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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	**Hetero Labs Limited (HLL), Unit IX**
Corporate address of the manufacturer	Hetero Corporate RMZ Nexity, Survey No. 83/1, Knowledge City Raidurg Village, Serlingampally, Adjacent to ITC Kohenur Hyderabad – 500081 Phone: +91-40-23704923 Ext.: 6901 Mobile: +91-8008002882
Name & address of inspected manufacturing site if different from that given above	Plot No. 2, Hetero Infrastructure SEZ Ltd. N. Narasapuram (Village), Nakkapalli (Mandal), Anakapalli (Dist.), 531 081 Andhra Pradesh, India GPS Coordinates Longitude & Latitude Coordinates of the site: 17.3836788, 82.7250854

S. No.	Product Name	APIMF Number	Manufacturing Block	Pharma Block
1	Abacavir Sulphate (AL)	APIMF292	A&B	PA (Section-VII)
2	Abacavir Sulphate (AB)	APIMF126	A&B	PA (Section-IV/VI/VII/VIII)
3	Dolutegravir Sodium (GS)	APIMF400	B	PA-II (Section-II)
4	Ritonavir (RV)	APIMF409	A	PA (Section-VII)
5	Ritonavir Form-1 (RF) Ph. Eur	APIMF140	A&B	PA (Section-VII)
6	Ritonavir Form-1 (RF) USP	APIMF237	A&B	PA (Section-VII)
7	Efavirenz (EN)	APIMF164	H3, H4, H7, H8 & H10	PA-III (Section-IV)
8	Tenofovir Disoproxil Fumarate/TDF (TR)	APIMF098	A, H4, H7&H8	PA (Section I, II &IV)

	9	Emtricitabine (ER)	APIMF114	H2	PA (Section I-V)
	10	Emtricitabine (EW)	APIMF397	A & H2	PA (Section-V)
	11	Lamivudine (LU)	APIMF123	H2, H7, D & H10	PA-III (Section-I)
	12	Lamivudine (LM)	APIMF404	A, H2 & H7	PA (Section-V)
	13	Nevirapine Anhydrous (NS)	APIMF130	A & D	PA (Section-III)
	14	Sofosbuvir (SF)	APIMF352	B	PA (Section-IV Room-I)
	15	Zidovudine (ZD)	APIMF124	B	PA-III (Section-III)
	16	Darunavir Ethanolate (DT)	APIMF410	A& H8	PA (Section-VII)

Synthetic unit /Block/ Workshop

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1	Abacavir Sulphate (AL)	APIMF292	A&B	PA (Section-VII)
2	Abacavir Sulphate (AB)	APIMF126	A&B	PA (Section-IV/VI/VII/VIII)
3	Dolutegravir Sodium (GS)	APIMF400	B	PA-II (Section-II)
4	Ritonavir (RV)	APIMF409	A	PA (Section-VII)
5	Ritonavir Form-1 (RF) Ph. Eur	APIMF140	A&B	PA (Section-VII)
6	Ritonavir Form-1 (RF) USP	APIMF237	A&B	PA (Section-VII)
7	Efavirenz (EN)	APIMF164	H3, H4, H7, H8 & H10	PA-III (Section-IV)
8	Tenofovir Disoproxil Fumarate/TDF (TR)	APIMF098	A, H4, H7&H8	PA (Section I, II &IV)
9	Emtricitabine (ER)	APIMF114	H2	PA (Section-V)

10	Emtricitabine (EW)	APIMF397	A & H2	PA (Section-V)
11	Lamivudine (LU)	APIMF123	H2, H7, D & H10	PA-III (Section-I)
12	Lamivudine (LM)	APIMF404	A, H2 & H7	PA (Section-V)
13	Nevirapine Anhydrous (NS)	APIMF130	A & D	PA (Section-III)
14	Sofosbuvir (SF)	APIMF352	B	PA (Section-IV Room-I)
15	Zidovudine (ZD)	APIMF124	B	PA-III (Section-III)
16	Darunavir Ethanolate (DT)	APIMF410	A&H8	PA (Section-VII)

Dates of inspection	17-21 November 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Hetero Labs Limited (Unit IX) was established in 2009 and is located in N. Narasapuram Village, Nakkapalli Mandal, Anakapalli District, approximately 84 km from Visakhapatnam and 600 km from Hyderabad. Hetero Labs Limited (Unit IX) is surrounded by the following: East: API manufacturing facility; West: Open area; North: Hetero API manufacturing facility; South: Hetero Intermediates manufacturing facility.
General information about the company and site	Hetero Labs Limited (Unit IX) is engaged in the manufacture and distribution of Active Pharmaceutical Ingredients (APIs) & Intermediates in the domestic as well as in the US, Europe, and other markets.
History	The HLL Unit IX has been regularly inspected by the WHO PQ Inspection Services. The last on-site inspection was conducted in September 2014, whereas the desk assessment was conducted in December 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management system - Personnel and training - Qualification and validation - Documentation and data integrity assessment - Premises and process equipment - Materials management - Production (synthesis, crystallization, and pharma areas) - Air handling units - Purified water system - Sygmos training center and HLL Unit-III (Domestic API Warehouse)

Restrictions	None
Out of scope	The activities not related to the WHO prequalified and under assessment APIs were out of the scope of this inspection.
WHO APIs covered by the inspection	1. Abacavir Sulfate (AL) APIMF292 2. Abacavir Sulfate (AB) APIMF126 3. Dolutegravir Sodium (GS) APIMF400 4. Ritonavir (RV) APIMF409 5. Ritonavir (Form-I) (RF) Ph. Eur APIMF 140 6. Ritonavir (Form-I) (RF) USP APIMF 237 7. Efavirenz (EN) APIMF164 8. Tenofovir Disoproxil Fumarate (TR) APIMF098 9. Emtricitabine (ER) APIMF114 10. Emtricitabine (EW) APIMF397 11. Lamivudine (LU) APIMF123 12. Lamivudine (LM) APIMF404 13. Nevirapine (NS) APIMF130 14. Sofosbuvir (SF) APIMF352 15. Zidovudine (ZD) APIMF124 16. Darunavir Ethanolate (DT) APIMF410 (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 manufacturing site implemented a quality management system (electronic QMS for change controls, incidents, OOS, and CAPA) in accordance with national and international GMP standards. The QMS encompassed the organizational structure, procedures, processes, and resources to ensure that the APIs met their intended quality and purity specifications. The quality unit was independent of operations and was responsible for QA and QC. The job descriptions of the key personnel responsible for releasing intermediates and APIs were specified. The following QMS elements were reviewed:

The SOP for preparing the annual product quality review/APQR report was discussed. The annual schedule was prepared before the start of the year and listed all on-site APIs. The site master file listed a total of 43 APIs manufactured on-site, including 16 WHO prequalified/under assessment APIs. The annual schedule listed 55 APIs, including the same APIs (e.g., Darunavir Ethanolate (DT) for WHO, Darunavir amorphous (DS), and Darunavir Ethanolate (DZ) for different markets and customers with different manufacturing processes). The APQR was conducted on a calendar-year basis (Jan-Dec), and the report should be completed by the end of March each year. The procedure cross-references the process validation procedure to perform statistical analysis using Minitab. A separate procedure was available that provided instructions for operating Minitab to calculate process capability. If the CpK

values are found to be outside the set limits, an investigation will be performed as part of the recommendations.

The SOP for Management Review/MR was discussed. The MR was conducted every 3 months, and the 2025 schedule was available. The procedure described various QMS elements that should be discussed during the MR. The meeting was chaired by the plant head and attended by the department heads. The last MR was conducted on 30/10/2025 between 15:00 and 16:30 hours. The minutes of the meeting were reviewed, and the following items were discussed:

- Product-related activities,
- Internal, external, and customer audits
- Customer feedback (complaints)
- CAPA (initiated due to complaints, incidents, OOS, OOT, audits)
- Review of QMS (trend data of change controls, incidents, OOS, OOT, LIR)
- Details of drug master files/dossiers submission
- New vendors, safety, training, and status of QMS elements

The MR included recommendations for improvement, particularly for USFDA audit-related CAPAs and fixing the public addressing system for alarms.

The SOP Handling of incidents was the primary SOP for deviation management, together with the operation procedure for the incident management system (IMS) module of the QMS Spectrum. The QMS application was implemented at the site in 2021 to handle deviations, changes, and OOS events. The inspector reviewed the 2023-2025 recorded events in the QMS; no critical deviations were recorded; most were classified as minor; major deviations were mainly due to human errors in the use of equipment/instruments.

The SOP corrective and preventive actions (CAPAs) and the operation procedure for the CAPA management system module were reviewed.

The SOP for internal audit was established to conduct internal audits in accordance with GMP requirements. The procedure was applied to the warehouse, production, engineering, QC, QA, human resources, plant R&D, IT, purchase, and marketing departments. The QA team was responsible for executing this activity with a cross-functional team. The internal audit was performed once every 6 months, covering all identified areas. The internal audit schedule for 2025 was available, noting that the most recent audit was conducted in June 2025 and the next will be in December 2025. A department-wide checklist was used to perform an internal audit. Before the internal audit began, an internal communication was sent to the auditee. A list of auditors, along with their qualifications and requalification dates, was available. An audit report was prepared, along with a list of observations, and the status report was finalized, confirming the actions taken to close the observations.

The SOP for Quality Risk Management/QRM was discussed. The risk was assessed as part of the process, including system, equipment, instruments, and facilities, as well as the introduction of new products. Also, it was performed both proactively and reactively. A cross-functional team performed the risk assessment. The FMEA was used to assess risk, whereas other tools were also described in the procedure. The procedure was not prepared in accordance with the current ICH Q9 (r1), particularly

regarding formality, subjectivity, risk-based decision-making, product availability, and other aspects. The risk register was maintained based on change controls raised and risks initiated following receipt of complaints, audit observations, and other relevant information. A separate log was maintained for Darunavir Ethanolate.

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

2. Personnel

The site's workforce comprised 1948 people, distributed mainly across production activities and evenly between the QA and QC departments. The organization chart was provided, but the IT department was not included. Personnel's training was regularly conducted using the LMS (Learning & Management) Application. Training sessions for Robotic Process Automation (RPA, an application recently introduced to automate analysis and verification in Empower CDS systems) were conducted, with QA, QC, and IT personnel in attendance, and the training materials were reviewed. Job descriptions were also reviewed. Only one person in the IT department was qualified and trained as an RPA manager. The job description for the IT manager, including administrator and user management, was reviewed.

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

3. Buildings and facilities

Buildings and facilities used in the manufacture of intermediates and APIs were located, designed, and constructed to facilitate cleaning, maintenance, and operations as appropriate to the type and stage of manufacture. Facilities were designed to minimize potential contamination. The flow of materials and personnel through the buildings or facilities were designed to prevent mix-ups or contamination. There were defined areas and control systems in place for storage, processing, and quality control activities, along with auxiliary, toiletry, and change facilities. The changing, washing, and toilet facilities were provided for personnel equipped with water as appropriate, soap or detergent, air driers, or single-use towels. The washing and toilet facilities were separate from, but accessible to, manufacturing areas.

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

4. Process equipment

Equipment used in the manufacture of intermediates and APIs were of an adequate size, and located for its intended use, cleaning, sanitization, and maintenance. Major equipment (e.g. reactors, storage containers) were identified. Production equipment were used within its qualified operating range. A set of current drawings for equipment and critical installations (e.g. instrumentation and utility systems) was available. Equipment maintenance schedules and procedures (including assignment of responsibility) were established. Written procedures were established for the cleaning of equipment and its subsequent release for use. Control, weighing, measuring, monitoring, and test equipment were calibrated in accordance with written procedures. The equipment's current calibration status was verifiable.

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

5. Documentation and records

A hybrid system was used for documentation management. The Document Management System (DMS) application was used for managing the documentation flow, including distribution. Hard copies of documents were controlled and approved by the QA. Use, maintenance, calibration, and cleaning equipment/rooms logbooks, and product batch records were paper-based. Records of print-outs of electronic data were also archived as hard copies. The QMS spectrum application was in place at the site to manage records of changes, deviations, and OOS events. Selected records (reported in the specific inspection report paragraph) were reviewed by the inspector in the QMS application to verify compliance with changes/deviations/OOS/OOT management, along with the steps of issuing, reviewing, approving, and authorising signatures and attached annexes. The manufacturer provided a list of all SOPs organised by department.

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

6. Materials management The SOPs for storage, handling, retesting, receipt, verification, quarantine, and sampling of raw materials were reviewed. The specific SOP entry and exit procedures for solid materials were reviewed during the tour of the solid raw materials WH-III. Material status was appropriately identified for quarantine, release, and rejection, and sampling activities using labels, physical segregation, and the WMPS, the electronic portal used to manage material from receipt to dispatch. The raw material/RM sampling activities were carried out by the QC (8 qualified analysts). The sampling operations were found not to have been appropriately assessed to control the risk of contamination. Rejected RM and products were physically segregated in dedicated areas with controlled access. Packaging materials and the centrifuge bags used for API late-stage manufacturing operations were sampled and stored in a dedicated ISO-8 room in WH-III.

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 inspector visited Production Block B. Dolutegravir Sodium Stage II was being produced. The measuring scales used for the methanol and methylene chloride (MDC) measuring tanks were calibrated once every 5 years. The final crystallization was performed under an ISO-8 area, and the area was requalified once every 5 years. Production Block A was used for manufacturing process validation batches of Darunavir Ethanolate (DT) stages I and II, as well as for final powder processing. At the time of the inspection, no production activities were carried out. The process equipment, including the measuring tanks, used in the manufacturing of DT, were verified. The hoppers were used for charging materials into the reactors. The logbooks used for the leaf filter and the candy filter were verified. The filter bags were replaced after each use. In the powder processing area, an entry/exit procedure was in place for visitors and staff. The facility was equipped with a handwash, dryer, and a crossover bench, and personnel were required to wear a facemask, shoe covers, and headgear, and to sanitize before entering the classified (ISO-8) powder processing area. The area was equipped with a datalogger.

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

Different packaging was in place for APIs manufactured at the site to control product quality, including hygroscopic and/or photosensitive APIs. Dolutegravir Sodium (GS) required cold storage conditions and was packed in Trilaminate bags under a nitrogen atmosphere.

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

9. Storage and distribution

Controlled storage conditions were set for intermediates and APIs in the dedicated areas, warehouse-IV (<35°C) and pharma storage areas (<25°C), respectively, and monitored for relative humidity. Upon the customer's request, API dispensing activities were carried out in the dedicated areas of the pharma storage. The activities for the QA batch release before distribution for the Dolutegravir Sodium (GS) batch GS25080067 were reviewed, together with the QA release.

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

10. Laboratory controls

The inspectors visited the quality control laboratory. The laboratory was divided into sections such as physical/chemical, instrumentation, and stability sample analysis. The laboratory lacked a microbiology testing facility, and tests were outsourced. The laboratory was equipped with 45 HPLCs, 16 GCs, 2 Malvern Mastersizer, 3 UV-VIS spectrophotometers, 3 FTIR spectrophotometers, 1 melting point apparatus, and others. The laboratory has a staff of 204, serving Unit IX, and is also supported by 33 analytical QA (AQA) personnel. The LIMS was used to manage labels, reserve samples, analyst qualifications, generate certificates of analysis, handle stability samples, perform calibrations, maintain columns, reference (RS) & working standards (WS), chemical reagents, and volumetric solutions. In view of the USFDA inspection in Sept 2025, the manufacturer decided to interface the analytical balances with the LIMS. Windows 10 was being used for chromatographic systems. Equipment such as an auto-titrator, FTIR, UV-VIS, and Malvern Mastersizer were connected to a local server for online backup.

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

11. Validation

The SOP for the validation master plan/VMP provided definitions of various terms and cross-references to various SOPs and regulatory guidelines. The VMP provided the manufacturer's philosophy for validation and qualification activities. The process validation was performed in three stages: stage I was carried out at R&D, stage II (performance qualification) was conducted on-site across three batches, and stage III was performed using Minitab software. The data were entered into Minitab every 6 months, for a total of 60 batches. For cleaning validation, batch-to-batch cleaning, product changeover (PCO) cleaning, and periodic cleaning were carried out. Batch-to-batch cleaning included visual examination of residues, whereas PCO and periodic cleaning required sampling after cleaning using swabs and rinse

samples. The water system validation was performed in three phases. The VMP also described policies for analytical method validation, personnel qualification, and other areas.

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

12. Change control

The electronic QMS application was used for change management in accordance with the SOP change control. Permanent changes and temporary changes (not more than 3 times) were allowed and classified as minor or major. The inspector reviewed the selected changes recorded in the QMS from November 2023 to 17 November 2025. Most of them were related to manufacturing processes, such as the introduction of new starting material vendors and the replacement of old equipment.

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

13. Rejection and re-use of materials

A site-specific procedure for the use of recovery solvents for intermediates and APIs was discussed. The procedure stated that recovery solvents will not be used for equipment cleaning and must be used only on-site. The recovery was performed directly during manufacturing by distillation from mother liquors or recovered using a solvent recovery system. The specifications were developed by the R&D for the recovered solvents, and a specific batch record was issued for the recovery solvents. The recovery procedure was validated using three batches prior to regularization. It was noted that the annual product quality review included assessing recovered solvents. A separate procedure titled “retest dates for recovery solvents and recovered materials” described the retest dates for each recovered solvent and material. The recommendations were given by the R&D to prepare specifications for recovered solvents. It was confirmed that specifications for all recovered solvents were available.

The SOP for reprocessing was reviewed. The reprocessing was initiated following a CAPA after the investigation due to OOS, OOT incidents, returned goods, or failures. This was followed by initiating change control, preparing protocols, preparing batch production records, conducting training, and executing the reprocessing activities. Reprocessing was allowed for intermediates and finished APIs, and requirements had been established before their initiation. In particular, the procedure stated that 3 batches will be required to validate the reprocessing. Regulatory approval will be sought, and the respective batches will undergo stability studies. A suffix (Rp) was used after the batch number to distinguish between the normal and reprocess batch. The procedure stated that “reworking should not be done for any failed product obtained during the manufacturing process and not in the scope of Hetero’s API manufacturing processes”.

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

14. Complaints and recalls

The SOP for handling customer complaints was reviewed. Risk assessment was performed as part of the complaint management. Quarterly review and yearly trends were performed. Complaints management was paper-based. Since 2023, nine complaints have been recorded, out of which 7 have not been confirmed. Four complaints were recorded for the WHO APIs, and no batch was returned. All production aspects, QC analyses and results, transportation, and other closely manufactured batches were part of Hetero's investigation, and the batch was re-tested at Hetero Labs, confirming the original results and not confirming the complaint. The batch was not returned.

The SOP for Product recall was reviewed. No recalls were recorded in the last 3 years. Mock recall was performed every 3 years. The last one simulates the recall of Lamivudine distributed to customers from India to Argentina.

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

15. Contract manufacturers (including laboratories)

The SOP for the qualification of service providers and contract testing laboratories was discussed. Service providers and contracted laboratories were audited once every 3 years after the initial audit. The questionnaire was first sent to the service provider before the on-site audit.

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, ***Hetero Labs Limited, Unit IX***, located at ***Plot No. 2, Hetero Infrastructure Limited, N. Narasapuram Village, Nakkapalli Mandal, Anakapalli District- 531081, Andhra Pradesh, India*** 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-nNinth 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

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