

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

<b>Part 1</b>	<b>General information</b>
<b>Manufacturers details</b>	
Name of manufacturer	<b>Apitoria Pharma Private Limited, Unit-IV</b>
Corporate address of the manufacturer	Apitoria Pharma Private Limited, Galaxy, Floor Nos. 22-23 & 24, Plot No. 1, Survey No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad-500 032, Telangana, India.
Name & address of inspected manufacturing site if different from that given above	Survey No's: 52,53,58, 59, 61 to 78, 127 & 128, Pydibhimavaram Village & Survey No's: 1, 2, 4 to 9, 11, 29, 30, 31 & 32, Chittivalasa Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh State, India, PIN: 532 409.
Synthetic unit /Block/ Workshop	Stage II (intermediate): Block 8 Finished API: Block G (Module III) and P (Module II)
<b>Inspection details</b>	
Dates of inspection	24-28 November 2025
Type of inspection	Routine GMP inspection
<b>Introduction</b>	
Brief description of the manufacturing activities	Apitoria Unit IV is located around 75 KM from Visakhapatnam airport. It is a multi-product facility spanning 161 acres. Unit IV is distinguished as Phase I, Phase II, Phase III, and the intermediates section. Unit IV comprises 14 production blocks, split into 43 modules and 11 intermediate blocks. Dolutegravir Sodium (DS) was manufactured in two stages: Stage II (intermediate) in Block 8, and the finished API in Blocks G and P.
General information about the company and site	Aurobindo Pharma Limited was established in December 1986. Due to business restructuring, Aurobindo's API business was transferred to Apitoria. Apitoria is a 100% subsidiary of Aurobindo Pharma Limited. Apitoria Pharma Private Limited (APL) is engaged in the manufacture of Active Pharmaceutical Ingredients (drug substances) and intermediates (drug intermediates). It has multiple manufacturing facilities in India. Apitoria Pharma Private Limited, Unit IV, formerly known as Aurobindo Pharma Limited, Unit-XI, is one of Apitoria Pharma's manufacturing facilities and produces API (Drug substances) and Drug Intermediates.
History	The manufacturing site was desk assessed in October 2022. This is the first on-site inspection after the submission of the Dolutegravir Sodium dossier.
<b>Brief report of inspection activities undertaken – Scope and limitations</b>	
Areas inspected	The following areas were inspected: <ul style="list-style-type: none"> <li>- Quality management</li> <li>- Premises and equipment</li> <li>- Validation and qualification</li> </ul>

	<ul style="list-style-type: none"> <li>- Visit to production blocks, 8, G &amp; P</li> <li>- Visit to air handling units, purified water system</li> <li>- Visit to solid raw material, key starting materials (KSM), API, packaging warehouse, sampling, and dispensing areas</li> <li>- Visit the microbiological and chemical-physical QC laboratories for testing API, Intermediates, raw materials, and solvents.</li> <li>- Visit the retention samples and stability studies areas.</li> </ul>
Restrictions	None
Out of scope	Products and areas other than those for WHO Prequalification were outside the scope of this inspection.
WHO APIs covered by the inspection	Dolutegravir Sodium (WHOAPI-466)
<b>Abbreviations</b>	<b>Meaning</b>
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
MPCR	Master Production and Control Record
BPCR	Batch Production and Control 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

<b>Part 2</b>	<b>Summary of the findings and comments</b>
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## 1. Quality management

The manufacturing site implemented a quality management system in accordance with national and international GMP standards. Quality management encompasses the organizational structure, procedures, processes, and resources to ensure that the API meets its intended quality and purity specifications. The quality unit was independent of operations and was responsible for quality assurance (QA) and quality control (QC). The job descriptions of the key personnel responsible for releasing intermediates and APIs were specified.

The SOP for product quality review was discussed. The PQR was performed on a calendar basis using a checklist, and it was to be completed within 3 months (by the end of March each year). It was noted that Dolutegravir Sodium was manufactured for the US market, and the same manufacturing process was filed with the WHO PQ. Minitab and Excel Spreadsheets were used to calculate process capability, and the acceptance criteria were described in the procedure.

The SOP Quality review/management review (MR) meeting was a corporate SOP. Responsibilities for the QMR were assigned at the corporate and site levels. Meetings were held monthly (with at least the API Quality Head/Senior Management team and their respective sections/departments) and yearly (with the Cluster / Site Quality Head and Senior Management). The CAPAs, which follow up on the previous MR, critical situations (if applicable), facility/equipment concerns, OOS, deviations, recurrence of events, continued process verification, critical and recurring audit trail trends, and human errors, were included in each meeting. Last MR was performed in November 2025. The meeting attendance list related to the management review was missing the signatures of the Director, Head-Quality, and GM-CQA, who attended remotely. Specimen template for minutes of meeting reported a discussion on the recurrence of LIR and OOS in October 2025, which the inspector reviewed.

The SOP Handling of Deviation was in place, together with the Agile system to manage deviations classified as Incident, Minor, Major, and Critical. Corporate and site responsibilities and timelines were defined, as well as impact assessment and CAPA implementation. Deviations were quarterly reviewed by the QA and trended, as verified by the inspector for Q3 2025. The company provided the list of deviations recorded in the period 2023-2025 related to the DS. Five deviations (2 Incidents, 3 Minor) related to QC and manufacturing activities were recorded.

The SOP Corrective Action and Preventive Action (CAPA) was discussed. Responsibilities included planning, assessing, implementing a risk-based approach, managing, and evaluating the CAPA post-implementation. The SOP was recently revised to assign responsibilities (the CAPA executing department's HOD is responsible as CAPA Owner), review of implementations after modification of the procedure for at least 6 instances of SOP execution, and verification of at least the next 10 batches of quality & yield, CAPA execution after implementation of the proposed CAPA. CAPAs were managed by the AGILE PLM QMS system. Several CAPAs were reviewed during the inspection, including deviations, OOS, and changes.

The SOP for Handling Corporate Quality Audits was recently revised to include a provision for verification change implementation at the site level and to update the checklist. Internal audit was divided into corporate, internal, and in-process QA Audit (IPQA), each with a different frequency and involving different responsibilities.

The SOP for quality risk management (QRM) was reviewed. The procedure was prepared in accordance with ICH Q9 (R1). The risks were assessed proactively (as part of the change initiation) and reactively (based on the QMS elements). The FMEA was used to assess risks. If there are no changes in the systems or processes, risk will be reviewed every 5 years; otherwise, it will be handled through change management.

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

## **2. Personnel**

Organization charts, including the current organogram, were reviewed. The last SOP revision was due to changes in the company name (from Aurobindo Pharma Limited, Unit XI), logo, manufacturing Unit number, and SOP number (from KQA025). The organogram, approved on 04.09.2025, was changed to replace the Vice President/Operations Manager and General Manager. The digital organogram was related to the computerized systems and IT responsibilities. At the site level, three different responsibility levels were in place: Assistant Manager Digital, Technical Assistant, and Outsource – Digital.

The SOP related to the employee's job description (JD) and specimen signature was reviewed. The new revision was due to the implementation of the training system EPIQ Learn IQ at the Corporate level (not yet implemented at the site) and to the inclusion of external people's signatures in the site's list. JDs were approved by the Head of the department, accepted by the employee, and approved by the department representative. In the JD of "Digital" (IT) department personnel, the Administrator's responsibility was stated in a generic way as "Authorized to act as administrator for all computerized

systems in the entire unit,” without specifying whether the responsibility was for the system, application, or software.

The SOP training was reviewed alongside the book for the Digital Assistant's employee training history card.

The SOP for conducting medical examinations was reviewed, and it was found that personnel outsourced for various IT activities and stationed on-site were not included in the routine medical examinations.

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

### **3. Buildings and facilities**

Warehouse/WH-I ground floor (Equipment lay-out & men, material management included:

- Solid raw material with “Ambient” main areas where the temperature was only monitored together with the Humidity by a datalogger. Parameters were recorded once daily in a paper logbook. The datalogger logbook was reviewed, showing humidity >70% and Temperature <35°C.
- Controlled temperature room (Between 20 and 25°C) for DS stage-I (coming from the Unit VI) and stage-II (manufactured at the site); logbook 25-00023 for storage conditions recorded by the datalogger was reviewed.
- Cold room 2-8°C for the Dolutegravir Sodium KSM; the logbook for storage conditions recorded was reviewed.
- Two raw material sampling rooms (sampling room-1 with a change room in common with the RM sampling room-2); each room was equipped with a sampling booth and a material pass-box. The SOP operation and cleaning of the sampling booth were reviewed, along with the data and information manually recorded. No records of the HEPA filter pressure check were available during the raw material sampling and dispensing operations carried out in the LAF booths, except for the initial value recorded when the booth was switched on.
- Two dispensing rooms were also available. Split air conditioners were used in sampling room-1 and dispensing room D.B-1 in WH-I (solid raw material) and were found to be inappropriate for the pharmaceutical intended use.
- Rejected solid material segregated area was available.

The SOP for pest control included activities such as weekly insecticide spraying. The activity was outsourced to Steeple Hudson Pest Control Pvt. Ltd. Rodent traps (for rodents, crawling insects) were checked every day by APL’s personnel, as well as the Pest-O-flash lamps. Alert and action limits were in place for operational and non-operational areas; seasonal trend evaluation was performed, and, if needed, CAPA was implemented. The annual trend data for the insects were reviewed.

Air handling units/AHUs: 90% of the air was recirculated, and 10% was supplied as fresh air to the cleanrooms. The cleanrooms were requalified once every 6 months for non-viable particle counts, air velocity, and air changes per hour (ACPH). In addition, requalification was performed every 12 months for viable, non-viable particle counts, ACPH, air velocity, and filter integrity. AHU was used for the drying area and comprised fresh-air inlets and 10µm, 5µm, and 0.3µm filters. The 0.3µm HEPA filter

was mounted on the plenum. Temperature, humidity, and differential pressure were monitored once every shift.

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 was to be 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 according to written procedures and a schedule. 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**

The SOP Document control was reviewed. The printout of SOPs and master production control records (MPCRs) from the AGILE PLM QMS system was a privilege of the QA HOD (head of department) group. SOPs or other document printouts were identified as “controlled” copies and “for reference purposes,” with a 24 hr validity. Batch production and control records (BPCR) were issued after QA approval. The batch number was generated by the ERP interface with AGILE. The SOP assigning batch numbers and manufacturing dates for materials, intermediates, and active pharmaceutical ingredients (CQA003 rev. 03, effective date 01.04.2024) was in place for the batch-numbering system. API batch number was XX (year), OOO (organization; Unit 461 for Unit IV), and YYYYYY (Serial number).

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

#### **6. Materials management**

Materials used in manufacturing activities were managed by the ERP system. Material status was appropriately identified for quarantine, release, and rejection, as well as for sampling activities, by labels, physical segregation, and in the ERP. RM/Intermediates/API sampling activities were carried out by the QC analysts. Cleaning activities were carried out by the WH personnel. The manufacturing “Unit-VI” was wrongly labeled as “Unit XIV” instead. It was noted that the mislabeling resulted from the 2023 failure to update the Unit’s name in the ERP system, as verified by the inspector. Rejected RM and APIs were physically segregated in dedicated areas with controlled access. Packaging material was sampled and stored in a dedicated room.

The SOP “identification, selection, and qualification of external vendor raw material” was in place to qualify a new external vendor, an alternate external as a new manufacturer, and a new existing supplier for final API/Intermediates/starting material. Periodic evaluation of qualified suppliers was conducted at a frequency determined by the material's criticality.

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 manufacturing block 8, which was used for Stage II manufacturing. The process equipment used in the manufacturing of Dolutegravir Sodium were verified through the manufacturing process flow diagram. Separate MAL and PAL were provided, and a common change room was provided for both visitors and staff members. A hand washing and drying facility was provided before donning the gown and entering the synthesis areas. The first floor was equipped with all synthesis reactors, whereas the ground floor housed centrifuges and dryers. Temperature indicators used for sensors were found to be calibrated every 6 months. At the time of the visit, Dolutegravir Sodium was being produced. The respective batch-processing and control records were available for use. The manufacturing area was well-maintained at the time of inspection.

The inspector visited manufacturing block P, which was used for manufacturing finished API of Dolutegravir Sodium (micronized). The manufacturing block spanned three floors. Mainly, the ground, first, and second floors were used, and for the past two years, Dolutegravir Sodium has been produced. The facility was equipped with a handwashing station and a dryer. Separate MAL and PAL were provided, and powder transfer systems (PTS) were used to transfer materials.

The inspector visited production block G (Module III), where batches of Dolutegravir Sodium (micronized) were produced for process validation. Module III had a hand wash, drying, and gowning facility in place. Carbon treatment, crystallization, and powder processing are carried out on the first floor, while centrifugation and drying are carried out on the ground floor. At the time of the visit, no activity was underway.

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 required cold storage conditions and was packed in Trilaminate bags.

## 9. Storage and distribution

Controlled storage conditions were set for the activities of APIs in the dedicated area, WH-VI, on the first floor, with a controlled temperature of 20 to 25°C. The activities for the QA batch release before distribution SOP were reviewed, along with the assigned responsibilities (QA, QC, and Manufacturing). Authorized personnel for QA release were listed in the QA authorized personnel list for batch release.

## 10. Laboratory controls

Five QC labs were available on site, dedicated to RM/intermediates, microbiological, APIs, IPC, and stability testing. The following laboratories were visited:

- API QC Lab: Quality Control Lab-I (Main QC) (Equipment layout & Men, material movement) was reviewed. Areas were available for sample receiving, preparation, and distribution. Sampling, testing, and analytical release activities were managed by LIMS. CoA was issued and approved by QA only after the QC and Analytical QA review. Three Wet labs (I, II, and III) were available. API discarding locations were available to collect the remaining sample quantities and send them to the waste treatment department once the analyses were closed. A sample destruction audit trail was in place to verify the reconciliation between the quantity used for the tests and the quantity discarded.
- First floor (Equipment layout & Men, material movement). GC Lab-I with 12 GCs and 2 GC-MSs, along with related sample preparation and mobile rooms, was available. Preventive maintenance was carried out every 6 months by an external service; In-house and semi-annual calibration were carried out by the company's engineering team and managed via LIMS. LIMS was used for column use and management. The HPLC-I room was equipped with 16 HPLCs. A retention sample (RS) room (20 to 25°C) was available for APIs, with a walk-in chamber at +2-8°C used for RS of the KSM. Storage conditions were controlled and manually recorded. DS retention sample packaging and quantity requirements were verified. The working standard (WS) room was used for refrigerated WS storage. Temperature monitoring of RS/WS was performed by the ICDAS system, whereas impurity standards were recorded manually. The fridge temperature records were reviewed in the system; every 24 hrs, the records were printed and manually backed up by the application's Admin.
- Second floor (Equipment layout & Men, material movement). Instrument labs I, II, and III, and the related sample preparation area, were available for two LC-MS instruments used for molecular identification and quantification, as well as one XRD instrument. The daily system suitability was performed, in which line position, line intensity, and shape parameters were verified.

The microbiological laboratory (equipment layout & men, material movement) was visited.

- Second floor block-A. Microbiological, biological (endotoxin test- gel clot), and PW testing were carried out in the lab. Classified D and C areas were available for media preparation and testing. The chemical testing room was equipped with a Millipore Elix-MilliQ system, regularly tested as PW. One TOC instrument was available; in the event of unavailability, the TOC was outsourced to Unit XIV (formerly VI) under the quality technical agreement. Two pH meters were available. NIST-certified buffer solutions were used for daily calibration and verified against the calibration records. The incubator room was equipped

with 9 incubators, each with a different temperature and humidity monitored by ICDAS. One pass-through autoclave for sterilizing material (tool garments) and media used in the LAF rooms I and II was available. The Bowie-Dick test and the vacuum leak test were routinely and regularly performed. Calibration was outsourced. Two sterilizing cycles were validated for High Pressure High Vacuum (HPHV) steam for garments and tools, and a 121°C gravity cycle for media. Two media prep-rooms and media storage were available; purchased and in-house-prepared media were tested for GPT and pH.

Stability labs consisted of two floors. Analysis was performed on the first floor and stability chambers located on the second floor (Equipment layout & Men, material movement). Five walk-in stability chambers, two back-up, and one photosensitivity chamber were available. Stability conditions were monitored by the ICDAS system and were monthly backed up to three different hard drives. Data records for October 2025 were reviewed in the system, as were the LIMS stability protocol management records. Annual DS batches, process validation batches, batches for customer requests, and batches for changes were regularly placed in the stability chambers.

OOS results were managed by the AGILE system, along with the SOP Handling of Out-of-Specification (OOS) results, recently revised to include details on HPLC/GC analysis management. For Assay by HPLC/Titrimetry/GC, related substances or content methods by LC, IC, and GC, residual solvents, and acceptance criteria for replicate test determinations, differences between replicates and cumulative analysis values were evaluated. In all cases, all individual results shall meet respective specifications. No re-sampling was allowed except for the listed situations, such as insufficient material, quality issues with the original samples, and as authorized by the QA.

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) was discussed. The SOP provided an overview of validation and qualification activities, including validation of processes, computerized systems, analytical methods, utilities, requalification, revalidation, and periodic qualification. In addition to the SOP, the VMP001, dated 20/11/2025, was available, covering validation and qualification activities. The quarterly validation plan was prepared.

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

## **12. Change control**

The SOP change control was in place, together with the AGILE system for change management. Responsibilities were assigned at the corporate and site levels. Changes were categorized as permanent and temporary, with no limit on raising the same temporary change within a defined period. No requalification/revalidation assessment was required. The risk assessment was initiated for major and moderate changes. Three changes related to the validation and cleaning activities for DS Stage-II equipment in Block-8 were reviewed.

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**

The SOP for reprocessing and rework was discussed. Reprocessing or rework was performed whenever the product did not meet the specification. A change control was initiated for every reprocessing or rework before executing the activities. The item code for reprocess or rework shall differ from the regular batch, and the reprocess or rework shall be performed in accordance with the approved batch production and control record (BPCR). Process validation for reprocessing and rework will be performed in accordance with the process validation procedure. Similarly, batch numbering will be followed as per the batch numbering procedure. The procedure stated that upon satisfactory review of 3 months' stability data and based on regulatory updates/recommendations/customer agreement, the reworked batch can be released for market dispatch. The manufacturer did not file reprocessing or rework processes to the WHO PQ. It was also noted that the manufacturer filed for reprocessing of Stages I and II, as well as the finished API, with the USFDA.

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

### **14. Complaints and recalls**

Complaints were managed by the AGILE system and SOP for handling market complaints. Responsibilities in the management were assigned to QA, cross-functional teams, the Plant Head, and CQA. No complaints were recorded for DS over the last three years.

Returns were managed by the AGILE system and SOP for handling returned goods. Responsibilities for management were assigned to warehouse personnel to record material returned in the ERP system and then record it in the AGILE system under a different batch number (a six-digit numerical sequence). The QA team, HOD, cross-functional teams, Plant Head, and CQA were involved in managing the returned batch. The storage condition data records for the returned batch were not explicitly requested by the customer, as verified during the assessment of handling return goods at the customer's site. No returned batches were recorded for DS in the last three years.

The product recall was in place to manage the API recall. The SOP was tested every three years. Mock recall protocol and mock recall report for Levetiracetam, recalled from two companies in the USA and India, were reviewed. The contact details list for recall communication was not periodically verified to keep information up to date, including the names and job positions of all parties involved (authorities, corporate, and site), telephone numbers, and email addresses.

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

## 15. Contract manufacturers (including laboratories)

The manufacturer confirmed that no products (except Stage KSM) were manufactured under contract or licensed. The KSM used in Stage-1 is procured from approved and qualified vendors. The manufacturer identified 19 contract laboratories and 9 calibration service providers in the site master file. Dolutegravir Sodium was fully tested in the in-house QC laboratory.

<b>Part 3</b>	<b>Conclusion – Inspection outcome</b>
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Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, *Apitoria Pharma Private Limited*, located at *Survey No's: 52, 53, 58, 59, 61 to 78, 127 & 128, Pydibhimavaram Village & Survey Nos: 1, 2, 4 to 9, 11, 29, 30, 31 & 32, Chittivalasa Village, Ranasthalam Mandal, Srikakulam, District, Andhra Pradesh State, 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.

<b>Part 4</b>	<b>List of GMP Guidelines referenced in the inspection report</b>
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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**  
<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/](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](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](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](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](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](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](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](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
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