World Health Organization

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**WHO Prequalification Unit – Inspection Services**
**WHO INSPECTION REPORT**
**(WHOPIR)**
**Desk Assessment of Finished Product Manufacturer**

| **Part 1** | **General information** | |
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| **Company information** | | |
| Name of Manufacturer | Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd | |
| Corporate address of manufacturer | 333 Jiangnan Road, Hengdian, Dongyang,<br>Zhejiang, 32218, China (People's Republic of) | |
| Contact person | Yun LAI<br>yun.lai@apeloa.com | |
| **Inspected site** | | |
| Name & address of manufacturing site | Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd, Site II<br>333 Second Jiangnan Road, Hengdian, Dongyang, Zhejiang, 32218, China (People's Republic of) | |
| Production Block/Unit | Site II, Workshop 7 | |
| Manufacturing license number | NMPA license: Zhe 20000362<br>Dosage forms: Tablets, Capsules, Small-volume Injection, Granules, Inhalation, Drug Substances<br>Issuing Authority: Zhejiang Medical Products Administration (Seal)<br>Date of issue: 10 January 2023<br>Expiry date: 15 November 2025 | |
| **Desk assessment details** | | |
| Start and end dates of review | 22 – 24 November 2023 | |
| Inspection record number | INSP-FPP-2020-0116 | |
| Products covered by this desk assessment | → CV 018, Nirmatrelvir 150mg (film coated) co-packed with Ritonavir 100mg (film coated)<br>→ TB 377, Levofloxacin Tablets, film coated 250mg<br>→ TB 378, Levofloxacin tablets, film coated 500mg | |
| Any documents missing? | Not applicable | |
| **Part 2** | **Summary of SRA/NRA inspection evidence considered** | |
| *FDA, USA* | Dates of inspection: | 24 – 28 July 2023 |
| | Type of inspection: | GMP |
| | Block/Unit: | Site II, Workshop 7 (FPP) and Workshop 16 (API) |
| | Type of products/Dosage forms covered: | ANDA 214110, Metoprolol Succinate Extended-Release Tablets and Fenbendazole API. The profile classes covered were TTR, Tablets, Extended Release, and CSN, Non-Sterile API by Chemical Synthesis. |
| | Physical areas inspected: | Site II consisting of entire facility and related equipment including Workshop 7 and quality control laboratory. |

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| *WHO PQT* | Dates of inspection: | 13 – 17 January 2020 |
| | Type of inspection: | Onsite GMP |
| | Block/Unit: | Site II, Workshop 7 |
| | Type of products/Dosage forms covered: | Levofloxacin 250mg, Levofloxacin 500mg |
| | Physical areas inspected: | Site II, Workshop 7 consisting of all manufacturing areas, Quality System, Warehouse Site I, Laboratory. |
| **Part 3** | **Summary of the last WHO inspection** | |
| Date and conclusion of most recent WHO inspection | The last WHO inspection of Zhejiang Apeloa Kangyu Pharmaceuticals was performed from 13 to 17 January 2020. This was the first WHO inspection of the manufacturing of FPPs.<br>The site was found to be GMP compliant. The identified deficiencies were successfully addressed by the company. | |
| Summary of manufacturing activities | Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. has two manufacturing sites. Site I is located at the 333 Jiangnan Road, Hengdian Town and Site II is located at 333 Second Jiangnan Road, Hengdian Town. The distance between two manufacturing sites is approximately 2.5km.<br><br>Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd, Site II manufactured APIs, tablets and capsules. There were no beta-lactams or high potency products manufactured on site. The company has been licensed by the Chinese regulatory authority for the manufacturing of Active Pharmaceutical Ingredients (APIs) as well as Finished Pharmaceutical Products (FPP). | |
| General information about the company and manufacturing site | The FPP Site II, Workshop #7 is the production workshop for Metoprolol Succinate Extended-Release Tablets, Levofloxacin tablets and Nirmatrelvir tablets, co-packaged with Ritonavir tablets for Oral Administration. The building is referred to as the "Export FPPs Comprehensive Building".<br><br>The manufacturing scope of Site #II covers tablets, capsules, small-volume injections, granules, inhalations and the following drug substances: Amantadine HCl, Memantine HCl, Dextromethorphan Hydrobromide, Papaverine HCl, Zonoterivir, Pallafovir Mesylate, Nirmatrelvir, Donafinil Tosilate, Oseltamivir Phosphate and Fenbendazole.<br><br>In addition, Site II contains a commercial production workshop- FPP Workshop #7, an automatic high rack warehouse, utilities system and QC laboratory. The FPP Workshop #7 is equipped with upgraded and advanced equipment and has larger capacity compared to that of the workshops in Site #I. This workshop occupied three storeys and elevator is used between storeys. The granulating, tabletting and packaging are performed respectively from the 3rd floor to 1st floor. The cleanness is class D. The automatic high rack warehouse located in the site # II is used for storing ingredients and FPP of Metoprolol Succinate Extended-Release Tablets, Levofloxacin Tablets, Nirmatrelvir tablets, co-packaged with Ritonavir tablets for Oral Administration, etc. | |
| Focus of the last WHO inspection | The WHO onsite inspection in 2020 of site II, workshop 7 was restricted to the production of Levofloxacin Tablet, Film-coated 250mg and 500mg manufacturing lines. As site II starting material automatic high rack warehouse was not yet qualified, the inspection included the Site I material warehouse. | |
| Areas inspected | Quality management system<br>Site II, Workshop 7<br>QC including chemical and microbiological laboratories<br>Water system | |

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| | Site I: Starting material warehouse |
| Out of scope and restrictions (last WHO inspection) | The inspection was restricted to the production of the Prequalified TB 377/ 378 Levofloxacin Tablet, Film-coated 250mg and 500mg manufacturing lines in Site II, Workshop 7 and Site I material warehouse. All other products and workshops were outside of the inspection scope. |
| WHO products covered by the last WHO inspection | TB 377 Levofloxacin Tablet, Film-coated 250mg<br>TB 378 Levofloxacin Tablet, Film-coated 500mg |
| Additional products to be covered by this desk assessment | CV018 Nirmatrelvir 150mg co-packed with Ritonavir 100mg |

| **Abbreviations** | **Meaning** |
|---|---|
| AHU | Air handling unit |
| API | Active pharmaceutical ingredient |
| BMR | Batch manufacturing record |
| BPR | Batch production record |
| 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:**

During the past 5 years the site, Zhejiang Apeloa Kangyu consisting of Site I and Site II was inspected by FDA USA; PMDA Japan and WHO PQT as per the table below. Site II (FPP manufacturing) received an onsite inspection only by FDA USA and WHO PQT as per the summary table shared by the site. PMDA performed various desk reviews during 2020 and 2022.

The most recent FDA USA inspection on Site II Workshop 7 (FPP), and Workshop 16 (API) from 24 to 28 July 2023 covered the manufacturing workshops for FPPs and APIs. The inspection outcome confirmed that "no action indicated" (“NAI”). The communication from US FDA confirmed that based on the inspection (24-28 July 2023), the facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

| Inspection Date | Competent Authority | Outcome | Inspection Type | Blocks/Workshops Covered |
|---|---|---|---|---|
| 3 – 7 December 2018 | FDA, U.S.A (Site Inspection) | VAI | GMP inspection of Amantadine HCl, Pseudoephedrine HCl, Dextromethorphan Hydrobromide and Fenbendazole | Synthesis Workshop #1 (site II), Synthesis Workshop #11 (site I), Synthesis Workshop #16 (site II), Synthesis Workshop #18 (site II), API QA/QC (site I) |
| 2 – 6 January 2020 | PMDA, Japan (Paper Audit) | Approved | Pre-Approval inspection of Memantine HCl | Synthesis Workshop #15 (site II), API QA/QC (site I) |
| 13 – 17 January 2020 | WHO (Site Inspection) | Approved | Levofloxacin Tablets 250mg and 500mg | FPP Workshop #7 and FPP QA/QC (Site II) |
| 8 – 14 September 2020 | WHO (Paper Audit) | Approved | GMP Compliance inspection of Levofloxacin Hemihydrate | Synthesis Workshop #3 and API QA/QC (site I) |
| 21 – 22 April 2022 | PMDA, Japan (Remote Inspection) | Approved | GMP Compliance inspection of Cilnidipine | Synthesis Workshop #15 (site II), API QA/QC (site I) |
| 4 November 2022 | PMDA, Japan (Paper Audit) | Approved | GMP Compliance inspection of Memantine HCl | Synthesis Workshop #15 (site II), API QA/QC (site I) |
| 29 November 2022 | PMDA, Japan (Paper Audit) | Approved | GMP Compliance inspection of Ofloxacin and Levofloxacin Hemihydrate | Synthesis Workshop #2, Synthesis Workshop #3, API QA/QC (site I) |

**b) Manufacturing authorization granted by national authorities:**
Manufacturing license was issued by Zhejiang Medical Products Administration (Seal), Registration No, Zhe 20000362, issue date: 10 January 2023, Expiry date 15 November 2025.

- Site II Dosage forms: Tablets, Capsules, Small-volume Injection, Granules, Inhalation, Drug Substances.
- Site I Dosage forms: Tablets (including cephalosporins), Capsules (including cephalosporins), Dry Suspension (cephalosporins), Oral Solution, Solution for topical use, Lyophilized powder for injection, Narcotics Precursor Chemicals (Ephedrine HCl, Pseudoephedrine HCl), Drug Subsances (Panolosectron HCl, Providone iodine, Cefetamet Pivoxil HCl, Levofloxacin Mesylate, Levofloxacin, Simvastatin, Alfacalcidol，Drotaverine HCl, Rimantadine HCl, Lomerizine HCl, Levofloxacin HCl, Azithomycin CitrateDihydro-Sodium, Ofloxacin, Calcium Pantothenate, Indapamide and Ubenimex).

GMP authorization was issued by NMPA, Certificate No ZJ 20190112, issue date: 17 October 2019, expiry date: 16 October 2024.

**c) Site master file:**
The Site Master File was submitted including various annexes and was found acceptable.

**d) List of all the products and dosage forms manufactured on-site Site II, Workshop 7:**
The list has been provided and reviewed as part of this desk assessment.

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

There was no commercialized production of any of the below products under Prequalification. No PQR was therefore conducted.

- **CV018** Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Film-coated 150mg +100 mg,
- **TB377** Levofloxacin Tablet, Film-coated 250mg and
- **TB378** Levofloxacin Tablet, Film-coated 500mg

**f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):**
Batch analytical records for Nirmatrelvir Tablets; Strength 150mg. No significant observations were made.

**g) Master batch manufacturing and packaging record(s) of the product(s) of interest:**
Master batch manufacturing and master packaging documentation were submitted for Nirmatrelvir 150mg (4 tablets) co-packed with Ritonivar 100mg (2 tablets) in 5 blister cards.

Master batch manufacturing records for Levofloxacin 250 and Levofloxacin 500mg were submitted.

Master batch Analytical record for Levofloxacin 250 and 500mg was submitted.

Master batch Analytical records for Nirmatrelvir 150mg was submitted.

Based on the review of the above documents, no objectionable conditions were noted.

**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:**
Not applicable

**i) Recalls in the past three years related to products with quality defects:**
Zhejiang Apeloa Kangyu submitted a confirmation that no recalls were executed over the past 3 years.

**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:**
Zhejiang Apeloa Kangyu submitted a confirmation that self-inspections are done as per the statement below.

> *"We, Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd. have performed a full self-inspection dedicated to all the products (including CV018 Nirmatrelvir Tablet, Film-coated+ Ritonavir Tablet, Film-coated 150mg + 100 mg; WHO API 467 Nirmatrelvir; TB377 Levofloxacin Tablet, Film-coated 250mg and TB378 Levofloxacin Tablet, Film-coated 500mg) and all matters dealt with".*

**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:**
Not applicable

**l) Out-of-stock situations:**
No out-of-stock situation was foreseen.

**m) Additional documents submitted:**
No additional information was requested.

| Part 5 | Conclusion – Desk assessment outcome |
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Based on the previous WHO inspection, the recent US FDA inspection (24-28 July 2023) and 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 **Zhejiang Apeloa Kangyu, Site II, Workshop 7**, located at **333 Second Jiangnan Road, Hengdian, Dongyang, Zhejiang, 32218, China (People's Republic of)** is 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 by this period is positive.

| Part 6 | List of guidelines referenced in this 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://www.who.int/publications/m/item/trs986-annex2

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***
   https://www.who.int/publications/m/item/annex-2-trs-957

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://www.who.int/publications/m/item/trs1010-annex9

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***
   https://www.who.int/publications/m/item/annex-3-trs-1033

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://www.who.int/publications/m/item/annex-4-trs-929

6. 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. 957, Annex 1***
   https://www.who.int/publications/m/item/trs957-annex1

7. 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://www.who.int/publications/m/item/trs957-annex3

8. 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/publications/m/item/Annex-8-trs-1010

9. 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**
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
***Short name: WHO TRS No. 1044, Annex 4***
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
***Short name: WHO TRS No. 1044, Annex 2***
https://www.who.int/publications/m/item/trs1044-annex2

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://www.who.int/publications/m/item/trs943-annex3

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://www.who.int/publications/m/item/trs961-annex2

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://www.who.int/publications/m/item/trs981-annex2

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://www.who.int/publications/m/item/annex-3-trs-981

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***
https://www.who.int/publications/m/item/tr961-annex14

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://www.who.int/publications/m/item/trs1019-annex3

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***
https://www.who.int/publications/m/item/trs992-annex4

19. 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://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

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***
https://www.who.int/publications/m/item/trs992-annex5

21. 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/trs-992-annex-6

22. 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***
https://www.who.int/publications/m/item/annex-4-trs-1033

23. 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***
https://www.who.int/publications/m/item/trs966-annex10
24. 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***
https://www.who.int/publications/m/item/trs1010-annex10

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**
https://www.who.int/publications/m/item/annex-2-trs-1033

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**
https://www.who.int/publications/m/item/trs-1025-annex-6

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/m/item/trs-1025-annex-3-water-for-injection

27. 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/m/item/trs1025-annex4