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20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Renata Limited
Corporate address of manufacturer	Renata Limited, Plot 01, Section 7, Mirpur, Dhaka 1216, Bangladesh
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Renata Limited, Rajendrapur Potent Product Facility, Noyapara, Bhawal, Mirzapur, Rajendrapur, Gazipur, Bangladesh
Unit / block / workshop number	Rajendrapur Potent Product Facility (RPPF)
Inspection details	
Dates of inspection	16-18 July 2022
Type of inspection	Initial inspection
Introduction	
Brief description of the manufacturing activities	The RPPF site was established in 2012 and it operated under an independent quality management system. Apart from the main RPPF building which included warehousing facilities, there was an annex building where secondary packaging materials and finished goods for the local market were stored. In addition, secondary packaging operations could also take place in the annex building. Exceptionally, excipients intended for the RPPF facility could also be stored in the General Facility Warehouse which operated under the QMS of the General Product Facility. There was also a dedicated area where iron (ferrous fumarate) tablets were manufactured which was connected to the RPPF manufacturing area via a bubble airlock.
General information about the company and site	Renata was established in 1972 as Pfizer Laboratories (Bangladesh) Limited, a subsidiary of Pfizer Corporation, USA. In 1993, the company was renamed "Renata Ltd." after divestment of shareholdings by Pfizer. The company has three campuses, namely in Mirpur, Rajendrapur and Bhaluka (under construction/commissioning). Each campus includes several independent plants. The Rajendrapur campus consists of the following independent plants: Cephalosporin Production Facility. Penicillin Production Facility Potent Product Facility (RPPF)

	General Manufacturing Facility Oncology Solid Facility Oncology API Facility Oncology Injectable Facility
History	This was the first WHO inspection. The site is periodically inspected by DGDA.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed included but not limited: - Job descriptions for key personnel - Training - Product Quality Review - Management Review - Complaints and Recalls - Deviation management - Change Control - OOS/OOT and investigations - Validation/ Qualification/ Calibration - Sampling and testing of materials - Batch processing records - Materials Management System - HVAC System Site visited: - Manufacturing areas including RPPF Annex (secondary packaging) - QC laboratories - Stability chambers and retained samples area - Warehouses including General Facility Warehouse and Annex building (raw materials, packaging materials, finished products)
Restrictions	N/A
Out of scope	Products not submitted for WHO Prequalification
WHO products covered by the inspection	Ethinylestradiol/Levonorgestrel Tablet, Sugar coated 30mcg/150mcg
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

1. Pharmaceutical quality system

A QMS was established with the major principles, policies and objectives being described in the company's Quality Manual. Senior management responsibilities were defined. Management review meetings were held quarterly in accordance with a written procedure and had a set agenda. Spot-checks on the agenda and the minutes of the April 2022 management review meeting, were made.

Product Quality Review

PQRs were conducted according to a written procedure. The procedure provided details on compiling the annual review and conducting trend analysis. PQRs were compiled on a rolling basis, based on the date the first batch was produced within the review period. A logbook was available to monitor product and manufacturing dates. It was noted that in certain occasions the review period was extended to more than a year because the company used as reference date, the date when the batch was issued (order) and not the date the batch was manufactured or released. The 2022 Levonorgestrel/Ethinylestradiol SC Tab PQR was reviewed.

Change Control

Changes were managed in accordance with a written SOP. They were classified as temporary or permanent and they were categorized as "minor", "major" or "critical", based on impact. A risk assessment had to be performed by QA to identify the areas and level of impact. Effectiveness of the change was checked after implementation within a given timeframe. Several change requests, their implementation and their effectiveness assessment were reviewed and were found adequate.

Deviations

Excursions from established procedures, processes and standards were managed according to a written SOP. Deviations had to be reported and registered as soon as possible and immediate action to mitigate the impact was foreseen. In addition, recurrence of a deviation was checked. Deviations were classified in three categories (critical, major or minor) based on the impact of the deviation. A quarterly review was performed. Applicable CAPA were implemented, and their implementation was monitored.

Quality Risk Management

Risk assessments followed the principles detailed in a written procedure. The risk assessments related to the above-mentioned changes and deviations were reviewed. In addition, risk evaluation of suppliers, the operations related to secondary packaging in the Annex building and storage of excipients in the Main Facility Warehouse were discussed.

2. Good manufacturing practices for pharmaceutical products

Manufacturing processes were generally clearly defined in SOPs and systematically reviewed. Qualifications/ validations, calibrations and maintenance were performed according to prepared protocols and followed the relevant established procedures. Necessary resources including qualified and trained personnel, adequate premises, suitable equipment and services, appropriate materials, approved procedures, and instructions were provided for the current operational level of manufacturing and testing. Master BMRs and BPRs were established and manufacturing steps were recorded in batch manufacturing and packaging records. Examples of BMRs and BPRs were spot-checked during the facility tour.

3. Sanitation and hygiene

There were procedures in place for cleaning equipment and facilities. Premises and equipment were maintained at a satisfactory level of cleanliness at the time of inspection and relevant records were maintained. There was appropriate gowning in all areas for staff and visitors, including instructions on pictorials, hand washing and sanitization before entry to production areas.

4. Qualification and validation

A Validation Master Plan was presented. It included the site's validation policy, approach, and activities, and it described the roles and responsibilities for involved personnel. Validation activities were carried out by a team and were approved by Head QA. A procedure for the management and follow up of qualification and validation activities was in place.

A Validation Status Report was used to monitor equipment requiring re/qualification. A procedure for writing qualification protocols and reports provided the principles that had to be followed in order to compile validation protocols and reports.

The High Speed Wet Mixer and the tablet press re-qualifications were reviewed and did not give rise to any significant comments.

Appropriate instructions for performing cleaning validation activities were detailed in a written procedure. A team was assigned responsibility for the cleaning validation exercise. HBEL acceptable limits were determined and PDE and MACO values were calculated. Before validating a cleaning procedure, a recovery study for both rinse and swab samples had to be performed. The cleaning validation protocol of Levonorgestrel/Ethinylestradiol SC tab was reviewed along with the toxicological reports for the two molecules.

5. Complaints

Reporting and handling of complaints was performed through a centralised system which was applicable to all Renata products and sites. A site-specific procedure was in place describing the actions for registering and handling a complaint. No complaints were received in 2021 and only two complaints had been received for 2022 (at the time of inspection). All complaints were reviewed in detail and did not give rise to any comments.

6. Product recalls

There was a procedure in place describing the actions required to recall a product from the market. Similarly, to complaints, recalls were handled centrally by Renata Ltd for all sites. Based on this principle, a mock recall for 2022 was carried out. The mock recall exercise was performed for one product manufactured in a different facility from the RPPF and was applicable to all Renata sites.

7. Contract production, analysis and other activities

No production and quality control activities with regards to Ethinylestradiol/Levonorgestrel SC tabs were contracted out.

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

Self-inspections were conducted in accordance with a written procedure. According to the procedure, self-inspections were to be conducted twice in a year, preferably every six months. Self-inspections, in special cases such as recalls, repeated rejections, significant number of non-conformances were also addressed in the procedure. Internal auditors were qualified by QA and an approved auditor list was maintained. Review of the self-inspection check list and the annual inspection plan indicated that all GMP areas were covered. Non-conformances were to be classified as critical, major or other, and a report was to be compiled within 15 working days.

Instructions for the qualification of vendors were detailed in a written procedure. The process involved vendor sourcing, assessment using a vendor questionnaire, and review of quality related documents (CoAs, TSE/BSE certificate or declaration, certificate of analysis of materials issued by the manufacturer, availability of material safety data sheet, proof of validation of manufacturing processes, license or GMP certificates).

The SOP further provided for vendor audit to be performed according to risk assessments on the materials (API or excipient) and the manufacturing facility. Ongoing evaluation of vendors was to be performed annually and this involved reviewing the performance indicators for each vendor (i.e., QC test results, presence of rejected materials, OOS reports, and complaints). The criteria for rejection and requalification of vendors were also sufficiently detailed in the procedure. The vendors and risk assessments related to Levonorgestrel and Ethinylestradiol APIs were discussed in detail. In addition, the Vendor tracking sheet for Ethinylestradiol - Annual periodic evaluation for vendors factoring in-quality trend, rejected sample, quantity and percentage of rejection, presence of out of specifications, and critical changes was reviewed.

9. Personnel

There were approximately 670 staff working on site. Personnel were observed to have qualifications in science-based subjects and relevant experience in the respective GMP activities undertaken. The RPPF organogram detailed the various positions and reporting relationships at the facility. There was a list available including the job positions, relevant number of employees and designations. The job descriptions of the Quality Control in-charge, the Head of Quality Assurance, and the Head of Manufacturing were reviewed.

10. Training

The training program was conducted according to the principles detailed in a written procedure. The SOP mentioned different types of training, including induction, on the job, annual refresher training, external training, training of outsiders, retraining, and training when required. Induction training 1, was imparted to all newly recruited personnel and contained basic GMP topics such as personnel hygiene, good documentation practices and data integrity policies, basic health, safety and environment, and quality policy. Induction training 2, was imparted to new staff who held the position of "Executive" or higher; topics included QMS related processes, basic validation approach, document control, and risk assessment.

Job specific trainings in key departmental functions were conducted through an orientation program. Refresher trainings were required in case of scores below the pass mark, prolonged absence from work, deviations, CAPA or change controls. Training effectiveness was assessed through multiple choice questions, oral test and task assignment. Training evaluation sheets were maintained for written tests and for oral evaluations. Trainers were selected based on their education background, previous and current job role, experience and expertise in the related area. A qualified trainer list was available. Spot check on the 2022 annual training plan and records were made.

11. Personal hygiene

The SOP for personal hygiene detailed the requirements for gowning, personnel hygiene and reporting of any illnesses to immediate supervisors.

Medical check-ups were performed according to a procedure. This included initial medical tests and routine periodic tests every six months including tests for exposure to hormones. A registered physician was available on site to conduct medical checks. An offer letter was available and duly signed. A health monitoring check list was presented and included the parameters to be checked.

12. Premises

The RPPF is an independent facility in terms of production, quality control, purified water system, HVAC and other utilities. It is dedicated to the production of hormonal products. However, excipients intended for the RPPF facility could also be stored at the General Facility Warehouse which operated under the QMS of the General Product Facility. In addition, there was an Annex Building where secondary packaging materials and finished goods for the local market were stored, and secondary packaging operations could also take place. The Annex Building was operating under the RPPF QMS. There was also a dedicated area where iron (ferrous fumarate) tablets were manufactured. This dedicated facility was connected to the hormonal area through a bubble airlock. According to the company (SMF), ferrous fumarate tablets were used exclusively as supplement in oral contraceptives packs. Layouts of the facilities were made available. The RPPF comprised of five floors. More specifically:
Ground floor: Core Production Area, Raw Material Warehouse, Secondary Packing Hall, Finished Goods and Secondary Packing Material Staging Area
1st floor: Quality Control Laboratory, Purified Water Treatment Plant, Discharge Station, Utility Service Floor
2nd floor: Secondary Packing Hall 2, Finished Goods and Secondary Packing Material Staging Area 2, Soft Gel Production Area and Injectables (Under Construction)
3rd floor: Office Area, Utility Services and Quality Control Laboratory
4th floor: Laundry Area, Microbiology Laboratory, Product Development, Retention Sample Area, Archive and Utility Service Floor.

In general, premises were constructed, designed and maintained to suit the operations to be carried out and prevent the risk of contamination of materials and products. Receiving and dispatch bays protected materials and products from weather conditions and were separated. Spot checks on rodent traps, insecticutors and their relevant maintenance records were made. Temperature and relative humidity were monitored at production and warehouse facilities.

13. Equipment

Production equipment was of appropriate standards and appeared to be well maintained. Records of preventive maintenance, use and cleaning were maintained. Spot-checks on production balances and differential pressure gauges indicated that equipment and devices were timely calibrated and where necessary verified daily. The workflow in the facility was appropriately designed, and the equipment appeared to be installed to facilitate production and reduce the risk of contamination and mix ups. All production equipment reviewed was identified as to its content or purpose with cleanliness status identified by appropriate labels.

14. Materials

Material receipt operations at the General Facility Warehouse were governed by a different Quality System and followed a different SOP from the QMS and SOP of RPPF. A separate vendor approved list for materials not used in the General Facility was available. Upon receipt of materials at the General Facility Warehouse, they were appropriately labelled and placed in quarantine. QC was informed of the receipt in order to perform sampling, testing and release/rejection of materials. Materials dispensed from the General Facility Warehouse could not be returned.

Packaging materials and finished products in the RPPF Annex warehouse were handled in accordance with a written procedure. Receipt of materials in the RPPF warehouse was performed in accordance with an SOP which provided detailed instructions. A vendor approved list was available and it was updated when new vendors were approved. Temperature sensitive materials were stored in refrigerators.

15. Documentation

There was a documentation system in place and good documentation practices followed the principles described in a procedure. In general, documents were designed, prepared, reviewed and distributed with care. Documents were regularly reviewed and kept up to date. Approved specifications and testing procedures were available for raw materials, packaging materials and finished products. Batch manufacturing records (BMRs) were retained for each batch processed.

16. Good practices in production

In general, production operations followed defined procedures. Detailed instructions for dispensing were included in a written procedure. Logbooks for maintenance, use and cleaning of the dispensing rooms were maintained and spot-checked. Weighing and measuring devices were of suitable accuracy for the intended use. Verification procedures and records for dispensary balances were presented. Dispensed material followed the established material flow. A procedure was in place providing instructions on containing and neutralizing accidental spillage of hormones. Punches and dies were stored in a separate room and records for cleaning and use were maintained. Three coating machines were installed and checks on spray guns were performed before coating operation. There were four primary packaging lines.

17. Good practices in quality control

The laboratory was established on two floors and was appropriately equipped. Procedures for sampling of raw and packaging materials were in place. Sampling of APIs took place in the dispensary while excipients were sampled in the sampling room located at the RPPF warehouse. Specifications for single use sampling tools were established. SOPs for the registration, storage, allocation, analysis and reconciliation of samples both for raw material and finished product were in place and logbooks were made available. On-going stability studies for Levonorgestrel/Ethinylestradiol were reviewed in detail.

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, *Renata Limited, Rajendrapur Potent Product Facility,* located at *Noyapara, Bhawal, Mirzapur, Rajendrapur, Gazipur, Bangladesh* was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

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

4. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4. ***Short name: WHO TRS No. 937, Annex 4***
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

5. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1. ***Short name: WHO TRS No. 957, Annex 1***
http://www.who.int/medicines/publications/44threport/en/

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3. ***Short name: WHO TRS No. 957, Annex 3***
http://www.who.int/medicines/publications/44threport/en/

8. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6. ***Short name: WHO TRS No. 961, Annex 6***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7. ***Short name: WHO TRS No. 961, Annex 7***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2. ***Short name: WHO TRS No. 961, Annex 2***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

14. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

16. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

17. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10. ***Short name: WHO Multisource guidance*** or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

19. 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/

20. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10. ***Short name: WHO TRS No. 1010, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

21. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

22. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
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23. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. ***Short name: WHO TRS No. 1025, Annex 6***
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24. Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. ***Short name: WHO TRS 1033, Annex 2***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations¨

25. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3. ***Short name: WHO TRS 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS 1033, Annex 4***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations