World Health Organization

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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Getz Pharma (PVT.) Limited**
Corporate address of manufacturer	29-30, Sector 27, Korangi Industrial Area, Karachi - 74900 Pakistan
Inspected site	
Name & address of inspected manufacturing site if different from that given above	As above Latitude: N 24°50'41.207" Longitude: E 67°9'18.344" External Warehouse: Plot No. 12 and 32, Sector 19, Korangi Industrial Area, Karachi, Pakistan
Unit / block / workshop number	Oral Solid Dosage (OSD) manufacturing facility
Inspection details	
Dates of inspection	25-28 February 2020
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Production and quality control of FPP of solid oral dosage forms (i.e. tablets, capsules, powder for oral suspension and sachets), parenteral (sterile liquid vials, sterile liquid ampoules and sterile lyophilized powders), MDIs (Metered Dose Inhalers) and DPIs (Dry Powder Inhalers)
General information about the company and site	Getz Pharma (Pvt) Ltd is a member of the Getz Group of Companies and started operation in Pakistan during 1995. The manufacturing plant is in the Korangi Industrial area. This site consists of: - Research and Development Block - Utility Block - QC and Stability Laboratory Block which consist of QC Lab II for Testing of APIs, Excipients, Finished Pharmaceutical Products & MDI, Stability –Analytical Lab and Stability Chambers - One main block:

<table>
<tr><td></td><td>
<table>
<tr><th>Level</th><th>Facilities</th></tr>
<tr><td>Basement Floor</td><td>Optical inspection Area, QC Packaging Laboratory, WIP Storage, Offices</td></tr>
<tr><td>Ground Floor</td><td>Central Warehouse, Oral Solid Dosage (OSD) Manufacturing Facility, Sterile Manufacturing Facility, OSD Packaging Facility</td></tr>
<tr><td>First Floor</td><td>Warehouse, QC Lab I for Testing of, Finished Pharmaceutical Products (FFPs), Utility Area, Offices</td></tr>
<tr><td>Second Floor</td><td>Sterile II Manufacturing Area, MDI manufacturing Area, Utility Area, Offices</td></tr>
<tr><td>Third Floor</td><td>Utility areas, MDI packaging Area, Offices</td></tr>
<tr><td>Fourth Floor</td><td>Utility Area, Training Hall, Auditorium</td></tr>
<tr><td>Fifth Floor</td><td>Auditorium</td></tr>
<tr><td>Sixth Floor</td><td>Utility Area</td></tr>
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The site had an external warehouse, located opposite the premises, dedicated to storage of finished goods.
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<tr><td>History</td><td>This was the third WHO PQ inspection. Besides, Getz Pharma was certified and accredited as follows:

ISO 9001:2015 Bureau Veritas Certification started in November 2010, with the last certification carried out November 2018 with expiry date 4 November 2019. The recent certification was completed on 19 December 2019. The audit report and certification will be issued as communicated with Getz Pharma</td></tr>
<tr><td colspan="2">Brief report of inspection activities undertaken – Scope and limitations</td></tr>
<tr><td>Areas inspected</td><td>Document Review included but not limited to:
- Product quality review
- Change control
- Deviation control
- Job descriptions
- Self-inspection
- OOS and atypical results
- Cleaning validation
- Quality risk management
- Batch manufacturing and packaging records
- Computer system validation
- Stability studies
- Validation master plan
- Electronic data and audit trail
Site areas visited:
- Tablet production area located at the main block
- Central Warehouse and Approved Finished Good Warehouse
- Manufacturing area covering granulation, compression, packing;
- QC laboratory-2</td></tr>
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Restrictions	Sterile, liquid and other dosage forms were out of the scope of the inspection.
Out of scope	Products not submitted to WHO for Prequalification
WHO products covered by the inspection	Moxifloxacin 400mg, Film-coated tablet (TB311)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
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
GPT	Growth promotion test
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
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
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
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	**Summary of the findings and comments (where applicable)**

1. Pharmaceutical quality system

In general, a PQS was implemented. Production and control operations were independently managed and specified in written form and GMP requirements were generally being followed. Managerial responsibilities were specified in job-descriptions. Product and processes were monitored, and the results considered in batch release and regular reviews of the quality of pharmaceutical products were conducted. Periodic management reviews were performed.

Product quality review (PQR)

The manufacturer has established a procedure to perform PQR. For the year 2020, the PQR schedule 2020 was available. Based on the PQR schedule, the manufacturer had identified products to be reviewed. This included Moxifloxacin 400mg tablet and Moxiget tablet 400mg. The manufacturer had conducted the review and prepared the PQR reports for both products, PQR Moxifloxacin – 2020 and PQR Moxiget-2020 (tablets). The process capability index (CpK) using Minitab software was used for calculating CpK. The procedure stated that more than 25 batches are required for CpK analysis, if less than 25 batches were produced in a certain calendar year, trend analysis will be performed using upper/lower control limit.

Change management

Change controls were managed based on SOP for Change Control Management. Currently, the manufacturer practices a dual system to manage change control with the change control form and number were initiated, generated and approved using the SAP system and the impact assessment conducted and reported in manual formats. The initiation of change control through the SAP system requires the initiator personnel ID. The change control form was printed and checked by the initiator's supervisor. The change control was reviewed by cross-functional team members, where 'the initiator will select the reviewer which may be one or more depending on the nature of the change & department having a direct or indirect impact of that change'. The manufacturer indicated that the QA and Compliance department review the change control document and advise the initiator if there is any additional team member required to be included as a reviewer. The changes were categorized based on high, medium and low risk. If the risk was identified as low, a detailed risk assessment was not required. The document was then submitted to QA and Compliance Department for final approval. Changes were implemented after the approval and closed after its verification for satisfactorily implementation by QA and Compliance Department.

Deviation management

Planned and unplanned deviation were handled through SOP for Handling of Deviation. Deviation incidences were monitored based on Deviation Tracking and Trending Record.

Quality risk management (QRM)

The manufacturer had in place, SOP QRM System to manage QRM. The QRM was implemented holistically which covered all quality system elements. The QRM annual plan for process improvement activities prepared early of the year.

Management review (MR)

The SOP for MR and minutes of meeting held on the 30th January 2020 was discussed. The MR minutes dated 30th January 2020 covered review period between 1st August and 31st December 2019. The meeting was chaired by Director Quality Operations and attended by various operational department heads (validation, QA, QC, production, HR, IT).

The issues noted from this section have already been addressed and will be verified during future inspections.

2. Good manufacturing practices for pharmaceutical products

Manufacturing processes were generally clearly defined and systematically reviewed. Qualifications and validations were performed where required and documents were produced where requested. Necessary resources were provided, and records were made during manufacture. Deviations were investigated, and appropriate root causes were identified. Procedures were in-place for tracking corrective and preventive actions and their implementation. A system was available to recall any batch of product from sale or supply and complaints about marketed products were examined, the causes of quality defects were required to be investigated, and appropriate measures taken in respect of the defective products.

Moxifloxacin 400mg tablets were produced in a shared facility. It was noted that the Getz Pharma had not produced any batches of Moxifloxacin 400mg tablets for WHO PQ markets since the last PQ Inspection. It should be noted that Getz Pharma produces Moxifloxacin 400mg tablets under the name of Moxiget for the domestic market has the same manufacturing formula but with a different API source.

The company was advised to ensure that WHO PQ name is not misused (training advertisement available on a Public Domain revealed the use of WHO PQ name for Moxiget) when Moxiget 400mg tablets are marketed which is not a WHO Prequalified Product. This concern was highlighted at the closing meeting and will be monitored.

The issues noted from this section have already been addressed and will be verified during future inspections.

3. Sanitation and hygiene

The company had a standard operating procedure as the basis for its approach to personal hygiene and sanitation in its production facilities. Areas were cleaned frequently following an approved written program and SOPs. The changing room was equipped with handwashing facilities. The manufacturing area, packaging area, warehouses and quality control laboratory were found with a satisfactory level of cleanliness.

4. Qualification and validation

The key elements of a qualification and validation program were defined and documented in the validation master plan.

Computer system validation

The CSV validation program was categorized into computerized system validation (lab and production, utility equipment) and computer system (SAP, SharePoint, application run on the standard system). The SOP for computerized system validation (CSV) of GxP automated machines was discussed and noted that a new procedure was developed to define a systematic procedure for the validation of computerized systems. Based on this new procedure, so far 26 HPLC systems (Shimadzu) had been reviewed. Rest of the laboratory HPLC systems, equipment, production equipment and utilities shall be performed as per the planner.

Qualification and requalification

The SOP for the qualification, requalification & review of GMP equipment and utilities provided instructions for the qualification, requalification and review of GMP equipment for production and utilities throughout their product lifecycle. Besides, the procedure described how DQ, IQ, OQ, PQ was performed following the approval of the URS. Requalification included a review of existing GMP equipment and utilities based on change control. Qualification review program was performed once every 3 years and was based on the VMP schedule.

Equipment qualification
High shear granulator software qualification comprised of DQ, IQ and OQ. PQ was performed by Getz Pharma using placebo product. It was noted from the OQ document that total of 8 user names (operator-1, operator, production supervisor, maintenance, pharmacist, Glatt Maintenance and Glatt Administrator) were identified and challenged as part of the OQ.

Warehouse
The central warehouse was initially qualified in 2007 with 2 AHUs and requalified in 2015 with the addition of 6 AHU and removal of 2 existing AHU. The requalification performed in 2018 included the impact of high outside environment temperature as discussed in details rationale in the last requalification report. Protocol for the requalification of central warehouse was discussed.

Air handling units (AHUs)
The manufacturer had performed the HVAC requalification for an oral manufacturing facility in 2019. The qualification protocol (for HVAC System Qualification of OSD Production Area) was approved. The re-qualification performed on each AHU and the result was reported in the test sheet for each AHU. The final qualification report (for HVAC System Qualification of OSD Production Area) was approved and concluded that the OSD manufacturing area and primary packaging area were qualified.

The issues noted from this section have already been addressed and will be verified during future inspections.

5. Complaints

Product complaint was received and managed based on SOP on Process Management of Product Quality Defect(s) Complaints. Summary list of complaints received and responded - (Local) 2019 and Summary list of Complaints received and responded - (Toll/contract Manufacturer) 2019 were prepared. Yearly trending was performed by the regulatory affairs (RA) department. Trending analysis included complaint types, number of complaints received, complaint received based on manufacturer involved (Local/Toll manufacturer) and total product complaints responded. The RA personnel submit a summary of product quality defect complaints to the QA department. The complaint trends were discussed during the Management Review meeting.

The issues noted from this section have already been addressed and will be verified during future inspections.

6. Product recalls

It was indicated by the company that there was no recall initiated since 2011. A mock recall was performed for the domestic market and indicated that export will be covered in 2020. No protocol was available at the time of the inspection for mock recall for the export market.

7. Contract production, analysis and other activities

No production or quality control related to the inspected product was out-sourced.

8. Self-inspection, quality audits and suppliers' audits and approval

Self-inspection was performed according to SOP for Internal Audit. Based on the SOP, the Lead Auditor was responsible for the internal audit planning, execution & report circulation. The audit team was responsible to evaluate the implementation of GMP objectively. Master list of auditors based on experience available. The manufacturer had performed its internal audit. Lead Auditor for the internal audit was appointed by the Director Quality Operations and he/she then will identify its audit team members. The lead auditor was responsible for the preparation of the audit, to ensure the execution of the internal audit and for preparation of the audit report. The 2019 audit report was available, and all the observation identified has been closed and verified. Audit checklist was used for the internal audit.

Supplier audit

The supplier qualification was performed based on SOP of Vendor Qualification for API, Excipients and Packaging Material. The scope covered vendors of API, excipient, packaging materials, locally and internationally. The qualification process for new API, new molecule or new vendor covered vendor profile and QMS assessment performed. Once it is satisfactory, lab sample was purchased, tested and submission of vendor certification checklist to QA Department. The QA approved the API and was then listed in the approved vendor list for Product Development Batch. The API was purchased for trial and stability batch, if the results were satisfactory, change alarm for induction to approve vendor list for commercial batch and full assessment including on-site audit was initiated. Once it is completed, the QA approved the API in the approve vendor list for commercial production. An on-site audit may be performed post-approval.

The issues noted from this section have already been addressed and will be verified during future inspections.

9. Personnel

The responsibilities of Director of Quality Operation, Head of Quality Assurance – QMS Compliance and Head of Quality Assurance –Audit & Compliance and Executive Quality Assurance-Document Control were satisfactorily defined in their job description.

10. Training

Training programs were managed based on SOP for Employee Training. Based on the SOP, new QA personnel must undergo orientation training, on-the-job training and detailed and specific training for the job scope. Training record for Executive Quality Assurance-Document Control responsible for handling change control was reviewed. Training record of SOP on Change Control which involved the creation of Change Notification in SAP and Closing of Change Control in SAP. Training certificate issued and signed by the immediate supervisor and Manager/HOD in the training record.

11. Personal hygiene

Gowning procedure to enter the warehouse and productions facilities was in place. Hand washing facility, mirror and production gown procedure were provided in the change rooms. Separate change rooms (for staff and visitors) were in place. In general, the gowning procedure was found adequate and was supported with SOPs and pictorial presentation.

12. Premises

The inspectors reviewed the company's site layout covering the ground floor and other areas. The warehouse was common for sterile products and OSD products and sampling was performed in the warehouse. The dispensing was performed inside the production area. A separate change procedure was followed for the warehouse and production areas.

Central Warehouse

The warehouse was found well lit, clean, and organized. Raw materials and packaging materials were received at the central warehouse. There was separate area for quarantine raw material & packaging material, sampling facility and approved raw material and packaging storage area. There was also a dedicated area for storage of quarantine finished product. Material that was ready to be transferred into production was kept at the holding area for in-process material. The warehouse and storage area were equipped with a racking system. Sampling room was equipped with separate MAL and PAL. Sampling tools were washed and cleaned in QC laboratory and taken to the sampling room daily. The temperature and humidity was monitored at 14 locations throughout the warehouse, three times daily and recorded in the logbook for temperature and relative humidity record of warehouse. The finished product was transferred from the production area into the quarantine finished product storage area. The movement of finished product into the area was logged in the quarantine finished goods location traceability log sheet.

Purified water (PW) system

The quality of PW produced was monitored based on the SOP for sampling and testing of Purified Water. The PW trending report which included the pH, conductivity and total aerobic microbial count prepared. The online TOC was installed at the PW returned loop. The addition of the component was qualified according to protocol for qualification of online TOC analyzer (PW Distribution Loop).

Production area

The production facility was located at ground floor and comprises oral solid dosage manufacturing, primary packaging & secondary packaging areas with a dry powder suspension area. The non-sterile zone consists of manufacturing suites, dispensing area, processing rooms, central washing area for equipment, and primary packaging. A common area is situated between the two zones for secondary packaging. Each zone has its entrances and gown change rooms. The facilities used to manufacture Moxifloxacin 400mg included non-dispensed staging Room, dispensing Rooms, granulation suite-2, compression room 3, coating room 2, and blister packing line 8. The changing room was equipped with the necessary facility such as sink for hand washing, hand dryer, crossover bench and appropriate uniform for gowning before entering the production area. The manufacturer has airlock room in the production and controlled through a visible alarm. The oral manufacturing facility including manufacturing & primary packing areas was classified as Class 100,000 (Grade-D). Secondary packaging area was classified as a pharmaceutical

cleaned area. The corridor was over-pressurized (limit 5 to 20 Pascal) concerning surrounding areas (airlocks and processing cubicles).

Air handling units (AHUs)
The air handling Units (AHU) serving for the production rooms were:

No.	Production room	AHU
1.	Dispensing 1	UTA-48
2.	Granulation suite 2	UTA-20
3.	Compress Room 3	UTA-19
4.	Coating Room 2	UTA-16
5.	Blister Room 8	UTA-03

The issues noted from this section have already been addressed and will be verified during future inspections.

13. Equipment

In general, equipment were located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of equipment was appropriate to minimize the risk of errors and permit effective cleaning and maintenance to avoid cross-contamination, build-up of dust or dirt.

The dispensing rooms were equipped with a laminar airflow cabinet. Granulation suite 2 was equipped with one unit of Fluid Bed Dryer, one unit of Fitz mill, one unit of High Shear Mixer and one unit of Octagonal blender. The compression machine was in operation during the inspection. The machine also equipped with a tablet deduster and metal detector unit. The solution preparation room was used to prepare the coating solution. The manufacturer has three coating rooms and each room was equipped with a tablet coater. Coating room 2 was equipped with coating machine and was in operation during the inspection. The blister room 8 was equipped with blister machine Uhlmann E.

The issues noted from this section have already been addressed and will be verified during future inspections.

14. Materials

The materials receiving process was performed according to SOP for receiving & storage of raw and packaging material. Material received were physically inspected and recorded in the material inspection note. Receiving documentation including confirmation from a supplier received from an approved supplier was verified by the warehouse personnel. The warehouse personnel informed the QC department on the arrival of materials in the warehouse. The material then transferred to the quarantine area for sampling activity by QC department. The QC department acknowledges the arrival of material and scheduled sampling process. The material transferred to the approved area after test approved and approved label pasted on each container by QC personnel. Material issued to the production based on batch picklist. The material moved to the holding area for in-process material before taken into the production area to be dispensed. Returned / excess material from production was labelled with ‘Loose slip’ which will then be stored in the approved area.

The issues noted from this section have already been addressed and will be verified during future inspections.

15. Documentation

Generally, during the inspection it was found that the manufacturer had established a documentation system where it constituted as an essential part of the Quality Assurance System. Following batch manufacturing records were reviewed:

- The batch manufacturing records of Moxiget 400mg tablets was briefly cited. These were the same batch records which were reviewed during the last WHO PQ inspection. The batch packaging record was reviewed.
- The batch manufacturing record of Moxifloxacin HCl 400mg tablet was reviewed. This batch was produced in 2018 following the WHO PQ assessment query to perform comparative dissolution profile. The batch packaging record for a pilot batch of Moxifloxacin tablets 400mg.

Batch release

The SOP for auditing of batch record and release of finished goods was reviewed. The SOP described the procedure for auditing of batch record and release of finished goods to ensure compliance with all established and approved written procedures before it is made available for sale. The Head of QMS compliance was responsible for approval of finished goods before released for sale. The QA representative audits the batch record, packaging record and analytical report before posted in the SAP system. Following an initial review by the QA representative, the batch record was reviewed by the Head of QA-QMS compliance through batch release checklist and posted in SAP by the QA representative. Batch release process flow chart was part of the procedure. A batch release certificate was issued by the Head of QA QMS Compliance.

Review of audit trail

The SOP for audit trail review was reviewed and noted that procedure applied to all computerized systems of analytical instruments of QC and R&D laboratory. The audit trail printouts from laboratory equipment and manufacturing equipment with part of the batch.

The issues noted from this section have already been addressed and will be verified during future inspections.

16. Good practices in production

The inspectors visited the production and packaging areas. In general, area was found to be clean, tidy, well-lit and properly maintained. Dispensing activity was being carried out at the time of inspection. The company had introduced the use of Photohelic gauges (analog magnehelic) which is manually monitored/recorded twice per shift by the production department. The OSD facility was supported with 19 air handling units (AHUs) (16 in manufacturing area and 3 in primary packaging) which were requalified every two years.

The production area had three granulation suits, blending area for direct compressed material and six compression machines. Granulation Suit-2 (granulator, drier, crusher and blender) was used for WHO PQ Moxifloxacin 400mg tablets (submission batches). XL Korsch compression machine was used for WHO PQ Moxifloxacin 400mg tablets (submission batches). Vacuum loading system was used for transfer of granules to compression machine hopper. The in-process tests including metal detector test were performed by the compliance QA, QA and production at regular intervals. The primary packaging area had 9 blister lines. Blister line 8 was used for WHO PQ Moxifloxacin 400mg tablets (submission batches).

The issues noted from this section have already been addressed and will be verified during future inspections.

17. Good practices in quality control

The quality control department consisted of several laboratories operating different testing activities. The laboratories were located as follows:

No.	QC laboratory	Location
1.	QC Lab II for testing of API, Excipient, FPPs and validation samples	Ground floor
2.	Stability - Analytical Lab	Ground floor
3.	QC Lab I for testing of Finished Pharmaceutical Products	First floor
4.	R&D Analytical Lab	First floor
5.	QC Packaging Lab	Basement floor

The QC Lab II was briefly inspected which was involved in the testing of API and excipients. The laboratory premises were found to be spacious with adequate working space and storage space for chemicals and documents. There were dedicated laboratory personnel to QC Lab II, to carry out the job assigned. API sampled were kept separately in a container based on the categories ‘sample under testing’ and ‘sample to be tested’. Samples received were recorded in the analytical record (AR) logbook. An analyst logbook then distributed to the analyst, for the execution of the test. The logbook is the primary raw data where all printed data were attached. Data/result from the logbook were transcribed to the SAP system by the analyst. All data and result were checked and verified by the lab supervisor and QA Lab Compliance. The certificate of analysis was issued from the SAP system.

Stability study data

Source/electronic data of stability study of Moxifloxacin 400mg tablets (36 months) were compared against the reported results.

Out of Specification (OOS)

OOS incidences were managed by the SOP for Handling of OOS & Atypical Result. The OOS report related to Paracetamol tablet was reviewed. The manufacturer had performed Phase IA and Phase IB investigation concluded there was no obvious root cause identified. Phase II investigation was then performed. Protocol & Report for Repeat Analysis of Dissolution prepared and concluded the requirement to conduct Phase III investigation including review of the manufacturing record. The Phase III investigation report prepared and approved with the conclusion of no obvious error identified for initial testing result and the batch will be considered for release based on the satisfactory result of 5 consecutive testing.

The issues noted from this section have already been addressed and will be verified during future inspections.

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, ***Getz Pharma (Pvt) Ltd***, located at ***Korangi Industrial Area, Karachi-74900, Pakistan*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 30 months, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of WHO Guidelines referenced in the inspection report

1. 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/

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   http://www.who.int/medicines/publications/44threport/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

6. 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

7. 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/

8. 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/

9. 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

10. 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

11. 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

12. 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

13. 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

14. 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***
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