

**Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)**

Desk Assessment of Finished Product Manufacturer

Part 1	General information
Company information	
Name of Manufacturer	Mepro Pharmaceuticals Pvt., Ltd (Unit II)
Corporate address of manufacturer	Mepro Pharmaceuticals Pvt. Ltd. 3rd Floor, The International Building, 16, Maharishi Karve Road, Churchgate, Mumbai — 400 020, INDIA. Phone: 022 61477171 Fax No: 022 t5bit5 ,539 Email: admin@mepro.in
Contact person	MR. RAJESH S. SHAH Phone No : 022 61477171 Fax No: 022 66385339 Mobile: +91 9820151045 Email: rajesh@mepro.in
Inspected site	
Name & address of manufacturing site	Mepro Pharmaceuticals Private Ltd, Unit II Q Road, Phase IV, G.I.D.C, Wadhwan City - 363 035, Surendranagar, Gujarat, INDIA. Phone No.: 02752 —241001 241002 Fax No: 02752-241003 Email: production@mepro.in Geographic location: - Latitude = 22.724296 - Longitude = 71.665387
Production Block/Unit	Unit II
Manufacturing license number	License in Form 28 No: G/28/1182 and License in Form 25 No: G/25/1663 retained until 22 March 2029
Desk assessment details	
Start and end dates of review	24 February – 1 March 2026
Inspection record number	INSP-FPP-2023-0038

Products covered by this desk assessment	NT014 - Albendazole Tablets, Chewable 400mg	
Part 2	Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments	
<i>National Centre for Public Health & Pharmacy, Hungary</i>	Dates of inspection:	27-30 October 2024
	Type of inspection:	Routine inspection
	Block/Unit:	Unit II
	Type of products/Dosage forms covered:	<p>The inspection covered the manufacturing of non-sterile medicinal products for human use: tablets, hard shell capsules and semi-solids.</p> <p>Products marketed in the EU at the time of inspection: Metformin 850 mg Tablet</p> <p>The Following Products Under registration in EU:</p> <ol style="list-style-type: none"> 1. Ticagrelor 90mg tablets 2. Pentosan cream/gel 3. Mupirocin ointment 4. UDCA capsules 250mg
	Physical areas inspected:	<p>Site tour to the production area included visits to these areas: Dispensing, Granulation I, Granulation II, Compression II, Compression IV, Coating II, Capsulation II, Cream Manufacturing, Packing Cubicle I, Primary Packing Cubicle II, IV and V.</p> <p>Warehouse and QC laboratory were also inspected.</p>
Part 3	Summary of the last WHO inspection	
Date and conclusion of most recent WHO inspection	14-17 March 2023. The company was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.	
Summary of manufacturing activities	<p>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.</p>	

General information about the company and manufacturing site	<p>The Mepro Group has three units in Gujarat:</p> <ol style="list-style-type: none"> Unit I manufactures 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. Unit II has submitted Albendazole chewable tablets for WHO PQ. Unit III is 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.
Focus of the last WHO inspection	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.
Areas inspected	<p>The following areas were inspected:</p> <ul style="list-style-type: none"> - 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)
Out of scope and restrictions (last WHO inspection)	Products other than Albendazole chewable tablets 400mg were out of the scope of this inspection.
WHO products covered by the last WHO inspection	Albendazole chewable tablets 400mg (NT014)
Additional products to be covered by this desk assessment:	None.
Abbreviations	Meaning
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	<i>Batch production record</i>
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product

GMP	Good manufacturing practices
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
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
SMF	Site master file
SOP	Standard operating procedure

Part 4	Summary of the assessment of supporting documentation
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a) List of all regulatory inspections performed in the last 5 years and their outcomes:

The company submitted a list of inspections from the last three years (2023 to date) provided below:

No	Date of Inspection	Inspection Body	Outcome
1.	27 – 30 October 2024	EU-GMP National Centre for Public Health & Pharmacy	Positive response obtained

However, the site master file also listed the following inspections for the last 5 years:

No	Date of Inspection	Inspection Authority
1.	06 December 2025	GMP as per revised schedule M (Food and Drugs Control Administration Gandhinagar, Gujarat State)
2.	02- 03 June 2025	DIQC B.V. (Nederlands instituut Voor Kwatiteitscertificering) [ISO 13485: 2016]
3.	27 – 30 October 2024	EU- GMP — Hungary
4.	15-16 May 2024	DIQC B.V. (Nederlands Instituut Voor Kwaliteitscertificering) [ISO 13485: 2016]
5.	20 – 23 February 2024	State Service of Ukraine on Medicines and Drugs Control
6.	23 November 2023	GMP as per revised schedule M (Food and Drugs Control Administration Gandhinagar, Gujarat State)
7.	03 – 04 July 2023	National Drug Authority - UGANDA
8.	20 – 21 March 2023	GMP as per WHO TRS No. 908 of 2003 (Food and Drugs Control Administration Gandhinagar, Gujarat State)
9.	14 – 17 March 2023	WHO GMP (WHO HQ Geneva)
10.	08 – 12 August 2022	WHO GMP (WHO HQ Geneva)
11.	09 December 2021	GMP as per revised schedule M (Food and Drugs Control Administration Gandhinagar, Gujarat State)

b) Manufacturing authorization granted by national authorities:

Mepro Pharmaceuticals Private Ltd, Unit II, Gujarat, India

24 February – 1 March 2026

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Retention of License certified that Form 28 No: G/28/1182 and Form 25 No: G/25/1663 which were issued on 23 March 2004, were retained up to 22 March 2029 on 29 May 2024. The company also had two GMP Certificates from the Food and Drugs Control Administration Gandhinagar, Gujarat State:

1. Certificate No. S-GMP&GLP/25126300 which was valid from 12 December 2025 to 11 December 2027. The certificate covered the activity of Tablet (Coated and Uncoated), Capsule (Hard Gelatine), and External Preparation (Ointment/ Cream/ Gel) manufacturing under the provisions of Drug and Cosmetics Act 1940 and Rules thereunder.
2. Certificate No. 23044044 based on inspection dated 20-21 March and 3 April 2023. It was issued on 12 April 2023 and remained valid until 11 April 2026. The certificate covered the activity of Tablet (Coated and Uncoated), Capsule (Hard Gelatine), and External Preparation (Ointment/ Cream/ Gel) manufacturing under the provisions of WHO TRS No. 908 of 2003.

The company also submitted Certificate of GMP Compliance of Manufacturer from National Centre for Public Health and Pharmacy Hungary No. NNGYK/16134-2/2025 dated 17 February 2025 was issued based on the inspection on 30 October 2024. The certificate covers the activity non-sterile manufacturing of hard-shell capsules, semi-solids, and tablet.

SMF also mention several valid accreditations at site aside from those mentioned above such as:

1. TGA — GMP Clearance (Dosage form —Tablets) valid until 24 April 2026
2. TGA — GMP Clearance (Dosage form — Tablets, Hard Capsules, Semi solids) valid until 30 April 2028
3. GMP Certificate No. No. 117/GMP/2023 from National Drug Authority – UGANDA valid until 4 July 2026
4. GMP Certificate No. 045/2024/GMP from State Service of Ukraine on Medicines and Drugs Control valid until 23 February 2027
5. DIQC B.V. (Nederlands Instituut Voor Kwaliteitscertificering) [ISO 13485: 2016] valid until 30 May 2027
6. GMP Certificate No. RWA-FDA/DD/02-2025/ 4528/0084/4412 from Rwanda FDA valid until 18 August 2028

c) Site Master File (SMF):

Site Master File of Mepro Pharmaceuticals was submitted. Overall, the content of the SMF has been in accordance with the WHO guidelines for drafting a site master file, WHO Technical Report Series, No. 961, Annex 14.

Inspection report by the National Centre for Public Health and Pharmacy Hungary stated that the manufacturing area consists of 2 granulation, 4 compression, 2 coating, 1 blending, 2 capsule filling, 1 ointment compounding, 2 ointment filling, primary and secondary packaging, store, wash and change rooms. Based on the layout provided with the Site Master File, there had not been substantial change of manufacturing areas.

d) List of all the products and dosage forms manufactured on-site:

The list of products was submitted. Albendazole chewable tablets was included in the list. The company did not manufacture or handle any specifically toxic and hazardous drug including penicillin and or beta lactam drug, hormone and cytotoxin agents.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

Annual Product Quality Review Report for Albendazole Chewable Tablets 400 mg (Review Period January 2025 to December 2025) was submitted for review. The APQR was reviewed and found satisfactory.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

The completed batch manufacturing and packaging records, including the full analytical documentation, for the most recently manufactured batch of Albendazole Chewable Tablets 400 mg were submitted. The manufacturing and packaging records used the most recent BMR according to the APQR.

The manufacturing processes of Albendazole Chewable Tablets 400 mg were performed and recorded according to instructions in the batch production records. Production and testing instructions were followed. No issues were identified from the batch records. The in-process checks were performed, manufacturing time cycle was tracked, and verification by a second person was conducted. Final batch release by Head QA/ Designee for sale and distribution was conducted following a checklist which had included review of BMR and BPR to ensure the batch has been manufactured, packed and tested in accordance with the principles and guidance of GMP.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

Master copy of the Albendazole Chewable Tablets 400 mg and BPR were submitted for review. The documents were the same document used in the manufacturing and packaging of the latest released batch .

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:

Sterile product is not under the scope of the assessment.

i) Recalls in the past three years related to products with quality defects:

The company submitted a signed declaration which stated that there were no confirmed discrepancies that had been identified at the site, nor had they been reported by the relevant authorities, in relation to the products manufactured and packed at the site that could have resulted in a product recall. Furthermore, there have been no product returns or recalls from the market.

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:

The company submitted a signed declaration, confirming that:

1. A Comprehensive self-inspection/ external GMP audit dedicated specifically to the product Albendazole Chewable Tablet 400 mg and associated manufacturing, testing, storage, and quality management activities was conducted in accordance with the company's approved self-inspection program by qualified auditors (Internal and External) and based on the WHO GMP guidelines.
2. All observations identified during the self-inspection / external audit were documented in accordance with internal procedures, risk-assessed based on potential impact on product

quality, and addressed through appropriate CAPAs, which have been completed / are under controlled implementation with defined timelines.

k) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:

The company submitted a signed declaration which stated that there was no warning letter, regulatory action, GMP non-compliance statement, import alert, notice of concern, suspension, or equivalent enforcement action has been issued by any national or international regulatory authority with respect to Mepro Pharmaceuticals Pvt. Ltd Unit II, Q Road, Phase-IV, G.I.D.C, Wadhwan, Dist: Surendranagar, Gujarat 363 035, India for the Albendazole Chewable Tablet 400 mg or any application submitted by the company to regulatory authorities for any of the listed product(s) at site.

l) Out-of-stock situations:

The company submitted a signed declaration which stated that there was no regulatory action identified or received resulting in foreseen situation of out of stock with respect to the product manufacturing, packing and testing at the site.

m) Additional documents submitted:

The company submitted a signed declaration which stated that there was no regulatory notification received for the inspection with respect to the product manufacturing, packing and testing at the site.

Part 5	Conclusion – Desk assessment outcome
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Based on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Mepro Pharmaceuticals Pvt., Ltd (Unit II)** located at **Q Road, Phase IV, G.I.D.C, Wadhwan City - 363 035, Surendranagar, Gujarat, INDIA** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

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

Part 6	List of guidelines referenced in this inspection report
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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://digidocuments.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 (digidocuments.net)**

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. **Short name: WHO TRS 1010, Annex 9**
<https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf>
4. 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 \(who.int\)](https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf)
5. 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>
6. 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>
7. 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>
8. 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>
9. 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>

10. 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>
11. 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>
12. 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>
13. 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>
14. 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>
15. 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/>
16. 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/>

17. 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
18. 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>
19. 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
20. 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 \(digicollections.net\)](https://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
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 \(who.int\)](https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
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 \(who.int\)](https://www.who.int/publications-detail/9789240020900-eng-pdf)
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 \(who.int\)](https://www.who.int/publications-detail/9789240001824-eng-pdf)
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>