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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Shanghai Desano Chemical Pharmaceutical Co., Ltd.**
Corporate address of the manufacturer	No. 1479, Zhangheng Road, Zhangjiang High Tech Park, Shanghai, China, 201203
Name & address of inspected manufacturing site if different from that given above	417 Binhai Road, Laogang Town, Pudong New Area, Shanghai 201302, China
Synthetic unit /Block/ Workshop	Production buildings: B14, B15, B16, A16, C16, C18, L17, L18, K13, K16-2, K17, K15, K18, B19, B20, C20
Dates of inspection	18-22 August 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	The company's focus was on the production of APIs, including anti-HIV, anti-malarial, and anti-COVID-19 agents. The site does not produce any highly sensitizing, biological products, β-lactam structural products, steroid hormone contraceptive products, or cytotoxic products. The APIs and saleable intermediates were supplied to main markets, including China, India, South Africa, Brazil, Russia, Thailand, Australia, the US, the EU, Korea, Japan, and countries supported by the Global Fund (WHO PQ) & PEPFAR (FDA).
General information about the company and site	Shanghai Desano Bio-Pharmaceutical Co., Ltd. (abbreviated as Desano Bio-Pharma) was established in 2000, and is headquartered at 1479 Zhang Heng Road, China (Shanghai) Pilot Free Trade Zone, Shanghai 201203, China. Desano Bio-Pharma focuses on R&D, production, and sales of medicinal products, APIs, and intermediates. Shanghai Desano Chemical Pharmaceutical Co., Ltd. was founded in May 2002. The inspected Desano facility was built in February 2006.
History	The site is regularly inspected by regulatory authorities like the US FDA, MHRA, COFEPRIS, ANVISA, PMDA, and TGA. This was the 9th WHO PQ inspection. The last was conducted in 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management - Personnel and training

	- Premises, utilities, equipment, and instruments - Process, cleaning, analytical method, and computerized system validation - Production and packaging operations - Quality control laboratory and microbiology laboratory - Material management
Restrictions	None
Out of scope	The inspection was limited to the prequalified and under WHO PQ assessment APIs, as listed below. APIs not submitted to the WHO PQ and their respective areas were out of the scope of this inspection.
WHO APIs covered by the inspection	1. Tenofovir Disoproxil Fumarate/TDF, APIMF208 2. Lamivudine, APIMF046 3. Dolutegravir Sodium, APIMF302 4. Zidovudine, APIMF049 5. Efavirenz, APIMF108 6. Lopinavir, APIMF363 7. Ritonavir, APIMF191 8. Emtricitabine, APIMF202 9. Nevirapine, APIMF047 10. Atazanavir Sulfate, APIMF289 11. Artemether, APIMF080 12. Lumefantrine, APIMF035 13. Nirmatrelvir, APIMF469 14. Molnupiravir, APIMF449 15. Oseltamivir Phosphate, APIMF421 16. Praziquantel, APIMF309 17. Cabotegravir Sodium, APIMF478 (Under assessment) 18. Tenofovir Alafenamide Monofumarate/TAF, APIMF512 (Under assessment)
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	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
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments**

1. Quality management

The Quality Manual summarized the quality management system applicable to Shanghai Desano Bio-Pharmaceutical Co., Ltd. and clarified the company's quality management standards and requirements. The quality manual covered the quality management requirements for material reception, product production, packaging and labeling, testing, releasing, and distribution processes, as well as product after-sales quality feedback.

The SOP for product quality review (PQR) was reviewed. The QA was overall responsible for executing the PQR, and data were collected from various departments before being reviewed. An Excel spreadsheet was used to calculate upper control/lower control limits (UCL/LCL), whereas Minitab was used to calculate CpK. A separate procedure was in place for operating Minitab, and the Excel spreadsheet was validated. The PQR procedure described the acceptance criteria for CpK, which should be greater than 1.33. If the CpK was found to be below 1.33, an investigation would be performed. A minimum of 30 batches was required for calculating CpK. The PQRs for TAF, Cabotegravir Sodium, and Lamivudine were reviewed.

The SOP for quality risk management (QRM) was reviewed. The process flow chart was part of the procedure. The risks were assessed based on recommendations from APQR, following a review of the quality system, including deviations, CAPA, complaints, OOS, the introduction of new products, new contract manufacturers, and new equipment. The risks were assessed using FMEA (RPN), HACCP, flowcharts, checklists, process mapping, fishbone diagrams, and the 5 Whys.

The SOP for data reliability management procedure was reviewed, which described the principles of ALCOA+. In addition, the procedure defined various terms, such as audit trails, paper-based and electronic data, contemporaneous, attributable, original, and accurate. The FMEA was used to perform a risk assessment (RA) for data integrity. The RA was performed considering the data handled at the warehouse in the final areas. No risk was identified, and all identified risks were concluded as “NA”.

The occupational health management procedure was reviewed. The detection and exposure assessment of the chemicals used in the manufacturing of Dolutegravir Sodium was discussed. The assessment was performed based on the information provided by the innovator company. A score of ≥80 was considered high risk, ≤80 acceptable, and a 3M mask was deemed sufficient to protect the operator.

Antimicrobial resistance

The manufacturer has analyzed the wastewater to determine whether an API residue is present before calculating the permitted no-effect concentration (PNEC). The PNEC values for Lamivudine and Lumefantrine were calculated based on the regular production, whereas for the rest of the molecules, they will be calculated during production.

The deviation investigations were initiated, handled, and recorded in accordance with SOP. The identification code for the events included the product code/facility code, serial number, and a reference to the year.

The CAPA management procedure was reviewed. The CAPAs were triggered by investigations like deviations, rejections, quality complaints, product returns, and recalls. The records related to the CAPA investigation of the quality complaint were discussed. The CAPA was initiated to modify the quality specification and the corresponding test method.

The management review was performed at least annually per the Management Review SOP. The records of the most recent management review were discussed. The management review protocol and the Management review report, including the conclusion, rectification measures, and recommendations, were discussed.

Management procedure for internal audit was in place. An internal quality audit was performed by a team from various departments and areas, managed by the QA. Self-inspection reviewed the performance of a department. The annual internal audit plan and tracking details were provided.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Personnel

The organizational structure, including departments and reporting lines, was clearly indicated in up-to-date organizational charts. The quality functions, including quality assurance and quality control, were independent of the production. The following is the breakdown of the staff working on-site:

- Production (538), Engineering/Maintenance/Utilities (95), Warehouse (28),
- Quality Control Laboratory (105), Quality Assurance/QA (33), RA (7), EHS (36)
- HR (7), Other (131)
- Total employees (980)

The production worked 24/7 (2 x 12-hour shifts), and QC/Engineers provided support as needed. The working hours for other departments were 9:00 AM – 5:30 PM.

The company's general organizational chart and the detailed organizational charts for the QA, Production, and Warehouse departments were discussed. The employee's tasks and responsibilities were summarized in the job descriptions, which were signed by the employee and the supervisor. The job descriptions of the VGM, the QA director, a warehouse keeper, and the warehouse shift master (Liquid Warehouse) were discussed. The job descriptions aligned with the organizational charts.

The company's training system was described in the Management Procedure for Quality Training. The training included an orientation session after assuming the position, followed by job-specific induction and regular training. The trainings were organized at the company and department levels, as outlined in the training plans. The trainer was usually a staff member listed as the authorized trainer. The training files of the warehouse keeper and the warehouse shift master (Liquide Warehouse) were discussed.

The gowning and hygiene rules were described in written instructions. Color coding was implemented to control the personnel movement in the facilities.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

3. Buildings and facilities

The following buildings and facilities were in the scope of the inspection:

- Building A18: Quality Control
- Buildings A11, B11, A12, A15-2, A13-2: Warehouses
- Areas B12, C19: Tank farm
- Production buildings: B14, B15, B16, A16, C16, C18, L17, L18,
- K13, K16-2, K17, K15, K18, B19, B20, C20
- A15-1, A19, B17, L12, L13, L14: Utilities, including purified water generation systems.

Dedicated facilities were used when required (see asterisk in the table below). Powder processing was performed in controlled and classified areas (class "D"; see bold in the table below).

APIs	Product Code	Building Number
Tenofovir Disoproxil Fumarate (TDF)	DBH101	C18B, C18C, K13B, L17, C16B, **B16A, C16A, B19A**
Lamivudine	DBH010	B14, C18A, C18B, **B15B, B20C**
Dolutegravir sodium	DBH242B	K18, A16C, B16B, K17-2B, **B15A, C18C**
Zidovudine	DBH016/DBH006	B16B, **B16A, K13A, K16-2**
Efavirenz	DBH012	C18B, **K13A, K16-2, A16A**
Lopinavir	DBH106E	K18, L17B, **K16-2**
Ritonavir	DBH105	B16B, K15, C18B, K17-2C, K18, K18B, **B15A, C18C, K16-2, B16A**
Emtricitabine	DBH110	B16B, A16B, **A16A, C18C**
Nevirapine	DBH027	C16B, C16C, **C16A**
Atazanavir Sulfate	DBH148	A16C, K18, **K16-2, C18C**
Nirmatrelvir	DBH287	L17B, **K16-2**
Oseltamivir Phosphate	DBV089	C16C, C16B, K17-1, K17-2C, **C16A**
Molnupiravir	DBV283	L17B, **K16-2**
Lumefantrine	DBM86A/DBM86D	C18A, C16B, B14, B16B, **A16A, C16A**
Artemether	DBM98A	K18, B14, K17-2, **K13A, C18C, K16-2**
Praziquantel	DBS234	C18B, A16B, **A16A**
Cabotegravir sodium	DBH266	L19, **B15A**
Tenofovir Alafenamide Fumarate (TAF)	DBH251	K13B, L17, K18, **B15A, C18C**

The facilities were cleaned and maintained in accordance with the written procedures. Pest and rodent control was managed and supervised by the workshop managers.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

4. Process equipment

The process equipment was identified, qualified, and regularly maintained. The identification consisted of an asset number for location identification and a processing number for the unique identification. The instruments were classified into three types: Type 1 (key equipment), Type 2 (middle critical), and Type 3 (other). The list of process equipment, air handling systems, measuring devices, and other relevant items was managed in an Excel database and printed out annually. The process equipment was qualified in accordance with the SOP for Equipment Verification. The requalification frequency was generally 5 years, or in the case of a major change. The re-qualification due date of the equipment was indicated on the first page of the equipment logbooks.

The measuring devices were calibrated regularly (every 6 months) in accordance with the annual schedule.

Purified water was used for the final processing. The powder processing (controlled) areas were supplied by the PW systems.

Controlled areas were equipped with air-handling units that supplied clean air. The newly constructed B20C final processing areas were supplied by two air handling units, each equipped with HEPA (H14) filters. The facilities were classified as Class D, with controlled temperature (18-26°C) and relative humidity (25-75%). The AHUs were qualified and operated in accordance with the written procedure.

The process equipment were regularly maintained in accordance with the annual and monthly maintenance schedules and the equipment-specific maintenance protocols.

5. Documentation and records

The document control system was paper-based. No electronic data system was used for managing the documents and records. The different levels and types of documents were identified, such as Quality Manual, Site Master File, SOPs, Lists, Drawings, Batch Production Record Masters, Batch Analytical Record Masters, Batch inspection records, Validation documents, Batch Production Records, Analytical Records, and Logbooks. The retention period of the documents was defined and summarized in the SOP.

The SOP for product release, including the intermediate and finished API, was discussed. A process flowchart was part of the procedure. Production and QC review their documents against the checklist/SOP before the QA team reviews them. A checklist was used by the QA to ensure relevant records were reviewed, including OOS/OOT, deviations, incidents, and variation/change approval by the customer/authority. As part of the procedure, an annexure was available detailing the names and responsibilities of the QA personnel responsible for releasing in-process materials from one stage to the next. The qualified person was responsible for releasing the saleable intermediates and finished APIs. In her absence, the quality director or QA manager was responsible for releasing the products. The batch release record for Lamivudine was reviewed. The final release was performed based on the review of the BMR and QC records.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Materials management The material management procedures and the warehousing facilities have not changed since the previous WHO inspection. The storage conditions in the warehouses were as follows:

- API warehouse: 15 to 30^0C
- API cold warehouse: 2-8^0C
- RM warehouse: including below 30^0C and below 35^0C area
- Packaging material warehouse: below 35^0C.

The materials were managed according to the written instructions below, including the following activities: initial reception, quarantining, sampling, labelling, warehousing and dispensing of incoming raw materials, packaging materials and intermediates, primary and secondary packaging (including special provisions - usage of nitrogen as applicable), labelling, warehousing and dispatch of APIs.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

7. Production and in-process controls The dispensing/weighing was conducted under appropriate conditions. The identification of materials during processing included the following information: material name and/or item code, receiving or control number, and weight or measure of the material. The processing status of equipment and facilities was indicated. Written procedures were established to monitor the progress and control the performance of processing steps. In-process controls and their acceptance criteria were defined based on the information gained during the development stage or historical data and approved by the quality unit.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

8. Packaging and identification labelling of APIs and intermediates
The receipt, identification, quarantine, sampling, examination, testing, release, and handling of packaging and labelling materials were described in written procedures. Packaging and labelling materials conformed to established specifications. Records were maintained for each shipment of labels and packaging materials. The containers provided protection during transportation and storage.

9. Storage and distribution
The storage facilities were available for storing materials under suitable conditions. Environmental conditions were controlled and recorded. Raw and packaging materials, intermediates, and APIs had to be formally released before consumption or dispatch.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

10. Laboratory controls

The laboratory facility was independent of the production facility, and it was divided into several groups (sampling, physical/chemical, stability, validation, equipment calibration, reference/working standards, etc.). It was well-equipped with a chromatographic data system (28 HPLCs and 11 GCs from Agilent and Waters), an FTIR spectrometer, a UV-VIS spectrometer, analytical balances, a KF apparatus, and other equipment/instruments. The QC was responsible for sampling incoming materials and finished APIs, whereas production sampled in-process samples, intermediates, and recovered solvents and sent them to the laboratory for testing. The preprinted logbooks were used to log incoming samples before they were assigned to analysts for testing. The competency matrix was available. Incoming samples were stored at temperatures below 30°C and 2-8°C for specific materials/products. The laboratory defined the timeline for completing the analysis. The analytical balances were verified daily, calibrated quarterly, and yearly. The balances were password-controlled by the IT administrator and attached to printers. The FTIR was calibrated once per month and annually.

The HPLC and GC were calibrated internally every 6 months and externally every 2 years by a third-party laboratory. At the time of the visit, assay testing for Lamivudine was being performed, and chromatograms were integrated. There were 7 user types described (admin, administrator, chemist, junior analyst, manager, QA, and senior analyst). Senior analysts were given access privileges to modify integration parameters. Two IT administrators were responsible for managing user accounts, data backup, and restoration. Backups were performed weekly and quarterly on portable discs. The HPLC/GC systems were networked, whereas the rest of the equipment and instruments were standalone.

The SOP for OOS and out-of-trend was reviewed, and it was noted that it had recently been revised to provide greater clarity. The process flow chart describes the investigation to be performed in phases. A preliminary investigation was conducted using a checklist to identify any obvious errors prior to a detailed investigation, where applicable. The initial investigation was completed within one working day.

The laboratory has 8 stability chambers (4 for 30°C /65%, one each for 40°C /75%, 25°C /60%, 30°C /75% and -20ºC. The chambers were connected with an audio/visual alarm and were challenged annually. Stability samples for TAF were available up to 60 months at 30°C /65% relative humidity, and cabotegravir sodium was available up to 36 months at 30°C /65% relative humidity.

The primary reference standard for Lamivudine was stored at 2-8°C. The inventory and usage logbook was maintained. The working standard of Lamivudine was prepared against the USP RS, and multiple vials were prepared/stored for routine use. The working standards for TAF and Cabotegravir Sodium were available.

The microbiology laboratory, located on the second floor of B17, was primarily responsible for sampling and testing water and environmental samples, as well as finished API, as applicable.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

11. Validation

The Validation Master Plan/VMP was discussed. The VMP included facilities, utilities, logistics, equipment/instrument qualification, process, cleaning, analytical method validation, computerized system validation, etc. The qualification included URS, DQ, IQ, OQ, and PQ, whereas requalification was performed every 5 years. The frequency was common for HVAC, production, and laboratory equipment. The processes were validated prior to commercialization, and revalidation was performed whenever any changes were made.

The SOP for cleaning validation covered all on-site equipment. A flowchart was part of the procedure, which requires performing a risk assessment. The protocol largely outlined the contents described in the WHO guidance document. The acceptance criteria of 10 ppm, ADE/PDE, and Therapeutic Daily Dose (TDD) were described, and the worst-case scenario was selected. The 100 ppm criterion was applied to the intermediate. The procedure also describes a minimum of three consecutive runs to validate the cleaning procedure. The samples were collected using swabs and rinse samples, and also verified visually.

The Process Validation/PV SOP was reviewed. The process validation procedure required the use of process design (define the CQAs and CPPs), process qualification (verify process capability), and continued process verification (CPV) (in a state of control). The number of batches would be determined by the process's complexity, but at a minimum, three batches were required. The PV protocols and reports for TAF and Cabotegravir Sodium were reviewed and found to be adequate.

The SOP for analytical method validation/AMV was reviewed. The AMV was performed by the on-site quality control laboratory. The pharmacopeial methods were verified, whereas in-house methods were validated (accuracy, precision, specificity, LOD, LOQ, linearity, range, and robustness).

A list of computerized systems was available. The list included various PLCs used in HVAC systems, a temperature-monitoring system for reactors, and QC-related systems. Empower 3 (11 GC, 24 HPLC, 4 UPLC, 1 LCMS, 1 IC) and Chromeleon (1 HPLC) were used for the Chromatographic Data System.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

12. Change control

The Change Control SOP was reviewed. The process flow chart was part of the procedure, and changes were classified as critical, major, or minor. The changes had to be closed within 15 days after their implementation. The scope of the procedure encompasses changes related to documentation, products, equipment, materials, facilities, cleaning methods, and other areas. The template for the change controls was part of the procedure, whereas a unique code for the change control was described in the procedure. Change controls related to the introduction of TAF and Cabotegravir Sodium were reviewed and found adequate.

13. Rejection and re-use of materials

The general principles of reprocessing and rework were captured in the Management Procedure for Reprocessing and Rework. Reprocessing was a regular activity, but rework has not happened since 2023. If the OOS investigation results proposed rejection, the rejection investigation was initiated and recorded in the rejection investigation sheet. The initiation of rejection investigations was always recorded in the Rejection Investigation Logbook, accompanied by a unique identification code. The outcome of the rejection investigation can be reprocess, rework, or destruction. The blended batches were identified by specific batch numbers and handled in accordance with the Management Procedures for Blending, Micronization, and Packing.

Solvents were recovered according to the Management Procedure for Recovered Solvent and tested to meet their quality specifications. Usage was restricted to the same process or the corresponding upstream process. The solvents allowed to be recovered had a unique material code with clearly defined source and the usage process steps. Any modification of the table (list) of recovered solvents was supported by formal change control.

14. Complaints and recalls

The quality complaints were received, recorded, and investigated in accordance with the Management Procedure for Complaints. The quality complaints were received by the marketing department and then forwarded to the QA immediately. The main data of the complaint were recorded in a logbook, including a description, classification (critical, major, minor), and a unique identification number. All the concerned departments were involved in the investigation (initial and extended, as applicable) and the CAPA development, if applicable.

15. Contract manufacturers (including laboratories)

Vendors (manufacturers) of the raw materials were qualified in accordance with the SOP. The list of qualified vendors was approved by the QP on 12/08/25. The list contained the manufacturer's name and address and the vendor's name (if different).

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, ***Shanghai Desano Chemical Pharmaceutical Co., Ltd***, located at ***417 Binhai Road, Laogang Town, Pudong New Area, Shanghai 201302 China*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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

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

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***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/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***
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
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