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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	**HLL Lifecare Limited**
Corporate address of manufacturer	HLL Lifecare Limited Mahilamandiram Road Poojappura Thiruvananthapuram - 695 012 Kerala India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Kanagala 591 225 Dist. Belagavi Karnataka India
Unit / block / workshop number	UniPill Block
Inspection details	
Dates of inspection	21 - 25 February 2022
Type of inspection	Real time remote assessment
Introduction	
Brief description of the manufacturing activities	Production and quality control of hormonal oral contraceptive tablets in UniPill Block.
General information about the company and site	HLL Lifecare Limited is a Public Sector Enterprise under the administrative control of Ministry of Health and Family Welfare, Government of India (GOI). The company commenced in 1966 to assist various family planning programs implemented by Ministry of Health and Family welfare, GOI. HLL Kanagala Factory Belagavi (KFB) site produces various products including condom, sanitary napkin, API and FPP in different production blocks.
History	WHO inspection of the site with the first on-site inspection held 16 - 19 January 2017.
Brief report of inspection activities undertaken – Scope and limitations	

Areas inspected	• Pharmaceutical quality system • Production block • QC including Chemical and Microbiological Laboratories • Personnel • Utilities • Materials
Restrictions	• The inspection was restricted to the production of the product listed in the inspection scope. • A placebo product was in operation at the time of this virtual inspection as there was no supply order at the time of inspection. • Access to production and quality control was limited due to the remote assessment and unstable Wi-Fi connection.
Out of scope	Products out of scope of WHO PQ
WHO products numbers covered by the inspection	RH065 Levonorgestrel Tablet 1.5mg (Prequalified) RH096 Ethinylestradiol/Levonorgestrel 30µg/150µg tablets (Under assessment)
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
BSC	Biological safety cabinet
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
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
MR	Management review
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OQ	Operational qualification
PAO	Poly alpha olefin
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
STP	Standard test procedure
TOC	Total organic carbon
TSE/BSE	Transmissible Spongiform Encephalopathy/Bovine Spongiform Encephalopathy
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

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

1. Pharmaceutical quality system

The quality management system was generally established, documented, and implemented. Quality-related activities were defined and documented. The Quality Assurance and Quality Control departments were independent from Production. The persons authorized to release products were specified.

Product Quality Review (PQR)

An SOP for product quality review was available and reviewed. APQR was required to be completed by end of March next year. APQRs of RH065 Levonorgestrel Tablet 1.5mg (Prequalified) for year 2021 and RH096 Ethinylestradiol/Levonorgestrel 30µg/150µg tablets (Under assessment) for year 2019 were reviewed during the inspection. No critical or significant deviation and OOS reported for the products.

Management review (MR)

An SOP for management review and an approved management review meeting minutes were reviewed and discussed.

Quality risk management

Quality risk management was managed according to an approved written procedure. The risk assessment report for process validation of Ethinylestradiol/Levonorgestrel 30µg/150µg film coated tablets was reviewed and found to be generally acceptable.

Change Control (CC)

An SOP for change control was reviewed. The scope of CC management included initiation, review, evaluation, approval, implementation, effective verification and closing of change controls. The procedure was applicable to both permanent and temporary changes and classified as major or minor. A logbook for change control issued in 2020 was available and checked.

Deviations

An SOP for handling of deviations was reviewed and found to be generally acceptable. The procedure described the processes for identification, investigations, approval, and trending of deviations. Logbooks for deviation register in 2019 and 2020 was available and checked. Several deviation investigations and CAPAs were reviewed during the inspection.

CAPAs

An SOP for corrective and preventive action was reviewed. The procedure indicated that it was the responsibility of a cross functional investigation team to establish and document the cause of the non-conformance and to recommend CAPAs. CAPAs for implementation approved by Head of QA. A CAPA Register issued in 2021 was reviewed.

Out of Specifications (OOS)

An SOP for handling of out of specifications (OOS) including chemistry OOS and microbiology OOS were checked during the inspection.

Product release

Product release of finished product was managed according to an approved written procedure. The procedure was reviewed and found to be acceptable in general.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Manufacturing processes were generally adequately defined. The manufacturing processes and procedures were documented in the BMRs and BPRs. Product and processes were monitored, and the results were checked as part of the approval process for batch release.

It should be noted this inspection was performed remotely with a placebo product. The access to manufacturing facility and product production and its visibility were limited. A full on-site inspection should be scheduled in due course when travel is feasible.

3. Sanitation and hygiene

Premises and equipment in the FPP production area appeared to be maintained at a satisfactory level of cleanliness at the time of the remote assessment.

4. Qualification and validation

Validation Master Plan was documented and required review every 5 years.

Process validation

Process validation performed according to an approved written SOP.

The following documents related to Ethinylestradiol/Levonorgestrel 30µg/150µg tablets (RH096) were reviewed:

- Process validation protocol/report
- BMRs and BPRs of PV batches

Equipment qualification

The following equipment qualifications in Production and Microbiology Laboratory were checked.

- Re-qualification of Blister pack inspection system
- Biological Safety Cabinet (BSC)
- Double Door Autoclave
- Temperature mapping of incubator
- Glassware validation

Cleaning validation

Cleaning validation was managed according to an SOP. UniPill Block was dedicated to hormonal oral contraceptive tablets. The cleaning validation was not reviewed in detail due to time constraints and should be followed up in future on-site inspection.

5. Complaints

An SOP for handling market complaints was reviewed. Compliant number was allocated by QA for each complaint. QA performed classification and initial investigation. Complaints classified as critical, major, and minor. Depending on the nature of the complaint, representative samples would be required to be tested; batch records reviewed to identify the root cause and necessary CAPAs implemented. The complaint registers issued in 2019 and 2020 were reviewed and showed no product complaint received.

6. Product recalls

An SOP for product recall was reviewed. Product recall was classified into three classes and time frames from receiving information. Based on the seriousness and legal implications, each recall would be assigned a definite time frame and progress of recall continuously monitored by Head QA. Mock recall performed on in 2021 was reviewed and discussed.

An SOP for handling of returned goods was reviewed. No batches of WHO PQed product RH065 was returned from market in 2020 and 2021.

7. Contract production, analysis, and other activities

No manufacture was contracted out. Some QC testing of API, raw materials, potable, and raw water was contracted to external laboratories. Calibration and validation activities also contracted out to 3rd party service providers. A quality agreement with a testing lab was checked and found to be acceptable.

Pest Control

An SOP for pest and vermin control was available. Pest control was contracted out. An agreement with an external company was checked. A monthly pest control report was reviewed and found to be satisfactory.

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

Self-inspection

An SOP for internal audit was reviewed, which specified the frequency for internal audits by trained internal auditors. Internal audits may be conducted on special occasions e.g., in the case of repeated market complaints, repeated rejection or product recalls.
A list of auditors was in place. The internal audit schedule for 2020, 2021 and 2022 and the areas audited in 2021were checked during the inspection.

Vendor approval

An SOP for contractor and vendor management, a vendor audit schedule, and an audit report for Levonorgestrel API manufacturer were reviewed and found to be acceptable.

9. Personnel

The personnel met during the inspection appeared to be knowledgeable about GMP. Key personnel responsibilities were required to be defined in job descriptions. An organization chart was available and documented.

Number of employees was 90 at the time of inspection. The adequacy of number of personnel, particularly in the production department, suitably qualified by education and training to perform and supervise the manufacture of FPPs, was discussed.

Training

An SOP for employee training plan and procedure stipulated different types of training including induction training, GMP training, On the Job training and On-going training.

Employees, who successfully completed On the Job training, would be allowed to perform his/her assigned duties and responsibilities. Training records (including GMP assessment) for several employees were checked.

10. Personal hygiene

Personnel hygiene observed during real-time remote assessment appeared acceptable. Staff observed in Grade D cleanrooms were dressed in appropriate protective clothing. However, the visibility was poor from the mobile phone camara due to the unstable connection and access limitation.

11. Premises

In addition to UniPill Block, the site had several separate production blocks for API, domestic FPPs, sanitary napkin and condom products. UniPill Block, which is a separate, dedicated facility to products in the inspection scope. A virtual tour conducted on day 3 and day 4 of the remote assessment.

Warehouse

Warehouse areas consisted of the storage areas for raw material, packaging material and finished goods, as well as rejected and recall storage area and sampling room.

Manufacturing

The layout of the facility was appropriate for the manufacture of hormones which included a combination of environmental control systems (HVAC), extraction processes and PPE. A containment system was in place to protect the product, operator, and environment. The layout of the facility allowed for a unidirectional material and personnel flow to avoid contamination/cross contamination and facilitated the required pressure cascades and containment. An isolator was used for sampling and dispensing of API.

Quality Control laboratory

Chemistry and Microbiology laboratory and QA were housed in a separate facility.

Purified water (PW)

Water system comprised of a pre-treatment system, using bore well water as source water, and a purified water generation system. The quality of PW complies with USP specifications. Chemical and microbiological testing of each user point performed in a specified time interval.

HVAC

Adequate ventilation, air filtration and exhaust systems provided to meet the requirement for production of hormonal formulation products. Clean room areas in formulation block meets ISO Class 8 at rest condition.

12. Equipment

Design and construction

The manufacturing block had two equipment lines. Both the lines used for production of commercial scale batches. The difference between two lines is in terms of capacity - one line is smaller in capacity than the other line.

Equipment and instruments used in the manufacture, processing and packing appeared to be of appropriate design, and adequate size to facilitate operations for their intended use, cleaning, and maintenance.

Equipment maintenance, cleaning, and calibration

Equipment numbered and identified for preventive maintenance and calibration as per the standard procedures. All instruments and gauges calibrated periodically as per predefined schedules and Engineering department maintained the records.

Computerised System (CS)

Computerized systems used in QC laboratories, material management and warehouses. The following changes were made since last WHO inspection:

- Installation of a data management system for chromatography systems in QC Lab
- A CS for backup and storage of critical instruments data

These change controls were not reviewed in detail in this virtual inspection due to time constraints.

13. Materials

Incoming materials and finished products quarantined after receipt until released for use or distribution. Starting materials and packaging materials used for the WHO PQ FPP purchased from approved suppliers.

Several material management procedures were reviewed including,

- SOP for non-conformity products and raw materials
- SOP for handling of returned goods
- SOP for waste management
- SOP for handling rejected materials
- SOP for handling and storage of raw material, packing material, solvents and finished goods

Temperature mapping of raw material quarantine storage area was reviewed.

14. Documentation

Per SOP for document and data control, documents maintained by the QA department.QA responsible for the issue, control, and management of departmental SOPs. Standard Test Procedures (STPs), logbooks, record of analysis and other record formats. Documents stored and archived at the same site.

Batch numbering system managed according to an SOP. Batch manufacturing records (BMRs) retained for each batch processed. BMRs of Ethinylestradiol/Levonorgestrel 30µg/150µg tablets (RH096) reviewed found to be generally acceptable.

15. Good practices in production

The manufacturing processes were performed and recorded according to instructions in the batch production records. Currently, very little manufacturing scheduled. During the virtual tour observed the manufacturing of a placebo product batch of Ethinylestradiol/Levonorgestrel 30µg/150µg. The virtual tour in the production area including tablet compressing, coating, and packaging was checked from a distance and visibility was not ideal due to the unstable connection. The production steps should be checked in future on-site inspection.

Reprocessing and Reworking

An SOP for reprocessing and reworking was reviewed. There were no reworking/reprocessing batches reported in APQRs for the products in the inspection scope.

16. Good practices in quality control

Quality Control laboratory is present at site, which carries out chemical, microbiological testing, as well as analytical method validation. A virtual tour of the laboratories conducted on day 4 covered both the Chemistry and Microbiology laboratories. HPLCs and GC were networked with computerised system. The rest of analytical instruments were standalone. QC data integrity and management of the computerised system not checked in detail during this inspection due to time constraints and unstable connection. It should be followed up in next on-site inspection.

Sampling and sample management

SOPs for raw material sampling was reviewed. The hormonal APIs sampled in the sampling and dispensing isolator. Solvents sampled in the sampling booth available in the dedicated solvent storage area. Other raw materials sampled in the sampling booths in warehouse.

Sampling plan for API, excipients and finished product were reviewed.

Sample register for finished products was available and checked.

Testing of starting materials and packaging materials

The testing of the following raw materials and packaging material was reviewed:

- Levonorgestrel EP
- Magnesium Stearate EP
- Purified Water
- Foil-AL

The following SOPs/records were checked:

- SOP for analytical reference numbering system
- SOP for disposal of expired chemicals, left over samples and liquid waste
- Raw material and API sample waste disposal record
- SOP for retesting programme of approved materials

Stability monitoring of FPPs

A range of stability chambers were available at the QC lab. The stability study sample register was spot checked regarding sample quantity and identification of a batch.

Reserve/retention samples

There was a designated temperature-controlled area for storage of retention samples. Retention samples were managed as per SOP for management of reserve and residual samples. The retention sample register was checked.

Microbiology laboratory

Microbiological testing performed and supervised by persons qualified in microbiology. Access to the Microbiology Laboratory restricted to authorised personnel only. Media prepared in-house using PW obtained daily from the Chemistry Laboratory and sterilised in a double door autoclave.

Equipment used for testing was uniquely identified and records of maintenance and calibration schedules maintained.

The following SOPs were checked and found to be generally acceptable:

- SOP for media preparation and maintenance for routine microbiological testing
- SOP for sampling of raw materials and APIs
- SOP for handling, maintenance, and subculturing of microbial cultures
- SOP for performance validation of autoclaves
- SOP for cleaning and operation of biological safety cabinet

Part 3	Initial conclusion – Inspection outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***HLL Lifecare Limited, UniPill Block*** located at ***Kanagala 591 225, Dist. Belagavi, Karnataka, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

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

Part 4	List of GMP Guidelines referenced in the inspection report

1. WHO good manufacturing practices for 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***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

3. 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 No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

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
https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

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
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

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. 961, 957), Annex 1
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

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
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

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
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

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***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

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***
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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
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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
https://digicollections.net/medicinedocs/#d/s20177en/

15. 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
https://digicollections.net/medicinedocs/#d/s20175en/

16. 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

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

18. 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

19. 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***
Essential Medicines and Health Products Information Portal (digicollections.net)

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

21. 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 No. 1033, Annex 4***
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22. 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 TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. 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
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25. Points to consider when including Health-Based Exposure Limits 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 No. 1033, Annex 2**
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26. 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**
9789240001824-eng.pdf (who.int)

27. 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***
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28. 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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