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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
API Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Mangalam Drugs and Organics Ltd, Unit 1
Corporate address of manufacturer	Rupam Building, 3rd floor, 239, P D' Mellow Road, near GPO, Mumbai 400 001, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Plot No 187, 2nd Phase GIDC, Vapi, Gujarat, 396 195, Dist. Valsad, Gujarat India
Unit / block / workshop number	Unit 1
Inspection details	
Dates of inspection	21-24 June 2022
Type of inspection	21-24 June 2022
Introduction	
Brief description of the manufacturing activities	Unit 1 was the focus of this inspection and it consisted of several buildings within the compound. Namely: Raw Material, Finished Product Warehouse and Production Plant 1E (Block 7) Production Plant 1A (Block 10) Production Plant 1D (Block 9) Production Plant 1B (Block 13) Production Plant 1C -Recovery Plant (Block 42) Liquid and Hazardous Material Store (Block 11) Quality Control Quality Assurance Utility Building Tank Farm This was a multi-product manufacturing facility. No pesticides, steroids, hormones or beta lactams were manufactured on site. Major changes since the last WHO inspection: 1. Introduction of Corporate Quality Assurance 2. Expansion/ Modification of Plant-1E (Block 7) 3. Relocation of Finished Goods Warehouse, Packaging Material Store and Cold Storage Room in Plant-1E (Block 7)

	4. New stores for liquid & hazardous materials (Block-11) 5. New facility for intermediate manufacturing Plant-1B (Block-13) 6. New equipment in QC lab and Production
General information about the company and site	Mangalam Drugs & Organics Ltd. specializes in manufacturing active pharmaceutical ingredients and their intermediates. It was established in 1977 as an aromatic and specialty chemicals manufacturer and in 1996 started engaging in the manufacture of APIs and pharmaceutical intermediates. It has two manufacturing facilities, namely Unit 1 and Unit 2, located at two different areas, in Vapi, Valsad District, Gujarat State, India. Unit 1 became operational in 1998. Both units are of interest to WHO PQ and they operate under a recently introduced Corporate Quality Assurance System. Thus, it is recommended that they are consecutively inspected since QMS principles are the same and there are transactions of raw material and intermediates between these sites. This report should be read in combination with Mangalam Unit-2 inspection report since they both contain information on the Corporate Quality Management System and observations on Corporate procedures are applicable to both sites.
History	The site was previously inspected by WHO twice in 2011, in 2014 and in 2018. The most recent inspection by the Gujarat Food and Drug Administration was carried out in April 2019
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Pharmaceutical Quality System Documentation Facilities and Equipment (warehouses, tank farm, production blocks, laboratories) Utilities Production Quality Control Packaging and labelling Product Release
Restrictions	N/A
Out of scope	APIs out of WHO Prequalification scope
WHO products covered by the inspection	Lumefantrine [APIMF 100] Artemether [APIMF 138] Amodiaquine Hydrochloride [APIMF 134] Artesunate [APIMF 135] Piperaquine Phosphate [APIMF 149] Dihydroartemisinin [APIMF 151] Tenofovir Disoproxil Fumarate [APIMF 204] Primaquine Phosphate [APIMF 380] Sulfadoxine [APIMF 356]

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	Non conformity
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. Quality management

A formal documented system of quality assurance was established, with procedures covering all expected key quality elements being in place. The company had adopted a Corporate Quality Assurance System (CQA). CQA department was independent from production and reported directly to senior management. QA and QC departments were independent of production. Site QA and QC were reporting to CQA. The QM was briefly reviewed. Operations were specified in written form and GMP requirements were essentially being met. Procedures were in place for notifying responsible management of regulatory inspections, serious GMP deficiencies, product defects and related actions. The procedures that were reviewed and discussed during the inspection were generally of a satisfactory standard. Product and processes were monitored, and these results were considered during batch release. Management review meetings were conducted twice a year in accordance with a written procedure. An agenda with fixed topics was prepared and follow up on the previous meeting proposed actions, was performed.

Quality risk Management (QRM)

Quality risk management was incorporated in the QMS, and its application followed the principles described in a Corporate SOP. The procedure included definitions of the different stages of risk management, as well as descriptions of methods and tools. The implementation of risk management in the introduction of Sulfadoxine crude in Production Plant 1D and of Sulfadoxine pure in Production Plant 1E, were reviewed. In addition, examples of risk assessments in change control and deviation handling were checked.

Product Quality Review (PQR)

The procedure for Product Quality Review was reviewed in detail. PQRs had to be prepared by QA within 90 days after completion of the previous calendar year. The PQR consisted of the Summary report and the APQR. In case no batches were manufactured during the year only the Summary report was applicable. PQRs of the following APIs were reviewed:
Lumefantrine
Artemether
Primaquine Phosphate
Tenofovir Disoproxil

2. Personnel

Personnel met during the inspection appeared to have knowledge of GMP principles and showed that they received initial and continuing training, including hygiene instructions, relevant to their responsibilities. Measures were taken to prevent unauthorized people from entering production and QC areas and appeared to be effective.

Organization charts were issued and compiled according to a written SOP. Personnel in key positions were assigned with specific duties detailed in writing. The job descriptions were compiled according to a written procedure, and they were reviewed every three years. The job descriptions of the Unit 1 Production Manager, Block 1E Production Sr. Executive, Block 1E Production Shift Officer, QC Sr. Manager and QC Jr. Executive, were reviewed.

Training of personnel was conducted according to a written procedure. Initially, induction training of newly recruited personnel was given by the Head of the relevant Department including GMP, GDP and data integrity topics. Induction training had to be completed within 5 days of recruitment and evaluated. Subsequently, job specific training and on the job training, were provided according to a training program issued within 15 working days of recruitment of new personnel. Annual training programs were issued based on the duties of each employee including training needs that were identified during operations. Training assessment was performed by written questionnaires, with predefined success criteria and provisions were in place in case of failures. Trainers were selected and qualified according to specific criteria, and they underwent appropriate training. The implementation of the 2022 training program, training records of personnel and the list of trainers were reviewed.

The procedure for “personal hygiene and clothing” was reviewed. In addition, the SOP for “factory garment laundry management was spot-checked. Personnel working in general manufacturing areas were issued with two uniforms per year. Medical examinations were conducted upon hiring and yearly thereafter, and were applicable to all employees including temporary workers, according to a written procedure. Spot-checks on annual medical records were made.

3. Buildings and facilities

Inspected workshops and facilities were maintained at an acceptable level.
The new Finished Goods Warehouse, Packaging Material Store and Cold Storage Room in Plant-1E (Block 7) were visited as well as the new stores for liquid & hazardous materials (Block-11). Relevant SOPs and a copy of the approved vendor list were available.

The manufacturing facilities were not API dedicated. Adequate ventilation, air filtration and exhaust systems were provided. Lighting in the areas visited during the inspection was considered adequate. The HVAC system provided filtered air to the Grade D cleanrooms. The flow of materials and personnel through facilities were designed to prevent mix-up and cross contamination. Plants 1A, 1D, 1E, and 1B were visited. The expansion of Plant 1E and the new Plant 1B facilities were discussed in detail, especially in terms of design, personnel, and material flow

4. Process equipment

Process equipment in Plants 1A, 1B, 1D and 1E were not API dedicated. Materials of product contact were suitable. Reactor systems, and utilities, were installed to allow reflux, distillation and cooling required to make the APIs of interest. Tools and equipment were uniquely identified, and status labels were generally used. Similarly measuring equipment were labelled including calibration status. In general, they were maintained according to written procedures and a plan for preventive maintenance was available. The 2022 preventive maintenance schedule of equipment in Plant 1A was reviewed. Spot checks on the Logbook of equipment use for the centrifuge CF1E-101, the Powder Transfer System PT1E-101, and the Fluid Bed Dryer FB1A-102 were made. In addition, the procedure for cleaning and usage of drums and flexible hoses as well as the logbook for issuance of hoses in Plant 1E were reviewed. The introduction and qualification of new equipment in Plants 1B and 1E were discussed in detail.

5. Documentation and records

The documentation system was based on hierarchical order with the QM being on the top, followed by the SMF, the VMP and Corporate Policies and on the bottom of the pyramid the SOPs and records. The company had introduced a Corporate Quality Assurance System with many Corporate SOPs which were applicable to both Unit-1 and Unit-2. It was noted that several SOPs had been very recently reviewed and updated. Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved, and distributed according to written procedures. Specifications were established for raw materials, intermediates, and APIs. BMRs were retained for each batch processed. Batches were numbered according to a written procedure of product batch number.

6. Materials management

There were written procedures describing the receipt, labelling, quarantine, storage, and handling of materials, as well as procedures for sampling, testing and approval or rejection of materials. Occasionally, raw materials were transferred to Unit 2 and vice versa. These transactions followed the principles described in a written procedure.

Material suppliers were required to be managed according to a procedure. For each one the raw materials there was a list of approved suppliers. The list of approved vendors for Artemisinin was reviewed.

7. Production and in-process controls

In general, production operations followed defined procedures. Process flows (with IPCs) and routes of synthesis were available. Access to production premises was restricted to authorized personnel. The SOP for "entry & exit procedure in powder processing area for production Plant 1D" was reviewed. It is recommended that gowning pictorials include photos of handwashing as the first step before entering clean areas.

Weighing and measuring devices were of suitable accuracy for the intended use. Calibration procedures and records for scales were presented. Standard weights and their certificates were available. Closed systems and dedicated pipes were used for material transfers from reactors to centrifuges. Examination of the flow of the manufacturing process and relevant equipment was in line with the BMRs examined during the inspection.

Reprocess and rework were performed according to a written SOP. Batch records of Dihydroartemisinin, Amodiaquine and Lumefantrine were reviewed during the site tour.

8. Packaging and identification labelling of APIs and intermediates

Intermediates and in-process materials were handled in accordance a written procedure. Dedicated containers were used for intermediates, as required. Examples were seen of those used for Lumefantrine. The procedure for handling and packing of finished drug substances and salable intermediates was reviewed.

Quarantine, under test, inner bag and finished product labels were reviewed. The process of issuance, approval and control of labels was discussed in detail.

9. Storage and distribution

Raw Materials, Packaging Materials and Finished APIs were relocated to Block 7. For raw material and packaging material stores, temperature was recorded twice a day. Relative humidity was monitored. Cold storage and a temperature-controlled area were available and temperature mapping had been carried out and hot spots were determined.

10. Laboratory controls

The analytical laboratories were inspected. The premises were generally of an acceptable standard and well equipped. Documents were organized in an appropriate manner and retrieval was achieved in a timely manner. Practices in the laboratory were governed by written procedures.

Standards were handled and established according to an SOP. Three types of standards were described: Pharmacopoeial Reference standards, in house working standards which were tested against Reference standards and standards that were used when Pharmacopoeial were not available, which undergo extensive testing including structural characterization. Relevant documentation for the qualification of Artemether working standard was reviewed. Consumption registers were maintained. Volumetric solutions were prepared according to written instructions and kept properly labelled. Hold time study for HCl 1N volumetric solution was discussed as well

as the stability of Lumefantrine mobile phase for HPLC. Spot-checks on analytical balances were performed. Their calibration followed the principles described in a written SOP. Additionally, the SOP on calibration of pH meter was checked.

Out of specification results were handled according to a written procedure. The investigations were performed in a stepwise approach: Phase Ia preliminary laboratory investigation for the determination of obvious errors, Phase Ib Hypothesis testing, Phase II including manufacturing review and extended laboratory investigation and Phase III impact on the product. Trending of OOS is performed annually.

11. Validation

A Validation Mater Plan was available, and it was prepared according to a procedure. Procedures for validation and qualification of equipment, systems, utilities, processes, and analytical methods were in place.
Qualification protocols and reports for the Cold Storage room, Reactor RE1E-201 and Centrifuge CF1E-101were reviewed.

Cleaning validation
The principles of cleaning validation were described in an SOP, while a separate procedure detailed the sampling methods. The cleaning validation protocol in production plant 1E, the analytical cleaning method validation protocol and analytical cleaning method validation report were reviewed.

12. Change control and deviations

Change control was managed according to a procedure which provided the basic concepts of a formal system to handle, implement and evaluate changes. Changes were categorized into minor, major or critical. Several changes regarding new equipment installation, amendments in analytical methods and intermediate product specifications were reviewed in detail.

Deviations were handled according to a written procedure. Deviations were classified as minor, major or critical based on their impact on quality attributes, process parameters and potential impact on patient. All deviations had to be closed within 30 working days from the day of initiation, but major and critical ones required immediate investigation. Deviations were kept in the deviation registry, which was reviewed annually.

13. Rejection and re-use of materials

The company had in place an SOP for recovery and usage of recovered solvents. Batch numbers for recovered solvents were assigned according to a procedure. The operations relating to recovery of solvents based on boiling points and their use in the same stage and product. One re-distillation was allowed in case an OOS result was obtained after the first distillation.

14. Complaints and recalls

Complaints were handled according to a procedure. Complaints were classified by QA as critical, major or minor based on the potential to affect product quality, safety and efficacy. A review of open complaints was performed quarterly and of all complaints annually.

Product recalls were performed according to a procedure. They were categorized as voluntary or statutory. Recalls were categorized in three classes according to impact and urgency, and the

depth of recall was assigned based on three levels (level 1 being the most extensive one, reaching the consumer level). The procedure included instructions on performing a mock recall. The most recent mock recall was reviewed.

15. Contract manufacturers (including laboratories)

Vendors and suppliers were managed according to the SOP. The criteria for the selection of new vendors were described, including the evaluation of questionnaires, test results for three consecutive batches and vendor audit. Audits of secondary packaging material vendors could be performed by third parties. Vendors were audited periodically from qualified auditors, based on potential risk. The vendor audit schedule was presented, and its implementation was checked. Vendors were evaluated annually, and reports were generated.

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, *Mangalam Drugs and Organics Ltd, Unit1* located *at Plot No 187, 2nd Phase GIDC, Vapi, Gujarat, 396195, 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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***
http://www.who.int/medicines/publications/44threport/en/

3. 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
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

4. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

5. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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***
http://www.who.int/medicines/publications/44threport/en/

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***
http://www.who.int/medicines/publications/44threport/en/

8. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

9. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. 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**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. 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***
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13. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

14. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

16. 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

17. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. 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 Multisource guidance*** or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

19. 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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

20. 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

21. 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

22. 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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23. 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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https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. 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 1033, Annex 4***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations