Ahmadabad Railway Station and 125 km from the Ahmadabad International Airport. Unit II manufactures its own product range and carries out contract manufacturing of solid dosage (tablets, capsules) & semisolid (creams & ointments) formulations under third-party agreements.
General information about the company and site	The Mepro Group has three units in Gujarat: - **Unit I** manufacture cephalosporin dry powder injections in Wadhwan City, Surendranagar district and is located around 200 meters from Unit II, - **Unit II** is in Wadhwan city, Surendranagar district, and manufactures non-sterile solid and semi-solid formulations. This Unit II has submitted Albendazole chewable tablets for WHO PQ. - **Unit III** is located in Vadodara (Baroda) and manufactures solid (tablets, capsules, sachets) and lyophilized and non-lyophilized SVP products). In addition, the company has another Unit named

	"Mepromax Lifesciences Pvt. Ltd" located in Dehradun, Uttarakhand, India. This Unit manufactures tablets, capsules, creams, ointments and dry powders for carbapenems.
History	The WHO PQ first inspected Unit II in August 2022 and the follow-up inspection was carried out in March 2023 to verify CAPA implementation. The CDSCO and the State FDA of Gujarat inspect Unit II regularly. The State FDA of Gujarat issued a GMP/GLP certificate (S-GMP & GLP/21123055) valid until 14/12/2023. The Food & Drugs Control Administration of India (CDSCO) issued a GMP certificate (20031915) valid until 12/03/2023. The State FDA of Gujarat has informed the CDSCO (dated 7 March 2023, 12991-92) about an application submitted by Mepro Unit II for a GMP certificate. A joint inspection will be conducted on 20-21 March 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Pharmaceutical quality system - Good manufacturing practices - Personnel and training - Quality risk management - Complaints and recalls - Cleaning validation - Quality control laboratory, including stability study - Utilities (air handling units, water system)
Restrictions	
Out of scope	Products other than Albendazole chewable tablets 400mg were out of the scope of this inspection.
WHO products covered by the inspection	Albendazole chewable tablets 400mg (NT014)
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	Nonconformity
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

Mepro Pharmaceuticals Pvt. Ltd, Unit II was first inspected by the WHO PQ Inspection Services in August 2022. A follow-up inspection was conducted in March 2023 for the verification of CAPA. In general, the pharmaceutical quality system (PQS) had improved from the last inspection as several elements of the PQS had been implemented in accordance with the WHO GMP Guide. The senior management had appointed more personnel since the last inspection to attain its quality objectives.

The SOP for product quality review was revised and cross-referenced to the process validation procedure. The IPCs, CPPs and CQAs for tablets and other dosage forms were included in the PQR. The addendum to the APQR Albendazole chewable tablets 400mg included verification of IPCs, CPPs and CQAs using the process capability index.

The QRM SOP was revised, and the risk related to contamination and cross-contamination was revisited and updated. In addition, the data integrity risk assessment was for various equipment and instruments.

The SOP for corrective and preventive action was revised from the last inspection. As per the procedure, a follow-up action was required after the implementation of CAPA to verify the effectiveness

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

The Mepro Unit-II is a multi-purpose manufacturing facility which produces finished pharmaceutical products of different therapeutic areas. At the time of the first inspection, it was noted that the company uses manual and open processes for various unit operations. During the follow-up inspection, some improvements were observed by tidying up the areas. Since the last inspection, the company has amended the concept of over-gowning for the operators as core processing areas were not supported with airlocks.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

3. Sanitation and hygiene

The procedure relating to sanitation and hygiene for personnel, premises, equipment, and production areas had been updated since the initial PQ inspection. Forced draft ventilation (100% fresh air supply with no recirculation) was installed in the washrooms. The cleaning frequency of the washrooms has been increased, especially after each break (lunch break, tea break etc). The SOP for personal hygiene was reviewed. Instructions were provided about hygiene before entering the manufacturing areas. In addition, training material (PPT slides) on health, clothing and habits was developed in March 2019 covering hygiene aspects and training was imparted.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

4. Qualification and validation

The company had revised their validation master plan (VMP) from the first inspection. Version 17 has provided clarity on the three-stage process validation and computerized system validation (CSV). A planner was added for the CSV in the VMP. The cleaning validation procedure and practices were revised in accordance with WHO requirements. The company has started procuring the PDE reports from an alternate vendor along with OEL/OEB and toxicity categories for the products manufactured on-site.

The company has improved the AHU area by replacing manometers with magnehelic gauges for the monitoring of differential pressure across the filters besides replacing the AHU panels. The filter cleaning area was upgraded from the initial inspection.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

5. Complaints

The procedure for handling complaints was revised to include all types of complaints and possible counterfeits. There have been seven (7) cases of complaints in 2022 and 2 of them were reviewed during the inspection and were found to have a thorough investigation.

6. Product recalls

There was a provision in the “Product Recall System” to select the worst-case scenario and a protocol has been introduced for all the steps taken for the mock recall. There was a provision in the SOP to have the mock recall down to the customer and that a mock recall could be performed outside of office hours. At the time of the follow-up inspection, the mock recall was still within its valid period and hence it was not performed with revised SOP.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

7. Contract production, analysis and other activities

The company had confirmed that there was no production and packaging part of Albendazole chewable tablets 400mg was contracted out. The active substance and excipients were procured from the suppliers and the finished product was formulated on-site. The polymorphic determination (using XRD) was outsourced.

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

The SOP for the self-inspection program had been revised to include that the auditor should be independent of the inspected department. Training for the SOP has been organized. The self-inspection performed on 15 January 2023 using the checklist confirmed compliance in all manufacturing areas. Nevertheless, there were 6 observations that overlapped the checkpoints which were checked as OK.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

9. Personnel

The company recruited 11 personnel since the initial PQ inspection for different departments (QA, QC, microbiology, engineering, IT and packing).

10. Training

The SOP for training has provided for an annual schedule and the one for 2023 has been composed. There was a list of 36 certified and approved trainers from all the departments. Training material for data integrity and good documentation practices was reviewed. It is planned to be given two times a year, in three different groups each time. Several documents were verified regarding attendance and how they find out if somebody has missed any training. The system seems to be working and is being updated regularly. The questionnaire for end-of-training assessments was verified. The questionnaires were very simple and easy to get. The company uses external trainers, and it was recommended to maintain a short CV of each external trainer and a short report of the training material.

The company uses contract workers mainly for secondary packaging operations.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

11. Personal hygiene

Personnel received training in the practices of personal hygiene. The procedure on personal hygiene provided clear instructions about illness and open lesions. Similarly, instructions were provided, and training was imparted to the personnel about smoking, the use of tobacco products, jewellery, phones etc.

12. Premises

In general, the manufacturing site (Unit II) for Albendazole chewable tablets 400mg is located at the appropriate location i.e. not surrounded by pollution-emitting factories. The design and construction of the premises were adequate to minimize errors, cross-contamination, and effective cleaning. The toilets were separated from the manufacturing areas. The changes were made from the initial inspection by providing air handling units.

Receiving areas including the dedusting area were improved from the initial inspection. There were some changes made in the production areas wherein doors were provided with stainless steel plates.

The quality control laboratory was separated from the production areas. Changes were made in the laboratory by providing new furniture, cupboards and safety hoods.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

13. Equipment

In general, the equipment was designed to suit the required operations. However, the design of the equipment used in the production areas did not adequately minimize the risk of errors, effective cleaning and cross-contamination. For example, upon inspection of the production areas, two of the compression machines out of four were found to be poorly maintained.

14. Materials

Materials were purchased from qualified sources. Upon receipt of the materials, they were subjected to dusting and then weight verification. Upon receipt, the incoming materials were stored in quarantine areas and were demarcated with yellow lines. In general, the materials were stored under the appropriate conditions as noted during the visit to the warehouse.

The vendor assessment and approval system were performed according to the SOP.

In the quality control laboratory, an adequate facility was provided to store the HPLC columns.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

15. Documentation

The quality assurance department was responsible for producing, approving, issuing and withdrawing via the SOP. The company uses a paper-based system to control documents. The handling of logbooks and formats was performed according to SOP which is a system to issue and retrieve logbooks and formats and the preparation, approval, control & review of SOPs was via the SOP which was a system to produce and monitor all the SOPs issued. A logbook exists with 2 pages for every SOP issued so there was adequate control of the documents.

16. Good practices in production

The production operations were carried out following the approved procedures. The batch manufacturing records were used. The procedures were in place for the production and packaging of Albendazole chewable tablets 400mg.

The materials, in-process products and finished products were subjected to labelling. The access to production areas was restricted through biometric access. The in-process quality control laboratory has provided separate printers for various equipment used for the in-process checks.

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same will be verified during future PQ inspections.

17. Good practices in quality control

The quality control laboratory was independent of the production department. The QC manager reported to the Director of Technical Affairs, and he was ably supported by adequate staff. The changes were made from the initial inspection related to the competency matrix.

The HPLC, GC and FTIR were connected with LabSolution. The date/time stamp was synchronized and was observed to be locked. The laboratory is still exercising manual integration for related substance tests as noted during the visit to the laboratory. During the first PQ inspection, analysts were given the responsibility to integrate peaks using the manual process. Now, the responsibility to integrate chromatographic peaks was given to the QC reviewer. The company is required to ensure integration parameters are in line with the method validation of related substances for Albendazole chewable tablets 400mg.

The stability study source data related to the related substance test for Albendazole chewable tablets 400mg was verified for 36 months, 30 months and 24 months (30/75%).

The deficiencies noted from the pharmaceutical quality system section have been addressed satisfactorily and the same 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, ***Mepro Pharmaceuticals Pvt. Ltd (Unit-II)***,located at ***Unit-II, Q Road, Phase-IV, G.I.D.C, Wadhwan – 363 035, Dist: Surendranagar, Gujarat, India*** 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. 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 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***
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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-conditionning 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**
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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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