

**Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT**

Active Pharmaceutical Ingredient Manufacturer

Part 1		General information
Manufacturers details		
Name of manufacturer	Emcure Pharmaceuticals Limited	
Corporate address of manufacturer	Emcure Pharmaceuticals Limited, Plot No. P-1 & P-2 IT-BT Park, Phase-II, M.I.D.C., Hinjawadi, Pune, PIN – 411057, Maharashtra, India	
Inspected site		
Name & Address of inspected manufacturing site if different from that given above	Plot no. D-24 & D24/1, MIDC Kurkumbh Industrial Area, Daund, Pune District, Maharashtra 413802 India Latitude: N 18° 24' 143" Longitude: E 47° 31' 576" DUNS No.: 677602452	
Synthetic Unit /Block/ Workshop	API-4, API-7 and API-9	
Inspection details		
Dates of inspection	22 – 25 January 2024	
Type of inspection	Initial GMP inspection	
Introduction		
Brief description of the manufacturing activities	Emcure Pharmaceuticals Limited, Kurkumbh site manufactures and distributes active pharmaceutical ingredients (APIs) for the Indian and overseas markets. APIs manufactured at the site included antiretroviral, hematinic, antihypertensive, antineoplastic, anticonvulsant, anti-inflammatory, anaesthetic, antihyperphosphatemic, immunosuppressant, and antiemetic with a Total Reactor volume of about 340 KL (153 Reactors). Oncology and immunosuppressant APIs are manufactured in dedicated blocks namely API-5 and API-10 plants. The company declared that penicillin and cephalosporin APIs are not manufactured on-site.	
General information about the company and site	Emcure Pharmaceuticals Limited was established in April 1981. Emcure is involved in manufacturing and marketing of Finished Pharmaceutical Products (FPP), Active Pharmaceutical Ingredients (API) and Intermediates. Manufacturing of APIs and Intermediates takes place at two sites, Kurkumbh and Pimpri, Pune. The API Manufacturing facility is located at Kurkumbh on Pune -Solapur Highway, 68 km away from Pune and 219 km from Mumbai.	

History	This was the first WHO on-site inspection. The site is periodically inspected by CDSCO. The site was also inspected in January 2020 by USFDA and in April 2022 by ANVISA.
WHO APIs covered by the inspection	APIMF 430 Dolutegravir Sodium APIMF 439 Molnupiravir APIMF 488 Tenofovir Disoproxil Fumarate
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	<ul style="list-style-type: none"> Pharmaceutical Quality System Production blocks of API-4, API-7 and API-9 Warehouses Quality Control laboratories Utilities including water system, compressed air, nitrogen
Restrictions	The scope of the inspection was restricted to the APIs in the WHO PQ programme.
Out of scope	APIs other than those applied for WHO prequalification programme (PQP) were not covered during this inspection.
Abbreviations	Meaning
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
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
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
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory

MR	Management review
NC	Nonconformity
NRA	National regulatory agency
OQ	Operational qualification
PDE	Permitted Daily Exposure
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
RM	Raw material
RO	Reverse osmosis
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
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1. Quality management

A system for managing quality, involving participation of management and appropriate manufacturing personnel was in place. The quality-related activities were defined and documented. The quality department was independent of the production department. The persons authorized to release intermediates and APIs were specified. The quality-related activities were recorded at the time they were performed. The senior management responsibilities and commitments were defined.

Product Quality Review (PQRs)

Regular quality reviews of APIs were conducted, reviews were evaluated, and assessments were made to determine if any corrective action or any revalidation was necessary.

The SOP entitled “Product quality review” was checked. PQRs were performed annually or on a rolling base and had to be ready within three months of the the review target date. In general, PQRs were approved and released by the Head of Quality Management. The PQRs of the API products in the inspection scope were reviewed and discussed.

Quality Risk Management

The principles of QRM were described at a high level in the quality manual which indicated that the reviews were applied to all GMP related operations and activities. An SOP was in place to manage risks within the manufacturing site. Risk registers for the years 2022 and 2023 were checked, and risk assessment reports were reviewed during the inspection.

Management review (MR)

The SOP entitled “Quality Management Review” was checked. According to the SOP, QMR should be performed at the site level and at the corporate level. The corporate MR meeting held in 2023 was verified and found to be acceptable.

Internal audits (self-inspection)

The SOP for internal audit was reviewed. Schedules for 2022 and 2023 of the internal audit programme were also checked. Examples of internal audit findings were verified.

Deviations

A procedure for handling deviations was in place. The SOP defined deviation as any excursion from approved instructions or established specifications apart from those related to the QC laboratory as the latter was addressed by the procedure for OOS. Examples of deviation investigations and CAPAs were reviewed.

Product release

The SOP entitled “Release/rejection of raw materials, packaging material, intermediate and API” was checked. The QA department was responsible for review batch testing data and production data, then release the batch in the SAP. A template checklist was used for the purpose of BMR and QC testing reviews prior to product release.

2. Personnel

The site employed 530 employees at the time of the inspection. The company had an organizational chart that showed that there was a clear separation between the responsibilities and reporting of the quality and production units. The site had two QA managers. The job descriptions of the QA Managers were checked.

Staff training

Induction and continuous training were provided in accordance with the procedures for employee training. The SOP provided for training needs assessment, training planning, training implementation, including annual training plan and evaluation of training effectiveness. The training plans for 2023 and 2024 were reviewed and sample training records were checked for two staff: one from production and one from the QA department.

Personnel Hygiene

The personnel operating at the site, including those working for production and QC, were observed to practice good hygiene practices including suitable clothing and gowning at controlled and classified areas.

3. Buildings and facilities

The buildings and facilities inspected were designed and constructed to facilitate cleaning, maintenance, and operations as appropriate according to the type and stage of manufacture. The manufacturing areas provided good space for the installation of equipment.

The production blocks covered during this inspection were not product dedicated. The synthetic process steps and purification were performed in the chemical areas, followed by drying and packaging, which were performed in Grade D areas.

QC laboratories and warehouses for starting materials and finished products were available and well maintained at the site.

4. Process equipment

The equipment used for the manufacture of the inspected API products appeared to be of appropriate design and size for its intended use. In general, cleaning and maintenance of the process equipment appeared satisfactory. The manufacture and material transfer took place in closed systems wherever possible.

The equipment installed at the visited production plants were multi-purpose and each piece of equipment had a unique identification number. The measuring equipment were labeled, including calibration status. The equipment appeared to be of suitable design and construction for the allocated process in general.

Equipment maintenance was performed according to written procedures and a plan for preventive maintenance was in place. The preventive maintenance schedules for the years 2024 and 2023 were reviewed, along with preventive maintenance trending for the year 2022. The maintenance activities were adequately documented.

The cleaning of Equipment and accessories were performed according to written procedures. The equipment cleaning in production blocks were spot checked and discussed.

5. Documentation and records

The company used a manual-based documentation system. A written procedure was in place for issuance, approval, control, review, and withdrawal of procedures and quality documents. The procedures had to be reviewed periodically, unless otherwise required. The material and product specifications were detailed in written form. Similarly, the analytical methods for each material and product were documented.

The procedures for batch numbering system and BMR management were checked. The master BMR of WHO grade API Dolutegravir Sodium was checked and found generally acceptable.

6. Materials management

The incoming starting materials and finished API products were quarantined after receipt until released for use or distribution. The status of raw material was indicated, with respect to the material being under quarantine, approved, and retest, etc. The starting materials, packaging materials, and finished API products were stored in different warehouses under the specified conditions. A secured area for return and rejected materials was available. The starting materials and finished goods were managed

by a hybrid system with SAP and manually recorded on a whiteboard for location. The material stocks in SAP were spot-checked.

The warehouses for raw material, finished goods and packaging materials were visited. The management procedures for material receipt, sampling, testing, and release were checked during the inspection.

Vendor management

A system for evaluating the suppliers of critical materials was in place. The procedures for vendor qualification and management were checked. The vendor qualification and vendor audit report for an intermediate supplier used for an API covered within the scope of this inspection were verified.

7. Production and in-process controls

In general, the production operations followed defined procedures. The process flows and routes of synthesis were available. Access to API plants was restricted to authorized personnel. The entry to the production suites was done through change rooms. The examination of the flow of the manufacturing process and relevant equipment in line with the BMRs was checked during the inspection.

The inspectors briefly visited production areas within API-4, API-7, and API-9 plants. The APIs within the inspection scope were not in operation at the time of this inspection. The production of other APIs was in operation at API-4 and API-7. The BMRs were spot-checked.

The blending of API batches was managed following the written procedure. The blending was allowed for batches that complied with the specification and validation for blending operation. According to the company, no blending process was applied for the three APIs covered within the scope of this inspection.

Contamination control

The intermediates drying areas in production blocks were briefly visited and spot-checked for contamination/cross contamination control. Final API drying and packaging activities were performed using non-dedicated equipment in the clean area of the respective plants. Dust extractors were installed at the dust generation areas.

8. Packaging and identification labelling of APIs and intermediates

The packaging materials and labels were subject to quality control before release. The packaging and labelling were not in operation at the time of inspection. The packaging and labelling operations were described in the batch packaging instructions. The line clearance was checked and showed it was done before and after labelling/packaging activities. The procedure entitled “Packing/repacking and transfer of finished goods to finished goods Store” was reviewed along with the repacking batch records.

9. Storage and distribution

The finished APIs were stored in a designated warehouse and held until released by the authorized QA person. Materials were stored in suitable facilities under appropriate conditions. Records of storage conditions were maintained. Separate storage areas were provided for quarantine, rejected, returned, and recalled materials.

The temperature mapping report for the warehouse (bonded storeroom) had been performed by an external party and it was checked. The worst-case locations were identified for routine monitoring. As per in-house procedure, the temperature mapping was performed periodically.

Distribution procedures

The API products were released for distribution to third parties after they had been released by the quality unit and transported in a manner that did not adversely affect their quality.

The SOP entitled “Management of dispatch” was checked. An SAP system was in place allowing traceability of API batch distribution and facilitating recall, when warranted

10. Laboratory controls

Adequate quality control facilities were provided. Procedures were in place describing sampling, testing, approval and rejection of materials, along with recording and storage of laboratory data. Specifications, sampling plans, and test procedures were available. The physicochemical quality control as well as the microbiological laboratories were visited during the inspection.

Laboratory controls were followed and documented at the time of performance. Departures from procedures were documented and explained. OOS results obtained, were investigated and documented according to a well-established procedure.

The samples receiving/storage/distribution records were maintained, and samples were appropriately stored. The logbooks for received and distributed API finished products, as well as sample reconciliation records were checked and found acceptable. The API and intermediate samples were tested according to approved specifications and testing procedures.

All laboratory equipment had usage and calibration logbooks. The Micro Balance Calibration log was checked. Class “A” volumetric glassware was used. HPLC and GC were networked with Chromeleon Empower 3 software. The data backup procedure and access control of the Chromeleon system were discussed.

Out of specification (OOS) test results were managed according to a written procedure. Inspectors reviewed the procedure and checked the OOS flow chart and the same were found acceptable.

The reserve samples of each batch of dispatched API were retained in a dedicated room at controlled temperature for specified time as per a well-established procedure. Retention sample register was in place. The reserve samples and the visual inspection record spot-checked were acceptable.

Stability study

A range of stability chambers were available for conditions of 40°C/75% RH, 25°C/60% RH and 30°C/75% RH. The Molnupiravir Stability schedule was spot-checked.

Microbiological laboratory

The microbiological laboratory was visited. In conjunction with the visit to the microbiological laboratory, the protocol and report of the vertical autoclave requalification and of the BOD incubators were reviewed.

11. Validation

A Validation Master Plan describing the basic concepts of validation was in place as guided by the respective procedure. The procedure was applicable to qualification/validation activities including but not limited to buildings, facilities, equipment, production processes, cleaning, disinfection, and computerized systems.

Process validation

The SOP entitled “Process validation” was checked. The risk assessments for PV and PV reports for Dolutegravir Sodium and Tenofovir were checked. The PV batches were placed in stability studies at the following conditions: of 25⁰C/60% RH and 30⁰C/75% RH.

Cleaning validation

The procedure for cleaning validation, along with the validation reports of equipment cleaning for all products produced at the API-9 plant were reviewed. As part of the cleaning validation, clean equipment holding time (CEHT) and dirty equipment hold time (DEHT) studies were carried out for all major equipment at API-9. The cleaning validation approach considered two acceptance criteria: (1) visually clean and (2) maximum allowable carry over (MACO) based on health-based exposure limits (HBELs). The manufacturer’s approach was to redo the cleaning validation with each product introduced for production at the respective plant.

Utility system validation/qualification of utilities

The last two requalification/revalidation reports of compressed air were reviewed. In addition, HVAC validation SOP and reports of classified areas requalification were spot checked.

Computerized systems validation

The lifecycle management for the computerized systems was reviewed along with the list of GXP systems, their classification (according to GAMP[®] 5), and their traceability matrix. Examples of impact assessment for equipment/instruments were reviewed. Periodic reviews of the same were also spot-checked and verified.

12. Change control

A procedure for change management was presented. The SOP was applicable to all GMP-related activities. The department supervisors were responsible for initiating a change request and recording it on a template issued by the QA department. The department head was responsible for signing the request. The request would then be sent to the QA department for evaluation and decision with the engagement of a multi-disciplinary team. The team was responsible for conducting a risk assessment of the proposed change and advising on its implementation. At this stage, the request could be approved or rejected. A plan for the implementation would be established, including deadlines. QA was responsible for verifying the implementation and the effectiveness of the change. Several change requests were reviewed during the inspection.

13. Rejection and re-use of materials

The SOP entitled “Reprocessing and reworking” was checked and discussed. According to the company statement, there were no reprocessing and reworking batches for WHO APIs in the last three years.

The SOP entitled “Handling of returned goods” was checked. The returned intermediates or APIs were identified and quarantined in the returned goods room and checked by the responsible warehouse and QA personnel. The options for handling the returned goods were reprocessing, reworking, repacking and destroying by following the respective procedure.

The SOP entitled “Procedure for handling of recoverable/recovered material/solvent in production” was checked. According to the SOP, recovered solvents could be used in the same processing step or the same product previous processing steps. The company declared that recovered solvents were not used in the production of WHO APIs.

14. Complaints and recalls

A procedure for handling of customer complaints for API and saleable intermediates was in place. According to the mentioned procedure, the recipient of the complaint had to communicate the complaint information to the QA department which was responsible for registering the complaint. Recurrence of the complaint would be checked which will then have an impact on the initial categorization of the recall. Complaint investigations would be extended to different batches and/or products depending on the nature of the complaint and root cause. CAPA would be identified and applied, including the initiation of the recall process in case of confirmation of the accuracy of the complaint and identification of the root cause. Evaluation of the effectiveness of CAPA was in place. Examples of market complaints were reviewed.

The procedure for product recall was reviewed. An example of actual recall was reviewed. In addition, two examples of mock recalls in May 2021 and July 2023 were checked, considering the fact that the SOP for recall provided for a frequency of mock recall every 2 years.

15. Contract manufacturers (including laboratories)

The agreement between Emcure and a contract manufacturing site was checked. The product list was attached.

Part 3	Conclusion – Inspection outcome
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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, **Emcure Pharmaceuticals Limited, Kurkumbh site**, located at **Plot no. D-24 & D24/1, MIDC Kurkumbh Industrial Area, Daund, Pune District, Maharashtra 413802 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 GMP guidelines referenced in the 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-eight Report Geneva, World

Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. **Short name: WHO TRS No. 986, Annex 2**

<https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf>

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. **Short name: WHO TRS No. 957, Annex 2**

[untitled \(digicollections.net\)](https://digicollections.net)

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.

Short name: WHO TRS No. 1033, Annex 3

[9789240020900-eng.pdf \(who.int\)](https://www.who.int/publications/m/item/9789240020900-eng.pdf)

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.

Short name: WHO TRS No. 929, Annex 4

<https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf>

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**

<https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf>

6. 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>

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://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf>

8. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.

Short name: WHO TRS No. 1044, Annex 2

[TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products](#)

9. WHO guidelines on technology transfer in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
[TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing](#)
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**
<https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf>
11. 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>
12. 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>
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
<https://digicollections.net/medicinedocs/#d/s20177en/>
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
<https://digicollections.net/medicinedocs/#d/s20175en/>
15. 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
16. 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>

17. 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
18. 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/digicollections/essential-medicines-and-health-products-information-portal)
19. 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/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6>
20. 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/publications/m/item/9789240020900-eng-pdf)
21. 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
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf
22. 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
23. 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**
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24. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
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25. 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 \(who.int\)](#)
26. 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
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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**
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