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**Prequalification Unit Inspection services**
**WHO INSPECTION REPORT**

**Active Pharmaceutical Ingredient Manufacturer**

| **Part 1** | **General information** |
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| **Manufacturers details** | |
| Name of manufacturer | Jiangxi Desano Pharmaceutical Co., Ltd. |
| Corporate address of manufacturer | No. 417 Binhai Road, Laogang Town, Pudong New Area Shanghai, China, 201302 |
| **Inspected site** | |
| Name & Address of inspected manufacturing site if different from that given above | Jiangxi Desano Pharmaceutical Co., Ltd.<br>Salt Chemical Industry Base, Zhangshu City, Jiangxi Province, 331200 China. |
| Synthetic Unit /Block/ Workshop | A05, B06, B03, C05 |
| **Inspection details** | |
| Dates of inspection | 3 – 7 March 2025 |
| Type of inspection | Initial inspection |
| **Introduction** | |
| Brief description of the manufacturing activities | Production and quality control of APIs, intermediates and starting materials. |
| General information about the company and site | Jiangxi Desano Pharmaceutical Co., Ltd., owned by Shanghai Desano Chemical Pharmaceutical Co. Ltd., was founded in September 2020. The facility is located at Salt Chemical Industry Base, Zhangshu City, Jiangxi Province, China. The main products were starting materials, intermediates, APIs of anti-retroviral drugs, anti-malarial, anti-COVID-19 and others. Highly sensitizing, biological products, β-lactam structural products, steroid hormone contraceptive products, and cytotoxic products were not manufactured on the site. |
| History of the regulatory inspections | This was the initial WHO onsite GMP inspection. The site was regularly inspected by Jiangxi Province Medical Products Administration, China, and has not been inspected by other National Regulatory Authorities (NRAs). |
| WHO products covered by the inspection | 1. APIMF046 (Lamivudine)<br>2. APIMF191 (Ritonavir)<br>3. APIMF363 (Lopinavir)<br>4. APIMF 523 Darunavir (Ethanolate) |

| **Brief report of inspection activities undertaken – Scope and limitations** | |
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| Areas inspected | **Document reviewed:**<br>• Quality management<br>• Personnel<br>• Buildings and facilities<br>• Process equipment<br>• Documentation and records<br>• Materials management<br>• Production and in-process controls<br>• Packaging and identification labelling of APIs and intermediates<br>• Storage and distribution<br>• Laboratory controls<br>• Validation<br>• Change control<br>• Rejection and reuse of materials<br>• Complaints and returns<br>• Contract laboratories<br>**Site areas visited:**<br>• Production blocks<br>• Warehouses for starting materials and finished APIs<br>• Tank farm of solvents<br>• Retention sample area<br>• QC laboratories for Physio-chemical and microbiological<br>• Utilities:<br>  • Water system<br>  • HVAC |
| Restrictions | The scope of the inspection was restricted to APIs in the WHO PQ programme. |
| Out of scope | APIs which are not under the scope of WHO prequalification. |
| **Abbreviations** | **Meaning** |
| AHU | Air handling unit |
| ALCOA | Attributable, legible, contemporaneous, original and accurate |
| API | Active pharmaceutical ingredient |
| APR | Annual product review |
| BER | Batch Analysis Record |
| 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 |

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| 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 |
| 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 |
| QP | Qualified person |
| QMS | Quality management system |
| QRM | Quality risk management |
| RA | Risk assessment |
| RCA | Root cause analysis |
| 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 documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and were separate from the Production Department. Operations were specified in written form and critical GMP requirements were essentially being met.

**Annual Product Quality Review**

The company had in place a procedure for performing product quality reviews. APQR`s were performed annually for the period from January to December and should be finalised before end of March of the next year. The SOP for APQR included the purpose, scope, responsibility and procedure. Document history was part of the SOP. According to the random review of the document, all relevant topics were handled. This included information about related equipment and utilities, deviations, OOS results, changes and rejections, product

stability data, customer complaints, CAPAs, review of the authorization information, trending of relevant data, statistical evaluation and evaluation of adequacy of corrective actions after previous reviews.

The following PQRs were checked and discussed.

- 2024 Lamivudine PQR
- 2024 Ritonavir PQR
- 2024 Lopinavir PQR
- 2024 Darunavir Ethanolate

**Management review (MR)**

The SOP "Quality system review management" was available. According to the procedure MR should be performed at least once a year on the site level with attendance of senior management. The implementation of MR procedure was checked and discussed.

**Quality risk management**

The SOP "Risk assessment management procedure" was reviewed. The content was based on ICH Q9. Failure mode effects analysis (FMEA) was used as quality risk management methodologies.

The QRM was used by the company in various aspects such as introduction of a new product, elemental impurities assessment, cleaning validation, process validation, equipment qualification, change control, deviation, vendor qualification etc. The "risk assessment for adding Lopinavir in a shared production line" was checked.

**Deviations**

The SOP "Deviation investigation and processing" was available. The flowchart of deviation process was part of the document. Decision about corrective and preventive actions was made after impact assessment. Examples of deviation were examined during this inspection.

**CAPA**

The SOP "Root Cause Investigation and CAPA management procedure" was available. CAPAs could be related to deviations, OOS/OOT, deficiencies found during monitoring, customer complaints, recalls, results from PQR, etc. Examples of CAPA were examined during this inspection.

**Internal audits**

The SOP "Internal audit" and the audit programme for the current year was available. Details were not checked during this inspection due to time constraints.

**Product release**

Intermediates and finished APIs products were released following SOP "Product release management procedure" which was checked. The product release of API and intermediate was responsibility of the Qualified Person (QP) and can be delegated to a designated QA staff. The batch release for APIs in the inspection scope was spot-checked and discussed.

## 2. Personnel

An organization chart was available. The key personnel of the various department had pharmaceutical qualification and were experienced in pharmaceutical manufacturing. Quality unit was independent from Production unit. Roles and responsibilities were described in writing. Number of personnel employed at the site was 327 at the time of inspection.

**Job descriptions**
Responsibilities of personnel engaged in the manufacture of intermediates and APIs were specified in writing. The following job descriptions were checked and considered to be acceptable in general.

- "Qualified person and QA director job description"
- "QC head"
- "Production head"

**Training**
An adequate number of qualified, trained and experienced personnel was available. All employees were subject to regular training according to the company's training procedure. Training was not inspected in detail due to time constraints.

**Hygiene**
Personnel hygiene requirements were documented in written procedures. The requirements for entry to grade D cleanrooms were well documented, including pictorial drawings in change rooms. Staff observed in these areas were dressed in appropriate protective clothing.

**3. Buildings and facilities**
In general facilities were located, designed, and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Adequate space was provided for the orderly placement of equipment and materials.

Manufacturing areas were of a good standard and suitable for the activities conducted therein. The classified areas were monitored for temperature, relative humidity and pressure differentials. Exposed surfaces were smooth, impervious and unbroken to minimize the shedding or accumulation of particles or microorganisms and permitted the repeated application of cleaning agents.

The production blocks and equipment were not dedicated, and PQ related APIs were manufactured in the defined production blocks/production lines. The production blocks and grade D clean areas were briefly visited during the inspection. The production of Darunavir Ethanolate API was in operation at the time of inspection.

**QC laboratories**
QC laboratories were located in a building different from production blocks. The Microbiological laboratory was separate from physio-chemical Laboratory. QC laboratories were visited and seen generally in good order and clean.

**Lighting**
Adequate lighting was provided in all areas to facilitate cleaning, maintenance and proper operations.

**Sanitation and maintenance**
In general buildings used in the manufacture of intermediates and APIs were properly maintained and kept in a clean condition. Written procedures were established assigning responsibility for sanitation and describing the cleaning schedules, methods, equipment and materials to be used in cleaning buildings and facilities.

**Utilities**
Quality reports were provided for potable water, purified water, compressed air, nitrogen, and clean rooms.

***Purified water system (PW)***
The purified water system was visited. The city water was used as source water. After the pretreatment, PW was produced by double ROs followed by EDI with one generation system and two distribution loops in ambient temperature. Logbook was available at the water plant. Relevant parameters (e.g., TOC, conductivity, temperature) were recorded. Sampling points and sampling frequency were defined. The 2024 APQR for PW was available. Alert and action limits for bioburden were specified.

***Nitrogen Plant***
PSA Nitrogen generator (pressure swing adsorption principle) was installed using clean compressed air as raw material and carbon molecular sieve as adsorbent. Online nitrogen analyser was part of the installation. Nitrogen quality specifications and report were available. Monitoring points and frequency were defined. The proper running of the system was confirmed.

***Compressed air***
Compressed air was used as instrument air without any product contact. Appropriate generation system was installed.

***HVAC systems***
The HVAC system for the clean area in a production block was seen during inspection and found at good state. The temperature and humidity were controlled. Appropriate filter cascade was installed before final HEPA filters. Limits for differential pressure at the filters were specified. Monitoring of differential pressure was documented. Annual reports about the environmental monitoring activities were available.

## 4. Process equipment

**Design and construction**
Generally, equipment was of appropriate design and adequate size, and suitably located for its intended use, cleaning, sanitization and maintenance. Equipment and permanently installed processing lines used during the production of an intermediates or API were appropriately identified, calibration due date was specified on each equipment as well as cleaning status and cleaning certificate. Usage of dedicated equipment was decided based on process requirements and cleanability.

**Equipment maintenance and cleaning**
Schedules and procedures were established for the preventive maintenance of equipment. Written procedures were established for cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs.

**Calibration**
Control, weighing, measuring, monitoring and test equipment were calibrated according to written procedures and an established schedule. Equipment calibrations were performed using standards traceable to certified standards. The current calibration status of critical equipment was known and verifiable. Calibration Master plan and the calibration schedule for the current year were available.

The calibration of a scale used during packaging of finished API Lamivudine was checked. It was performed in accordance with SOP “Calibration and use of weighing instruments”.

## 5. Documentation and records

Documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved, and distributed according to “Document management procedure”. The issuance, revision, superseding and withdrawal of documents were controlled, and revision histories maintained. A procedure was established for retaining documents, the retention periods for documents were specified.

**Batch numbering system**

The SOP "Product code and Batch numbering system" was reviewed. A batch number consisted of digits included the material code, building code and batch code, production code (normal/reprocess batch), year, month, and serial number. A reprocessed/reworked batch was referenced in the batch number. The codes related to WHO APIs and intermediates were documented.

**Equipment cleaning and use record**

Records of major equipment use, cleaning, sanitization and maintenance showed the date, time, product and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance.

Equipment status was labelled including information about equipment ID, maintenance status, last product and current process status.

**Master production instructions**

Master production instructions were prepared, dated and approved, and contained detailed guidance on production activities.

**Batch production records**

Batch production records included complete information relating to the production and control of the batch. The batch production record was checked before issuance. Records were numbered with a unique batch or identification number, dated and signed when issued. The BMRs for released API batches were checked.

## 6. Materials management

Written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were available. Changing the source of supply of critical raw materials, if any, was managed according to the change control procedure.

**Supplier management**

The SOP "Vendor management procedure" was checked and found to be acceptable. The list of approved suppliers and qualified vendors was available. The suppliers of active charcoal as example were spot checked.

**Warehouses (WHs)**

The warehouses for solid and liquid materials, dedicated storage area for active carbon, warehouse for finished API products were visited during the site tour. Warehouses were seen clean, and materials placed in good order. Materials management was made using manual paper-based system, which was checked.

The storage conditions for solid raw material warehouse, liquid material warehouse, hazards warehouse, and package materials warehouse were monitored for temperature and relative humidity. The storage conditions for the final API product warehouse were controlled. The cold warehouse was in place with temperature controlled at 2 – 8 °C. Check lists were used for materials receipt.

**Tank farm**

Tank farm was installed for solvents supplied by tankers and for storage of recovered solvents. The SOP "Material reception, storage, distribution management procedure" was available. Documents for the receipt of solvents were checked during the plant tour.

**Release of materials**
The procedure for release of raw materials was implemented. The document was valid for all production materials delivered to the site. Register, release labels, and rejected labels were defined in the SOP.

Release register for recovered solvents was available. Numbering of pages was implemented. The processing and testing records of recovered solvents were checked.

## 7. Production and in-process controls

**Production and in-process controls**
Raw materials for manufacturing of intermediate and API were weighed/measured under appropriate conditions. Weighing and measuring devices were of suitable accuracy for the intended use. Critical weighing, measuring and other critical operations were witnessed. The processing status of equipment was indicated. In-process sampling was carried out.

**Blending batches of intermediates or APIs**
The SOP "Blending management procedure" was checked.

**Contamination control**
Production operations were conducted in a manner that prevented contamination of intermediates or APIs by other materials. The "Management procedure for preventing contamination in the production process" and "Production management procedure on the shared facility and equipment" were checked and discussed.

## 8. Packaging and identification labelling of APIs and intermediates

The SOP "Label management procedure" was checked. The procedure described the process and responsibilities of label printing and management.

**Packaging and labelling operations**
The SOP "Packaging and labelling of products" was checked. The API packaging was in operation in the clean room at the time of inspection. The packaging and labelling records of the product under production were checked and discussed.

## 9. Storage and distribution

**Warehousing procedures**
Facilities were available for the storage of materials and finished API products under appropriate conditions. Designated areas were available for quarantine, rejected, returned, or recalled materials.

**Distribution procedures**
Distribution was part of the SOP about reception, storage and distribution of finished APIs. APIs and intermediates were distributed to third parties after they have been released by the quality unit. Special transport or storage conditions for an API or intermediate were stated on the labels, if required. A system was in place by which the distribution of each batch of intermediate and/or API can be readily determined to permit its recall, if needed.

## 10. Laboratory controls

The QC function was independent from other departments. QC laboratories located in a building separate from production areas. It was housed including microbiological laboratory. The microbiology laboratory was segregated from the chemistry laboratory.

**Sample receiving and distribution**

An access-controlled area for sample receipt was available. Sample register and the information for receiving and distribution were checked. The traceability of raw data was available in the sampling records.

**Standard and reference substances**

Reagents and standard solutions were prepared and labelled following written procedures and expiry dates (use by) were applied.

Primary reference standards were obtained as appropriate for the manufacture of APIs. The source of each primary reference standard was documented. Records were maintained of each primary reference standard's storage and use. Secondary reference standards (working standards) were prepared following the SOP "Reference substance and working standards".

**Testing of starting material, intermediates and finished API products**

The testing of starting materials, intermediates and finished API product was performed following approved testing procedures and specifications.

Class "A" volumetric glassware was used. Control, weighing, measuring, monitoring and test equipment were calibrated according to written procedures and an established schedule.

**Stability monitoring of APIs / Holding time studies**

The SOP "Stability management procedure" was reviewed. Initial (long term and accelerated stability study) and ongoing stability studies and holding time studies were defined. Ongoing stability studies were mandatory for the commercialised products. At least one batch from every product / specification / type of packing should be included in the study. Details of testing schedule were part of the procedure. The SOP was applicable to, but not limited to, process validation batches, process changes, supplier changes, etc. Stability samples were stored in containers simulating market containers. There were three stability study chambers equipped for the condition of 25 °C – RH 60%, 30 °C – RH 65% and 40 °C – RH 75%. It was noted a backup stability study chamber was available.

The stability study of Lopinavir was reviewed. The stability test protocol and testing records were examined and discussed.

**Reserve/retention samples**

The retention samples were maintained inside of finished API warehouses. The reserve samples were stored in the locked cages and in the same packaging system in which the API was stored. The retention samples were managed following in house procedures. The reserved sample quantity of each batch allowed for at least two times full QC testing, if needed. The retention sample register was available.

**OOS management**

The SOP "Management procedure of OOS/OOT results investigation" was checked. The procedure was applicable to all OOS/OOT test results:

- Raw materials
- Packaging materials
- Intermediates
- Finished products
- Utility systems,
- Stability studies

The OOS/OOT logbooks for 2023 and 2024, 2024 annual review of OOS and a reported OOS related to single unknown impurity and total impurity of an API batch were reviewed and discussed.

**Data management**

The SOP "Data integrity management procedure" and SOP "User's security strategy and privilege" were checked. A check list of data integrity was in place.

Electronic analytical data management followed SOP "Testing e-data backup management procedure". The data back up and security were discussed. The data backup server was in a different building from where the QC server was located.

**Microbiology laboratory**

Microbiological laboratory was adequately equipped and appeared to be of an acceptable standard for non-sterile API products. Media preparation and sterilization procedure and records were reviewed. PW testing procedure, records and monitoring results for microbiological limit were spot checked. The monitoring results appeared acceptable.

## 11. Validation

**VMP**

Annual VMP was available including the schedule for the current year. VMP 2025 was checked. Overall information was documented and updated by QA on a regular basis.

**Process Validation**

Process validation was performed following the SOP "Validation management procedure". The Process validation protocol and report of APIs in the inspection scope were checked.

**Holding time studies**

Holding time studies were essential for intermediates for manufacturer's own use. During the study period the test data were required to allow trend analysis. Examples of holding time study for intermediates for Ritonavir and Lamivudine crude were checked.

**Equipment Qualification**

Before validation activities, appropriate qualification of critical equipment and ancillary systems was completed. The SOP for qualification of facilities and equipment was available. The requirement of DQ, IQ, OQ and PQ were defined in the procedure. PQ was considered as part of the process validation. The frequency of periodic requalification was defined. Risk assessment was demanded according to the SOP.

**Periodic review of validated systems**

According to the VMP, systems and processes were periodically evaluated to verify that they are still operating in a valid manner, including

- Process: continued process verification
- Cleaning validation
- HVAC
- PW system
- Equipment
- Analytical methods

**Cleaning validation**
The SOP "Cleaning validation Management Procedure" was checked. Cleaning validation was carried out as per validation mater plan. Swab and rinse sampling methods were required to be used. The lowest residue limit was defined based on the calculation results of 10ppm, PDE and daily dose. Swab, rinse, and solvent extraction was considered for sampling. The following documents were checked:

- The risk assessment report for adding Lopinavir in the existing facility. A shared equipment list was documented. The acceptable residue limits for cleaning validation were defined.
- "Cleaning validation protocol and report of Lopinavir API production equipment"
- "Cleaning validation report and protocol of Darunavir Ethanolate"

**Analytical method validation**
The analytical method validation report for Darunavir residue testing in cleaning validation was checked and discussed.

**Computerized systems validation**
The validation of computerised system installed in QC Laboratory was checked and discussed.

**12. Change control**
The SOP "Change control management procedure" was available and gave the basis for the process. Form for the change control log was part of the SOP and was categorized by product and by year. Changes were classified as: minor, moderate or major. Temporary changes were not part of the procedure. Some examples were reviewed during this inspection.

**13. Rejection and re-use of materials**

**Rejection**
The management procedure for rejected products of starting materials, packaging material, intermediates and APIs was available. All rejected materials and products were affixed with "Rejected certificate and transferred to the rejected materials warehouse for isolation". Rejected intermediates and final products could be reprocessed or reworked after approval by the quality head. The rejection registers 2024 was maintained.

**Reprocessing and reworking**
The SOP "Reprocessing and Reworking of APIs and intermediates" was checked and discussed.

**Recovery of materials and solvents**
An SOP on solvent recovery was available. They must have a complete and traceable production record. Sampling, testing and storage of recovered solvents were described.

Solvents were recovered in accordance with the specified recovery process and were used only after meeting the predetermined quality standard. Recovered materials had complete and traceable production record. Sampling, testing and storage of recovered solvents were described.

**Returns**
Procedure for returned APIs and intermediates was in place. The SOP "Management procedure for returned product" was discussed. Returned intermediates or APIs were identified as such and quarantined. The return register 2024 was checked.

**14. Complaints and recalls**

Complaints were classified into two categories: quality and non-quality complaints. Quality-related complaints were recorded, investigated and managed by QA and relevant departments according to a written procedure. Records of complaints were retained. Investigation report was required to be sent to customer when investigation was finished and the complaint closed with defined timeline. The APIs in the PQ scope were not commercialised yet and no complaints were reported.

**Recalls**

Product recalls procedure was available. Recall was classified as Class I, Class II or Class III defect, and the action was required to be initiated within specified time. The APIs in WHO PQ scope were not supplied to markets. No batches have been recalled.

**15. Contract manufacturers (including laboratories)**

Contract laboratories were evaluated according to a written procedure. Audit frequency to contract laboratories was specified in the "Vendor Site audit procedure".

Written and approved contracts/agreements between the company and the contract acceptor that defined GMP responsibilities, including the quality measures, of each party were available. Contracts permitted the contract giver to audit the contract acceptor's facilities. Where subcontracting was allowed, the contract acceptor could not pass to a third party any of the work entrusted the contract acceptor without the contract giver's prior evaluation and approval of the arrangements.

The contract laboratories used by the company were documented and technical agreements were available.

| **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 deficiencies listed in the Inspection Report, a decision on the compliance of ***Jiangxi Desano Pharmaceutical Co., Ltd.*** located at ***Salt Chemical Industry Base, Zhangshu City, Jiangxi Province, 331200 China*** 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 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***

2. 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***

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***

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***

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***

6. 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***

7. 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***

8. WHO guidelines on technology transfer in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4. ***Short name: WHO TRS No. 1044, Annex 4***

9. 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***

10. 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***

11. 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***

12. 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***

13. 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***

14. 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***

15. 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**

16. 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***

17. WHO Recommendations for quality requirements when plant – derived artemisin 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***

18. 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***

19. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
***Short name: WHO TRS No. 996, Annex 10***

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***

21. 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***

22. 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***

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***

24. 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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