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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	**APL Health Care Limited, Unit-IV**
Corporate address of the manufacturer	Aurobindo Pharma Limited Galaxy, Floors: 22-24, Plot No.1, Survey No.83/1 Hyderabad Knowledge City, Raidurg Panmaktha Ranga Reddy District, Hyderabad – 500 032 Telangana, India Telephone No: +91 40 66725000
Inspected site	
Name & address of inspected manufacturing site if different from that given above	APL Health Care Limited, Unit-IV, Plot No.16, APIIC Multiproduct SEZ, Menakuru Village, Naidupeta Mandal Tirupati District, Andhra Pradesh 524421, India Latitude: 13.902799° N Longitude: 79.821633° E
Unit/block / workshop number	Block A
Inspection details	
Dates of inspection	11-15 September 2023
Type of inspection	Initial GMP inspection
Introduction	
Brief description of the manufacturing activities	APL Health Care Limited manufactures solid and liquid oral dosage forms and topical and nasal dosage forms (non-beta lactam and non-cephalosporin's category of products). The site is named UNIT – IV and is located at Menakuru (V), Naidupeta (M), and Tirupati District (136 Km away from Chennai Airport and 75 Km away from Tirupati Airport).
General information about the company and site	Aurobindo Pharma Limited is a manufacturing company headquartered in HITEC City, Hyderabad, India. The company manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's area of activity includes six major therapeutic and product areas: antibiotics, antiretrovirals, cardiovascular products, central nervous system products, gastroenterological, and anti-allergic.
History	This was the first WHO PQ GMP inspection of the APL. The site has also been inspected by various drug regulatory authorities such as USFDA, INFARMED-Portugal, PMPB Malawi, PPB Kenya, NDA Uganda, Health Canada, MCAZ Zimbabwe, TFDA (TMDA) Tanzania, FMHACA Ethiopia, Ukraine and FDA Philippines etc.

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Pharmaceutical quality system 2. Good documentation practices and data integrity 3. Personnel and training 4. Hygiene and sanitization 5. Production (Block A) and packaging operations 6. Utilities (purified water, air handling units and compressed air systems)
Restrictions	None
Out of scope	The inspection scope was limited to the products submitted for the WHO Prequalification Program manufactured in Block A. The rest of the products and their related areas were out of the scope of this inspection.
WHO products covered by the inspection	HA781Dolutegravir/, Lamivudine/ Tenofovir disoproxil Fumarate 50 mg/ 300 mg/ 300 mg Tablets (henceforth referred to as DLT tablets)
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 airflow
LIMS	Laboratory information management system
MAL	Material airlock

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
PAL	Personnel airlock
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

The site had a formal, documented quality system that met most of the requirements of the current WHO GMP Guidelines. The QA and production departments were independent of each other. The site policies and procedures that were reviewed and discussed during the inspection were generally satisfactory. Product and processes were monitored, and results were considered during batch release. The site has been using several electronic software for the implementation of quality management systems, laboratory information management systems, process pads, share points, training management systems etc. The PQS elements such as product quality reviews, quality risk management, quality review meetings, change management, deviations and CAPA were managed through the approved procedures. The procedure guided how to perform the reviews, investigation, risk assessment etc.

The deficiencies raised in this section have been addressed satisfactorily.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were defined in standard operating procedures. Manufacturing and packaging steps were adequately defined in batch manufacturing records and batch packaging records. The storage and distribution of products ensured batch traceability from receiving to final product and testing. Required resources were available, including adequate premises, equipment, and utilities. Appropriately qualified personnel were employed, and in general, training was performed. Qualification and validation were performed following approved protocols.

APL Healthcare is a multipurpose manufacturing facility that produces pharmaceutical products of different therapeutic areas. In general, the design of the facility was adequate to prevent cross-contamination as most of the processes were closed in nature.

The Production Block-A used to produce DLT tablets was adequately designed. Similarly, a common packaging block was adequately designed and maintained for the packaging of DLT tablets.

The deficiencies raised in this section have been addressed satisfactorily.

3. Sanitation and hygiene

A considerable degree of sanitation and hygiene was in place from the changing room to the manufacturing floor and to the packaging of the final product. The personnel were provided with appropriate gowning at each activity area commensurate with the level of cleanliness. Production equipment was in a clean state, and cleaning procedures for equipment were in place. Containers used for transporting raw dispensed and in-process materials were clean and covered. Production materials were appropriately stored to avoid contamination and cross-contamination. The facility was generally in an acceptable state of cleanliness at the time of inspection.

4. Qualification and validation

The validation master plan was discussed and noted that VMP included validation policy, team, responsibilities, validation approach, qualification and revalidation approaches for facilities, processes, analytical methods etc. The VMP was reviewed once every 2 years or earlier whenever required. Process validation (PV) protocol for Lamivudine portion milled granules was reviewed and based on the protocol, three batches were manufactured for the process validation. Similarly, the process validation protocol for the TDF portion lubricated blend was prepared and three process validation batches were manufactured as part of the PV.

The cleaning validation procedure described the roles, personnel and responsibilities for executing the cleaning validation activities. It was executed through e-Residue-Pro whereby the worst-case product was calculated using solubility, hardest to clean (low cleanability), ADE/PDE and active concentration. With the help of the software, RPN was calculated.

The deficiencies raised in this section have been addressed satisfactorily.

5. Complaints

A corporate QA procedure on the management of product complaints in the automated quality management system software guided managing product complaints. A separate procedure was referenced for handling medical enquiries. The procedure also described the mechanism for handling field alert reports (FAR). The procedure also described the investigation timeline for handling complaints. The complaints were received through the marketing team and classified into minor, major and expedited. A separate procedure was referenced for failure investigation.

The deficiencies raised in this section have been addressed satisfactorily.

6. Product recalls

The company had two SOPs describing recall processes: Product Recall for US Distribution Practices, and Product Recall for all other markets. A Mock recall was to be performed every two years for all different markets including the USA, Canada, Europe, South Africa, and the rest of the world and was described in the Same SOP on product recall.

7. Contract production, analysis and other activities

The qualification of contract testing laboratories was available. The operating procedure included a checklist to be completed by the outsourced laboratory as well as the template for a contract/technical agreement. Responsibilities were adequately defined. It was confirmed that no outsourced laboratories were used for the DLT product. A contract between APL Health Care Limited, Unit-IV and Aurobindo Pharma Limited, Unit-VII, was available, and the tests that were outsourced were listed in this agreement but pertained to other products.

The deficiencies raised in this section have been addressed satisfactorily.

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

Self-inspections covered the entire facility, processes, quality management system etc. Three tiers were described in the standard operating procedure namely Tier I was a self-inspection within a section of a department and performed by the department head, Tier II was in a department and performed by a cross-functional team and Tier III was in a department or site and performed by independent internal audit team of global quality, external consultants, or subject matter experts. The intervals or frequency of self-inspections were determined via a risk assessment considering the complexity of the site and the compliance history of the site based on the data collected from monthly quality review meetings.

The audit schedule for 2022 and 2023 was reviewed and all audits were performed within the time frame provided.

9. Personnel

There were organograms available for the site and other functional departments such as QC, production, and warehouse to ensure that reporting lines between various levels of management, heads of the various departments, supervisors, and operatives were clear. Furthermore, the number of personnel in quality assurance versus production seemed to be adequate.

Job descriptions for the Site Production manager, Senior General Manager QA, and Senior General Manager QC were reviewed. All three incumbents had adequate experience and qualifications to fulfil their respective positions. The job descriptions were electronically signed and were found to be comprehensive and covered all the requirements for the job profiles for the said positions.

10. Training

The company provided induction training for all newly appointed staff and refresher training on concepts of Good Manufacturing and Good Laboratory practices. Training based on the employee's job description was provided as well. Enterprise Platform for Integrated Quality, Learn Intelligence Quotient (EPIQ Learn IQ) was used to schedule, record and assess training activities. Assessment was performed in three ways, namely immediate evaluation using a questionnaire or oral assessment. The passing grade was 80 %. Retraining would be conducted if a grade of less than 80 % was achieved. The second method was a short-term evaluation that would be carried out by the concerned supervisor and training coordinator as per an evaluation template and ratings were categorized as excellent, good, average, and poor. The third method was a long-term evaluation of new employees.

11. Personal hygiene

The procedure for personnel hygiene was as per SOP.

12. Premises

In general, the premises were designed and constructed to suit the operations to manufacture DLT tablets. The layout and design of the premises were logically maintained to avoid the risk of contamination, cross-contamination, and mix-ups. The temperature and humidity were controlled and maintained within the limits of NMT 25°C and NMT 55% RH. The heat-sensitive materials were stored in a cold room with a limit of 2-8°C. During the inspection, it was noted that the warehouse, production, packaging, and laboratory areas were adequately maintained.

The deficiencies raised in this section have been addressed satisfactorily.

13. Equipment

Equipment was adequately designed and maintained to suit the operations to be carried out for DLT tablets. Most of the equipment were installed to minimize the risk of contamination as noted during the inspection. In particular, the company used a pressure transfer system lifting and positioning device to avoid the use of manual and open processes.

14. Materials

The materials were received through the receiving bay, dedusted, and verified before being transferred to the warehouse. Gross weight verification was performed 100% for APIs whereas under root n+1 was followed for excipients. The balances used for the verification of gross weights were not linked with printers and weights were manually recorded on the respective logbooks. The ERP (oracle) was used for material management including the generation of barcodes. The handheld device was used to verify the status of the materials. The warehouse has one sampling area used for sampling active substances, excipients and colours. The sampling area was equipped with separate MAL and PAL. At the time of the inspection, there was no sampling activity carried out. A total of 2 dispensing areas were available and used for dispensing active substances, excipients and colours. Both dispensing areas were equipped with separate MAL and PAL. Dedicated scoops were used for APIs whereas common scoops were used for excipients.
The deficiencies raised in this section have been addressed satisfactorily.

15. Documentation

The QA department was responsible for the revision and distribution of documents and concerned departments are responsible for preparation and initiation of changes in procedures. The document management system module of the automated QMS software was used for the management of Standard operating procedures and Batch manufacturing and packaging records.

The deficiencies raised in this section have been addressed satisfactorily.

16. Good practices in production

The inspectors visited the manufacturing areas through the visitor changeroom. The gowning instructions were provided for entry/exit. The core processing areas were equipped with separate MAL and PAL. The manufacturing area was equipped with three granulation suites (sifter, RMG, FBD, material handling system and lifting/positioning device). At the time of the inspection, DLT was being processed in Granulation Suite 2. In granulation suite 1, a DLT was being processed. The secondary gowning was required before entering the core processing areas. The temperature and relative humidity were monitored using the BMS system by the engineering personnel and it was communicated to the shop floor personnel through phone. The packaging block was equipped with dispensed packing material hold rooms and WIP hold rooms. The area was equipped with 5 bottle lines, 2 blister lines, 2 sachets lines and 1 pouch filling line for the US market. The entire packing activities catered to products manufactured in General Block and Block A.
The deficiencies raised in this section have been addressed satisfactorily.

17. Good practices in quality control

The laboratory was staffed with 327 personnel who were mainly responsible for testing raw materials, in-process products, finished products, stability samples, method transfer samples, method verification samples, chemical testing of packaging materials and laboratory support activities. In addition, the laboratory was supported by 28 laboratory QA personnel. The analyst competency matrix was linked with sample allocation in the LIMS. The LIMS was used for sampling, column, working standards, stability samples and logbook management.
The deficiencies raised in this section have been addressed satisfactorily.

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, ***APL Healthcare Limited Unit-IV***, located at ***Plot No.16, APIIC Multiproduct SEZ, Menakuru Village, Naidupeta Mandal, Tirupati District, Andhra Pradesh 524421, India*** 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***
   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. 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

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

8. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.
   Short name: WHO TRS No. 1044, Annex 2
   TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products

9. WHO guidelines on technology transfer in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 1044), Annex 4.
   Short name: WHO TRS No. 1044, Annex 4
   TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing

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

11. 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***
https://digicollections.net/medicinedocs/#d/s21438en

12. 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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

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

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

15. 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

16. 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

17. 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

18. 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)

19. WHO Recommendations for quality requirements when plant – derived artemisinin 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

20. 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***
9789240020900-eng.pdf (who.int)

21. 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

22. 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

23. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

24. 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**
9789240020900-eng.pdf (who.int)

25. 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)

26. 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

27. 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*** https://www.who.int/publications-detail/978-92-4-000182-4