EDA Public Inspection Report (EDA-PIR) of biological products

Part 1	**General information**
Manufacturers details	
Company information	
Name of manufacturer	*Biological E limited India*
Inspected site	
Address of inspected manufacturing site	*Address: Plot No.1, Biotech Park, phase II, Kothur Village – 500078, Shameerpet, Medchal- Malkajgiri District, Telangana – India* *Telephone number: + 91-40-30213999, 27617831& +91-40-6738 8000* *Fax: + 91-40-27675003 & +91-40-30128159*
Inspection details	
Dates of inspection	*From 9 december to 13 december 2024*
Type of inspection	*Overseas inspection, planned, and announced for preapproval*
Introduction	
General information about the company and site	*Biological E Limited specializes in vaccine manufacturing, encompassing the entire process from drug substance production to the final drug product.* *This includes upstream and downstream processing, blending, formulation, and filling. The company produces vaccines in various presentations such as vials, prefilled syringes, and single or multi-dose formats, utilizing aseptic filling technology for product manufacturing*
Brief report on inspection activities undertaken	
Scope and limitations	
Areas inspected	***1.Blending & Filling Block – Shameerpet site including following building:*** ***A.*** *Block B: Polysaccharide, CRM197 Protein and Conjugation Suites (DS)* ***B.*** *Suite 1,2,3 for blending for drug product* ***C.*** *Line 1,3 for filling finish product* ***D.*** *Building 5 For quality control* ***E.*** *Building 6 for warehouse* ***F.*** *Utilities (Water station &HVAC)* ***Second Manufacturing site - SEZ Unit including following production areas:*** ***A.*** *Suite 4 for blending for drug product* ***B.*** *Filling line No.4* ***C.*** *Warehouse for raw material, consumable, and finished product* ***D.*** *Microbiological laboratory* ***E.*** *Utilities (Water station &HVAC)*

Restrictions	None
Out of scope	*None*
Inspected biological product	*Pneubevax 14, a pneumococcal polysaccharide conjugate vaccine (single-dose and 5-dose presentations).*
Abbreviations	
AHU	*Air Handling Unit*
ALCOA	*Attributable, Legible, Contemporaneous, Original and Accurate*
API	*Active Pharmaceutical Ingredient*
APQR	*Annual Product Quality Review*
BDL	*Below Detection Limit*
BMR	*Batch Manufacturing Record*
BPR	*Batch Packaging Record*
CAPA	*Corrective Actions and Preventive Actions*
CC	*Change Control*
CFU	*Colony-Forming Unit*
CoA	*Certificate of Analysis*
CpK	*Process Capability Index*
CPP	*Critical Process Parameter*
CQA	*Critical Quality Attribute*
DQ	*Design Qualification*
EM	*Environmental Monitoring*
FAT	*Factory Acceptance Test*
FBD	*Fluid Bed Dryer*
FMEA	*Failure Modes and Effects Analysis*
FPP	*Finished Pharmaceutical Product*
FTA	*Fault Tree Analysis*
FTIR	*Fourier Transform Infrared Spectrometer*
GC	*Gas Chromatograph*
GMP	*Good Manufacturing Practice*
HACCP	*Hazard Analysis and Critical Control Points*
HPLC	*High-Performance Liquid Chromatograph*
HVAC	*Heating, Ventilation and Air Conditioning*
IR	*Infrared Spectrophotometer*
IQ	*Installation Qualification*
KF	*Karl Fisher*
LAF	*Laminar Air Flow*
LIMS	*Laboratory Information Management System*
LoD	*Limit of Detection*
LOD	*Loss on Drying*
MB	*Microbiology*
	Microbiology Laboratory

MBL	*Master Formulae*
MF	*Management Review*
MR	*Nuclear Magnetic Resonance Spectroscopy*
NMR	*National Regulatory Agency*
NRA	*Operational Qualification*
OQ	*Process Hazard Analysis*
PHA	*Preventive Maintenance*
PM	*Process Performance Index*
PpK	*Performance Qualification*
PQ	*Product Quality Review*
PQR	*Pharmaceutical Quality System*
PQS	*Quality Assurance*
QA	*Quality Control*
QC	*Quality Control Laboratory*
QCL	*Quality Risk Management*
QRM	*Risk Assessment*
RA	*Root Cause Analysis*
RCA	*Standard Operating Procedure*
SOP	*Total Aerobic Microbial Count*
TAMC	*Total Fungi Count*
TFC	*Thin Layer Chromatography*
TLC	*User Requirements Specifications*
URS	*Ultraviolet-Visible Spectrophotometer*
UV	

Part 2	**Brief summary of the findings and comments**

1. Pharmaceutical Quality System

1.1 Management review *was established, implemented and documented, with written procedures covering essential quality elements being in place. The procedures that were reviewed and discussed during the inspection were generally of an acceptable standard. Production and quality control operations were independently managed and specified in written form. GMP requirements were essentially being met.*

1.2 Product quality review

Product Quality Review is performed to evaluate the performance of product with respect to all quality attributes as per SOP No.100022 for preparation, review and approval of annual product review report, the reviewing carried out by trend analysis of all product quality attributes through statistical and process control tools as per electronic trending software PQR tool according to SOP No. 106648

With the objective of verifying the consistency of the existing process, the appropriateness of current specifications for all Bulk, Final Bulk and finished product to highlight any trends and to identify product and process improvements which were reviewed during audit and found accepted level.

1.3 Quality risk management

The Contamination Control Strategies (CCS) for both sites were determined to be well established and comprehensive, addressing all potential sources of contamination, including premises, equipment, utilities, process flow, materials, and personnel. Each area was systematically assessed, with contamination risks identified and documented in a risk register. Appropriate risk mitigation measures were implemented, and their effectiveness was subsequently evaluated. The deficiency identified by the inspectors was addressed through a Corrective and Preventive Action (CAPA) plan submitted by the company, which was reviewed and found to be acceptable.

1.4 Deviation Management

Deviation management is conducted in accordance with the approved SOP. Deviations are initiated by the relevant department and recorded in the electronic tracking system, after which QA reviews and assesses the deviation report. Deviations are categorized, investigated for root cause, and evaluated to determine appropriate Corrective and Preventive Actions (CAPA). Implementation of CAPAs is monitored by QA, including follow-up through regular trend analysis.

Reviewed Deviation Examples

- *Deviation Example 1: Occurred during process validation and was related to a process parameter deviation. Root cause analysis was conducted using tools such as 5 Whys, Fishbone Diagram, and FMEA, with review of prior batches. Immediate action was taken to halt the process, and preventive measures were implemented, including updates to SOPs, introduction of additional process controls, and refinement of monitoring criteria.*
- *Deviation Example 2: Identified during equipment integrity testing. The CAPA implemented was reviewed and deemed sufficient to prevent recurrence.*

Overall, these cases demonstrate effective implementation of the deviation management system and a commitment to continuous improvement.

1.5 Change Control

The change control system is managed in accordance with the approved SOP and tracked through the electronic system. The process is structured such that change requests are initiated by the relevant user, reviewed by their supervisor, and assigned a unique identifier by QA. QA identifies all impacted cross-functional areas, which assess the proposed change and its potential quality impact. Based on this assessment, necessary actions are determined, which may include regulatory notification, validation activities, training, and internal communications. QA approves the change, establishes an implementation plan, and performs a post-implementation review to ensure effectiveness.

During the inspection, the change control log was reviewed. One change was observed to have an issue, which has been addressed through an appropriate and accepted CAPA.

1.6 Complaints

The complaint handling system is well established and governed by an SOP that defines the end-to-end process. Complaints are categorized as either safety or quality related. Both categories undergo a preliminary assessment within seven days to determine the need for further investigation. Where deficiencies are identified, complaints are required to be fully resolved within 45 days.

During the inspection, example from each complaint category was reviewed, and some deficiencies were identified and covered by acceptable CAPA.

1.7 Product Recall

Biological E has established a comprehensive product recall system defined in an SOP. The procedure describes two types of recalls: voluntary recalls initiated by the company in response to quality or safety concerns, and statutory (involuntary) recalls conducted in accordance with regulatory authority directives. Recalls are further classified into three classes based on urgency: Class 1 (closure within 24 hours), Class 2 (closure within 10 days), and Class 3 (closure within 30 days).During the inspection, recall examples were reviewed and found to be effectively implemented.

1.8 Self-inspection and CAPA managment

Each GMP area/department shall be audited once a year according to annual scheduled plan prepared by the person responsible for QA in December. This scheduled plan covers the four sites (Azamabad,Gaganpahad, shameerpet, sez), after preparation and approval of the plan the audit team will be selected by concerned QA head. Audit team will inspect and review the area /department /documents and verify the practices as per the SOP/checklist. After that compilation of observation by the lead auditor/QA there is a discussion with the auditee. QA head will approve the audit report and CAPAs which will be taken by the concerned departments .In case of critical observations CAPAs it will be finalized within 10 working days with immediate control and impact assessment .All CAPAs taken will be reviewed regularly and trending of all observations and finding will be done by the responsible QA person on a quarterly basis .This process clearly described at the related SOP.

1.9 Quality aduits and supplier's audit

The internal audit system was found to be satisfactory, encompassing audit planning, execution, reporting, communication, and follow-up of findings. Effective CAPA implementation was verified in accordance with the SOP for internal audits. All materials reviewed during the inspection were confirmed to be sourced from approved suppliers, and all suppliers and service providers are evaluated, approved, and qualified in accordance with the relevant SOP. The supplier qualification procedures were in place and demonstrated to be effective.

1.10 Personnel

Organization organogram

Responsibilities of key personnel were described in job descriptions in clear manners. Many job descriptions and related documents reviewed during inspection were well prepared.

Training and qualifications

Training was conducted in accordance with a written procedure, which requires the annual training plan to be developed based on the specific needs of each department. Training is provided through on-the-job training as well as internal and external courses and seminars. Department managers are responsible for planning and ensuring that training objectives are achieved. The relevant training records were reviewed and found to be satisfactory.

Personnel hyiagen

Different hygiene programs were established and adapted to different needs of the facility. Gowning in different stages was found adequate according to the zone and the activities to be performed as per written SOP for gowning & de- gowning.

1.11Documentation *The documentation system was in place, and quality management documents were controlled in accordance with the documentation SOP. A process for periodic document review was established, and overall document control was effective; however, some deficiencies were identified.*
1.12 Batch Release Process *The batch release process is managed in accordance with the relevant SOP, which governs the review of completed Batch Production Records (BPR) and the subsequent release of batches. The process includes the following key steps: completion of the BPR, QA review, issuance of the summary protocol, sampling and testing for the National Regulatory Authority (NRA), and final batch release.*
2. Production
2.1 Drug substance *Upon arrival, materials are inspected and accepted, then stored according to their specified storage conditions. Samples are taken under the same production conditions, and following approval of the assay, QA makes the final decision on material release. Qualified and approved materials are then transferred to the designated qualified products storage area. All materials were found to be properly managed and clearly identified.*
2.2 Fill and finish operations *The sterile bulk was transferred to PP containers for the filling line in accordance with the Master Formula, which also defines the Critical Quality Attributes (CQAs). The fill and finishing operations were observed to be well executed.*
2.3 Visual inspection SOP for visual inspection and related documents were found well recorded and the procedure was well performed.
2.4 Process validation *Process validation at this site confirms that the manufacturing process, when performed within established parameters, consistently produces products that meet their intended quality and performance criteria. Validation was carried out for the blending and filling of the 14-valent Pneumococcal Polysaccharide Conjugate Vaccine (5-dose) and was documented in an approved protocol. Both the protocol and the validation report were reviewed and found to be satisfactory.*
2.5 Reprocessing: NA
2.6 Batch manufacturing record *The Master Formula was reviewed and compared with the Batch Records and found to be complying. The company adheres to the approved and validated manufacturing process.*
3. Facilities and equipment system
3.1 Qualification and validation *Qualifications of HVAC were revised and found satisfactory. and All validation and calibration were conducted in accordance with a pre-defined protocol.*
3.2 Calibration *All equipment is calibrated or validated prior to use and is subject to a scheduled periodic recalibration plan.*
3.3 Maintenance

The manufacturing and laboratory areas at all sites are equipped with the necessary equipment to meet process requirements. Upon receipt, each piece of equipment undergoes an initial clearance process and is assigned a unique identification number. All equipment details are maintained in the QA database, and reviewed examples were found to be satisfactory.
3.4 Water System *The facility has a dedicated system for treating water obtained from the governorate's main supply. The treatment process utilizes reverse osmosis (RO) and RO/electro-deionization (EDI) to produce purified water, which is then used to produce Water for Injection (WFI) and pure steam. Each production area is equipped with a dedicated WFI tank. During the inspection, the most recent trend analysis of endotoxin and microbial results was reviewed and found to be satisfactory.*
3.5 HVAC system *The HVAC system is linked to an electronic Environmental Monitoring System (EMS) that continuously tracks and records critical parameters, including differential pressure (ΔP), temperature, and humidity. Deviations from set parameters are documented and managed in accordance with the relevant SOP. This SOP specifies the monitoring locations and the delay times after which alarms are activated, prompting appropriate corrective actions. During the inspection, several alarm records and the corresponding actions were reviewed and found to be satisfactory.*
3.6 Aseptic process simulation *As part of the manufacturing process validation, aseptic process simulation (media fill) was conducted using media that had been pre-tested for growth promotion with both normal flora and pharmacopeial organisms. Review of the protocol and the most recent report confirmed that the study was acceptable and compliant with the required standards.*
3.7 Cleaning Validation *The cleaning procedures for equipment parts and tools used in blending and filling were validated according to the approved validation protocol. The validation was performed over three consecutive batches and included assessment of cleaning effectiveness as well as evaluation of holding times for both cleaned and soiled equipment.*
3.8 Storage Equipment *Equipment with product-contact surfaces, including vessels, transfer lines, filtration systems, and formulation equipment, is constructed from materials such as SS 316, polypropylene (PP), polycarbonate (PC), or glass, chosen according to product handling requirements. Production equipment is designed for ease of cleaning, employing validated Clean-in-Place (CIP) and Sterilize-in-Place (SIP) systems. Key production equipment for the manufacture of Pneumococcal Polysaccharide (Intermediate), CRM197 (Carrier Protein), Pneumococcal Polysaccharide Bulk Conjugate (Drug Substance), and Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed, 14-Valent) (Drug Product) was available and reviewed during the inspection.*
3.9 Computerized system *The company utilizes several validated computerized systems to manage critical parameters effectively.*
3.10 Environmental monitoring *An environmental monitoring system was in place, designed according to area qualification and tailored to the classification of various areas. Monitoring activities were conducted based on the*

specific requirements of each area classification.
4. Laboratory control system
4.1 Analytical Method Validation *The adequacy of analytical method validation was reviewed, focusing on robustness, accuracy, precision, and specificity. Validated methods are used for routine testing, and comprehensive validation reports are available for all critical assays.*
4.2 Out of Specifications (OOS) *The processes for investigating OOS results were evaluated. The laboratory demonstrated a structured approach to OOS investigations, including documented root cause analysis and implementation of corrective actions.*
4.3 Reference Standard *Compliance with ALCOA principles (Attributable, Legible, Contemporaneous, Original, and Accurate) was reviewed. Data integrity was generally maintained, with audit trails showing no discrepancies; however, a few observations were noted and covered by submitted CAPA*
4.4 Animal house and testing facilities NA
5. Material System *For all materials, including raw materials, excipients, and packaging materials, receipt is followed by inspection and acceptance. Materials are then stored according to their specified storage conditions. Samples are taken under the same production conditions, and following assay approval, QA makes the final decision on material release. Qualified and approved materials are subsequently transferred to the designated qualified products storage area. All materials were observed to be properly managed and clearly identified, and the SOPs for material handling were reviewed.*
6. Packaging and Labelling System *The facility is equipped with an automated packaging and labelling system, and all packaging and labelling operations are performed in accordance with approved SOPs to minimize the risk of mix-ups. Reconciliation of packaging and labelling materials is conducted after each process to prevent misuse. Packaging and labelling materials are stored in a secure area with access restricted to authorized personnel. During the inspection, the traceability and location system of labelling materials were reviewed and found to be compliant. The storage area for labelling materials is temperature- and humidity-controlled, and monitoring of these conditions was verified during the site tour.*

Part 3	**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, (Biological E limited) Located at (Plot No.1, Biotech Park, phase II, Kothur Village – 500078, Shameerpet, Medchal- Malkajgiri District, Telangana – India), was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for biological products guidelines.* • *All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the EDA-PIR, were addressed by the manufacturer, to a satisfactory*	

level, prior to the publication of the EDA-PIR

- *This EDA-PIR will remain valid till next inspection, as long as there is any warning or recall from SRA.*

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-eight Report Geneva, World Health Organization, 2014

Short name: *WHO TRS No. 986, Annex 2*

https://www.who.int/publications/m/item/trs986-annex2

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

Short name: *WHO TRS No. 957, Annex 2*

https://www.who.int/publications/m/item/annex-2-trs-957

3.WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018

Short name: *WHO TRS 1010, Annex 9*

https://www.who.int/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021

Short name: *WHO TRS No. 1033, Annex 3*

https://www.who.int/publications/m/item/annex-3-trs-1033

5.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

Short name: *WHO TRS No. 929, Annex 4*

https://www.who.int/publications/m/item/annex-4-trs-929

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

Short name: *WHO TRS No. 957, Annex 1*

https://www.who.int/publications/m/item/trs957-annex1

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

Short name: *WHO TRS No. 957, Annex 3*

https://www.who.int/publications/m/item/trs957-annex3

8.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
Short name: *WHO TRS No. 1010, Annex 8*
https://www.who.int/publications/m/item/Annex-8-trs-1010
9.Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2
10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022
Short name: *WHO TRS No. 1044, Annex 4*
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf
11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: *WHO TRS No. 1044, Annex 2*
https://www.who.int/publications/m/item/trs1044-annex2
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
Short name: *WHO TRS No. 943, Annex 3*
https://www.who.int/publications/m/item/trs943-annex3
13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011
Short name: *WHO TRS No. 961, Annex 2*
https://www.who.int/publications/m/item/trs961-annex2
14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013
Short name: *WHO TRS No. 981, Annex 2*
https://www.who.int/publications/m/item/trs981-annex2
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
Short name: *WHO TRS No. 981, Annex 3*
https://www.who.int/publications/m/item/annex-3-trs-981

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
Short name: ***WHO TRS No. 961, Annex 14***
https://www.who.int/publications/m/item/tr961-annex14
17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019
Short name: ***WHO TRS No. 1019, Annex 3***
https://www.who.int/publications/m/item/trs1019-annex3
18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015
Short name: ***WHO TRS No. 992, Annex 4***
https://www.who.int/publications/m/item/trs992-annex4
19. 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
Short name: ***WHO TRS No. 961, Annex 9***
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport
20. 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
Short name: ***WHO TRS No. 992, Annex 5***
https://www.who.int/publications/m/item/trs992-annex5
21. 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
Short name: ***WHO TRS No. 992, Annex 6***
https://www.who.int/publications/m/item/trs-992-annex-6
22. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021
Short name: ***WHO TRS No. 1033, Annex 4***
https://www.who.int/publications/m/item/annex-4-trs-1033
23. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016
Short name: ***WHO TRS No. 996, Annex 10***
https://www.who.int/publications/m/item/trs966-annex10
24. 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
Short name: ***WHO TRS No. 1010, Annex 10***

https://www.who.int/publications/m/item/trs1010-annex10
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
Short name: WHO TRS No. 1033, Annex 2
https://www.who.int/publications/m/item/annex-2-trs-1033
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
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications/m/item/trs-1025-annex-6