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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Finished Pharmaceutical Product (FPP) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	**Macleods Pharmaceuticals Ltd**
Corporate address of manufacturer	Atlanta Arcade, Church Road, Andheri – Kurla Road Andheri (E), Mumbai 400059, India
Inspected site	
Name & address of manufacturing site	Macleods Pharmaceuticals Limited Unit II Plot No 25-27, Survey No.366, Premiere Industrial Estate, Kachigam, Daman (U.T.) 396210, India
Production Block/Unit	Unit II, Phases II, III, IV
Desk assessment details	
Date of review	18-30 April 2024
Products covered by this desk assessment	Lamivudine Tablet, Film-coated 150mg Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg Tenofovir disoproxil fumarate Tablet, Film-coated 300mg Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg Artemether/Lumefantrine Tablet 20mg/120mg Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg Pyrimethamine/Sulfadoxine Tablet, Dispersible 12.5mg/250mg Pyrimethamine/Sulfadoxine Tablet, Dispersible 25mg/500mg Pyrimethamine/Sulfadoxine Tablet, Dispersible+Amodiaquine (hydrochloride) Tablet, Dispersible 12.50mg/250mg+76.5mg Pyrimethamine/Sulfadoxine Tablet, Dispersible+Amodiaquine (hydrochloride) Tablet, Dispersible 25mg/500mg+153mg Ethionamide Tablet, Film-coated 250mg Ethambutol hydrochloride Tablet, Film-coated 400mg

	Cycloserine Capsules, hard 250mg Rifampicin/Isoniazid 150/75mg tab Pyrazinamide Tablet 400mg Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg Isoniazid Tablet 100mg Isoniazid Tablet 300mg Ethambutol hydrochloride/Isoniazid/Rifampicin Tablet, Film-coated 275mg/75mg/150mg Ethambutol hydrochloride Tablet, Film-coated 100mg Moxifloxacin (hydrochloride) Tablet, Film-coated 400mg Rifampicin/Isoniazid 300/150mg fc tab Pyrazinamide Tablet 500mg Rifampicin 150mg hard cap Isoniazid/Rifampicin DT 50/75mg Isoniazid/Pyrazinamide/Rifampicin DT 50/150/75mg Cycloserine Capsules, hard 125mg Rifampicin 300mg hard cap Ethionamide Tablet, Dispersible 125mg Ethambutol hydrochloride Tablet, Dispersible 100mg Pyridoxine hydrochloride Tablet 10mg Pyridoxine hydrochloride Tablet 50mg Ethambutol hydrochloride Tablet, Film-coated 400mg	
Part 2	**Summary of SRA/NRA inspection evidence considered**	
USFDA	Dates of inspection:	22-26.05.2023
	Type of inspection:	Surveillance inspection
	Block/Unit:	Phases II, III, IV
	Type of products/Dosage forms covered:	Solid dosage forms (tablets and capsules)
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	WHO Prequalification carried out an inspection during 19-22 June 2023. At the opening meeting the inspection team was informed that Phases II, III and IV had been inspect by USFDA 20 days earlier. The inspection team decided to cover Phase I (sterile products) and Phase II (only Rifa products and areas not covered by the USFDA inspection). Both Phase I and Phase II (Rifa products) were found to be in compliance with GMP.This desk assessment takes into account the areas covered by the WHO inspection as well as the findings of the USFDA inspection	
Brief description of manufacturing activities	The same QMS applied to all Phases (I, II, III, IV). The company provided two SMFs. The first one was dedicated to Phase I (sterile products) and the second one covered the remaining Phases (II, III, IV). The site consisted of nine main buildings and other supportive areas. Buildings 1 and 2 included Phase I and Phase II manufacturing facilities, warehouse for raw, packaging materials, and finished goods as well as part	

	of the QC laboratory. Building 3 included the printed carton warehouse, IT support and engineering, as well as HR offices. Buildings 4, 5 and 6 included Phase III manufacturing facilities, receipt, quarantine, sampling and approved area for raw materials and finished goods as well as the stability testing area. Building 7 consisted of the packaging area, control sample area and document storage area. Building 8 included the microbiological laboratory, QC and QA areas. The laboratories were common for all Phases. Building 9 (Phase IV) included manufacturing areas for non-Rifa oral solid dosage forms and the respective warehouse.
General information about the company and manufacturing site	Macleods Pharmaceuticals Limited (Macleods) manufactures and markets a wide range of pharmaceutical formulations and APIs. The headquarters are located at Andheri, Mumbai. Macleods has ten facilities: - Pharmaceutical Formulation (Unit I), Palghar (Maharashtra). - Pharmaceutical Formulation (Unit II), Daman (Union Territory). - Pharmaceutical Formulation (Unit III), Daman (Union Territory). - Research & Development (R&D) Centre, Andheri (Mumbai). - Active Pharmaceutical Ingredient and Pharmaceutical Formulation (Unit V), Sarigam (Gujarat). - Pharmaceutical Formulation (Unit VI), Nalagarh (Himachal Pradesh). - Pharmaceutical Formulation (Unit VII), Daman (Union Territory). - Pharmaceutical Formulation (Unit IX), Sikkim - Active Pharmaceutical Ingredient (Unit X), Dahej -Bharuch (Gujarat) - Pharmaceutical Formulation (Unit XI) Indore SEZ (MP). The Kachigam site is located approximately 200Km north of Mumbai. In Unit II (Phase I) only sterile API and FPP are manufactured. In Unit III (Phase II, III and IV) only OSD are manufactured. Some of the warehousing, sampling and QC facilities are shared.
Focus of the last WHO inspection	The inspection focused on Phase I and Phase II (Rifa products)
Areas inspected	Documents reviewed included but were not limited: • Quality Manual – management review meetings • Organization Chart • Job descriptions for key personnel • Personnel training and hygiene • Product Quality Review • Quality Risk Management • Responsibilities of the quality unit and production • Complaints and Recalls • Deviation handling and CAPA • Change control

	• OOS and OOT investigations • Material release • Self-inspection and vendor qualification • Validation and qualification • Equipment calibration • Data integrity • Sampling and testing of materials • Batch processing records • Materials management system • Analytical methods – stability • HVAC system • PW/WFI systems Areas visited: • Starting materials, packaging materials and FPP warehouses • Sampling and dispensing areas • Manufacturing operations for API and FPP • QC laboratories (Analytical and microbiological The inspection covered Phase I as well operations and activities related to Rifa products manufactured in Phase II.
Out of scope and restrictions	Products not submitted to Prequalification were excluded from the scope of this inspection.
WHO products covered by the last WHO inspection	Phase I MA152 Artesunate + Sodium Bicarbonate + Sodium Chloride Powder and solvent for solution for injection 60mg + 50mg/ml + 9mg/ml Phase II – Rifa Products TB158 Rifampicin/Isoniazid 150/75mg tab TB168 Rifampicin/Isoniazid/Pyrazinamide/Ethambutol 150/75/400/275mg tab TB183 Rifampicin/Isoniazid/Ethambutol 150/75/275mg tab TB231 Rifampicin/Isoniazid 300/150mg fc tab TB259 Rifampicin 150mg hard cap TB302 Isoniazid/Rifampicin DT 50/75mg TB309 Isoniazid/Pyrazinamide/Rifampicin DT 50/150/75mg TB332 Rifampicin 300mg hard cap

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

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
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) Manufacturing authorization and GMP certificate granted by the local authority:
The company provided a valid Manufacturing License and GMP certificate. These were also included in the SMF.

b) Site master file (SMF):
The company shared the SMFs for Phase I and Phases II, III, and IV prior to the on-site inspection. These documents did not give rise to any observations.

c) List of regulatory inspections performed in the last 5 years and their outcome:
This was the 8th WHO Prequalification on-site inspection. The site was regularly inspected by CDSCO. The most recent inspections by USFDA were conducted in May 2023 and in January 2019. The site had also been inspected by MHRA in December 2019. All the inspections concluded that the site was GMP compliant.

d) List of all the products and dosage forms manufactured on-site:
The list of products manufactured in Phases II, III & IV are included in Annex I of the SMF.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):
Product Quality Reviews were carried out in accordance with a written procedure using an approved template. PQRs were conducted and documented annually on a rolling basis considering one year from the start of the first batch for all approved and commercialized pharmaceutical drug products. PQRs had to be completed within two months of the due date. A PQR schedule was prepared the first two weeks of the year. PQRs were prepared regardless of the number of batches manufactured during the year, even if no batches were manufactured during the review period. Statistical tools (process capability, control charts) were applied to evaluate critical process parameters and product quality attributes. A minimum of 30 batches was necessary for statistical evaluation and batches from the 3 previous years could be used.

During the on-site inspection the following documentation was reviewed:

- Product Quality Review Plan (PQR Schedule)
- Product Quality Review Plan (PQR Schedule)
- Product Quality Review Plan for Product Not Manufactured during the Review Year
- Attachment 01 Product Quality Review Plan for Product Not Manufactured during the Review Year

Similarly, the following PQRs were reviewed:
Rifampicin/Isoniazid/Ethambutol tabs.150/75/275mg: No batches were manufactured during the review period.
Rifampicin/Isoniazid DT 75/50mg: 46 batches were manufactured during the review period.

Some observations were identified during the review of the PQR plans. CAPA were provided, and the observations were adequately addressed.

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

During the inspection spot checks on batch records were made. In general production operations followed defined procedures and records of activities were maintained. Checks on yields and reconciliation of quantities were carried out. Before processing operations were started, steps were taken to ensure that the work area and equipment were clean and free from any starting materials, products, product residues, labels or documents not required for the current operation. Environmental monitoring was conducted. Necessary in-process controls were carried out and recorded. Similarly, before packaging operations begun, steps were taken to ensure that the work area, packaging line, printing machine and other equipment were clean and free from any products, materials or documents used previously.

During the inspection QC activities were inspected. The QC function was independent of other departments. The QC laboratories including the microbiological laboratory were separated from production areas and served all Phases. Most of the QC laboratories were located in Building 8 along with the QA area. A new microbiological laboratory was established on the 1st floor of the building while analytical and instrumental analysis took place on the 1st, 2nd and 3rd floor. Software and hardware used in the laboratory were password protected. The computer access control procedure was reviewed and more specifically the privileges for analyst, reviewer, and QA roles. Sample receiving and distribution procedure and registers were available, inspected and discussed.

The calibration/qualification procedure and the 2023 calibration plan were presented. An example of HPLC calibration/qualification was reviewed in detail. The report indicated that the following parameters were considered: pump and flow rate accuracy, gradient composition, auto sampler (linearity and accuracy), detector (noise, drift, lamp intensity, wavelength accuracy).
In addition, qualification of the fume hoods was spot-checked. The hoods were calibrated every 6 months.

The stability summary review of Rifampicin/Isoniazid DT 75/50mg was reviewed. 5 batches were included in the review manufactured during 2019-2021. All batches were placed on 24-month on-going stability studies at 25C/60%RH. For two batches the studies had been completed. Raw data indicated that all batches met their specifications at all time points.

There was a procedure in place for registering and investigating out of specification test results in the laboratory. OOS were registered and handled in TrackWise. Examples of OOS investigations were reviewed.

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

During the inspection the recall system was reviewed. Product recalls were handled according to a written SOP. This procedure described the process of withdrawing products from the market. The responsibility of recalling was assigned to the site QA, cross functional heads, corporate quality head, pharmacovigilance head, regulatory heads, and marketing and distribution head.

The depth of recall was classified into 3 levels (i.e., customer/user level, retail level and wholesale level). Mock recalls were carried out annually to test the effectiveness of the recall procedure. The mock recall protocol, for Amlodipine Besylate tablet was reviewed. The scenario included the mock recall of 14 batches of 5mg tabs and 16 batches of 10mg tabs from differentcustomers in different countries.

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO inspections 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 ***Macleods Pharmaceuticals Ltd Unit 2 Phases II, III & IV*** located at Plot No 25-27, Survey No.366, Premiere Industrial Estate, Kachigam, Daman (U.T.) 396210, 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

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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
Short name: WHO TRS No. 1052, Annex 4
https://www.who.int/publications/i/item/9789240091030

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-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://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

28. Good trade and distribution practices for pharmaceutical starting materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
Short name: WHO TRS No. 996, Annex 6
https://www.who.int/publications/m/item/annex-6-trs-996

29. WHO guidelines for preparing a laboratory information file. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 13.
Short name: WHO TRS No. 961, Annex 13
https://www.who.int/publications/m/item/trs961-annex13

30. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 1.
Short name: WHO TRS No. 1052, Annex 1
https://www.who.int/publications/i/item/9789240091030