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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**GCBC Vaccines Private Limited**
Corporate and inspected manufacturing site address	Survey No. 274, Athvelli Village, Medchal Mandal-501 401 Medchal, Malkajgiri District, Hyderabad, Telangana, India
Inspection details	
Dates of inspection	17-21 February 2025
Type of inspection	Routine inspection for Shanchol [Cholera Vaccine (Inactivated, Oral)]
Introduction	
Brief description of the manufacturing activities and General information about the company and site	GCBC Vaccines Private Limited is part of the Gland Group of companies, founded in 1974. GCBC Vaccines Private Limited was established in 2023. GCBC Vaccines Business Domain encompasses the complete spectrum of human healthcare biotechnology by adopting a marketing and CMO (Contract Manufacturing Organization) approach. The manufacturing site of GCBC Vaccines Pvt. Ltd. is located in Athvelli Village, Medchal, North West of Hyderabad (80 Km from the Airport), Telangana. The total area is about 19.3 Acres, with an approximate built-up area of 38133 square meters. GCBC vaccines has acquired in 2024 the manufacturing facility for recombinant vaccines, bacterial, viral vaccines, and other medicinal products from its previous owner, which had previously acquired the facilities in 2009 from Shantha Biotechnics Private Limited, an Indian company founded in 1993 and the first company to develop, manufacture, and market recombinant human healthcare products (Hepatitis B Vaccine – Shanvac-B) in India. Shanchol was transferred to GCBC vaccines under a Business Transfer Agreement. Shanchol [Cholera Vaccine (Inactivated, Oral)] was co-developed with the International Vaccine Institute (IVI), Republic of Korea, was approved in India in February 2009, and was WHO Pre-qualified in September 2011.
History	The site has been inspected by Indian authorities (CDSCO, DCA & CDL). The previous WHO inspection under the previous ownership of the Medchal site occurred from 9 to 13 December 2019.

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Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	- Suite A - Drug Substance - Suite D2 - Formulation - Suite D - Filling, Visual Inspection and Packaging - Suite P - Seed store - Shanchol-related QC labs, storage areas, and utilities
Restrictions	The scope of the inspection was restricted to Shanchol [Cholera Vaccine (Inactivated, Oral)] manufactured at the Medchal site.
Out of scope	Other products than Shanchol [Cholera Vaccine (Inactivated, Oral)] manufactured at the Medchal site
WHO products covered by the inspection	FVP-P-249 - Shanchol [Cholera Vaccine (Inactivated, Oral)] – 1 dose vial
Abbreviations	**Meaning**
APQR	Annual Product Quality Review
APS	Aseptic Process Simulation
CAPA	Corrective Actions and Preventive Actions
CC	Change Control
CCS	Contamination Control Strategy
DP	Drug Product
DS	Drug Substance
EM	Environmental Monitoring
FMEA	Failure Modes and Effects Analysis
FTA	Fault Tree Analysis
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation and Air Conditioning
MB	Microbiology
MR	Management Review
NCA	National Control Authority
NCL	National Control Laboratory
NRA	National Regulatory Agency
OCV	Oral Cholera Vaccine
PHA	Process Hazard Analysis
PM	Preventive Maintenance
PQ	Performance Qualification
PQS	Pharmaceutical Quality System
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QRM	Quality Risk Management
RA	Risk Assessment
RABS	Restricted Access Barrier System
RCA	Root Cause Analysis
SIP	Sterilization In Place

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SMF	Site Master File
SOP	Standard Operating Procedure
TOR	Time Out of Refrigeration
VVM	Vaccine Vial Monitor
WFI	Water for Injection
WHO	World Health Organization

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

1. Pharmaceutical Quality System

In general, the principles of the QMS were adequately described in the Quality Manual, incorporating the Quality Policy. The GMP guidelines were usually followed. Production and Quality Assurance (QA) departments were independently managed, and their operations were described in documented procedures. The responsibility of QA was to ensure that all the operations, which might impact on the quality of product, were fully evaluated, and documented. QA was responsible for mandating GMP. There were procedures in place for the periodic assessment of processes and operations and release of products.

Management review (MR)

Site Quality Management Review was in place. Meetings were held periodically. Site Head and representatives from all departments involved in GxP activities were required to participate. The last meeting minutes were presented.

Product quality review

The previous Annual Product Quality Reviews (APQR) for the specific vaccine were conducted according to the SOP of the previous owner. A new SOP issued by GCBC was in place.

Quality risk management

Quality Risk Management (QRM) was implemented using tools such as impact evaluation, PHA, FMEA, and HACCP. Risk assessments were conducted proactively and reactively, and an annual QRM report was maintained. The list of risk assessments was available and some risk assessments were spot-checked.

Contamination Control Strategy (CCS)

A Contamination Control Strategy (CCS) has been developed for each production suite and was reviewed periodically.

Deviation management

Deviation and CAPA management procedures were in place. Deviations were categorized by criticality and investigated formally. Randomly, some deviations were selected from the logbook and spot-checked.

CAPA management

CAPAs were tracked for effectiveness and closure. Some CAPAs were spot-checked.

Change control (CC)

Change control procedures were in place, with documented evaluations and approvals. Some key change control reports were spot-checked during the inspection.

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Complaints

Procedures were in place for the classification and investigation of product complaints. At the time of inspection, no complaints had been received, as commercial production had not yet resumed. Complaints related to previously manufactured batches were managed by the previous manufacturer under the terms of the Business Transfer Agreement.

Product recalls

Procedures for the management of product recalls, including mock recall simulations, were in place and reviewed during the inspection. No recalls had occurred at the time of inspection, as commercial production had not yet resumed. In accordance with the Business Transfer Agreement, any recall related to batches manufactured prior to the transfer is the responsibility of the previous manufacturer.

Self-inspection

A documented procedure was in place for conducting periodic self-inspections. The annual programme was risk-based, prioritizing departments with higher scores. Self-inspections were led by qualified personnel with prior experience in similar audits. Final reports were required within 15 days of the inspection, and associated corrective and preventive actions (CAPAs) were to be approved within 20 days. All departments were subject to inspection at least once per year.

Management of Suppliers and Service providers

Procedures were in place for the identification, evaluation, and qualification of suppliers. A risk-based approach was applied using FMECA to determine the quality level required for each supplier. The qualification process included a pre-audit questionnaire assessing commercial and technical suitability, followed by analytical testing of samples from three separate batches for critical raw materials. Supplier audits were conducted to assess performance, and corrective and preventive action plans were requested where necessary. A list of approved suppliers was maintained and shared with the warehouse for verification of incoming materials. Annual performance reviews were conducted for both critical and non-critical suppliers. Virtual audits were performed for certain suppliers due to pandemic-related constraints. Corrective actions were initiated to address gaps in audit documentation and quality technical agreements.

Personnel

- ***Organization, organogram, independence of production from quality control***

An organizational chart was available at the time of inspection, showing that the Quality Assurance and Quality Control departments operated independently from Manufacturing. The site employed approximately 232 staff members at the moment of the inspection. Procedures were in place for defining job descriptions for both permanent and temporary personnel. Responsibilities of key personnel, including those in QA and QC, were clearly outlined in documented procedures. Selected job descriptions were reviewed and found to be consistent with the defined roles and responsibilities.

- ***Training***

An adequate number of personnel were assigned to manufacturing, quality control, and quality management activities. Staff interviewed during the inspection demonstrated appropriate GMP knowledge and competency. Training programmes were implemented in accordance with documented procedures. Newly recruited staff received role-specific training prior to commencing duties. Personnel involved in GMP-related operations were required to complete basic GMP training and follow department-specific training protocols. Dedicated gowning areas were available, and facility design supported segregation of personnel and material flow. Training on these procedures was provided and effectively implemented.

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- ***Personal hygiene***

Procedures were in place to manage personnel hygiene requirements. Annual health examinations were conducted by a qualified physician. Behavioural protocols for aseptic areas were defined, including requirements for sterile garment changes, with records maintained. Provisions were also established for the controlled entry of maintenance and service personnel into aseptic areas during maintenance activities.

- ***Qualification of visual inspectors***

Procedures were in place for the training and qualification of visual inspectors. New operators were required to complete a three-step qualification process involving visual inspection of vials, defect identification using a photographic gallery, and evaluation using a challenge kit. Annual requalification was also implemented. Prior to qualification, operators underwent eye examinations by a specialist. The training programme was supported by documented flow charts outlining both initial qualification and requalification steps.

Documentation

A procedure was in place for the management of GMP documents, with defined validity periods and controls for document lifecycle. Obsolete procedures were managed through a paper-based system, and a register was maintained to ensure traceability of document issuance and reconciliation.

Batch Release Process

Procedures were in place for the disposition and release of seed lots, bulk materials, drug products, and clinical study batches. Batch release was performed by Quality Assurance following completion of in-process and final product testing by Quality Control. Documentation for previously released batches was reviewed and found satisfactory. No batches had been released by the current manufacturer at the time of inspection, as commercial production had not yet resumed.

Lot Summary Protocol

Procedures were in place for the preparation and approval of Lot Summary Protocols (LSPs). Following product formulation, samples were tested by the Quality Control laboratory, and a test certificate was issued. The LSP, along with the certificate of analysis, was submitted to the national control laboratory for review. Upon confirmation of compliance, the product was released by authorized personnel. Documentation related to previously released batches was reviewed and found satisfactory.

2. Production System

Production operations were conducted in accordance with defined procedures and validated master formulas. The site manufactured cholera monovalent bulk using heat and formaldehyde inactivation processes. Aseptic processing was performed in classified areas using closed systems and sterile connections. Equipment used for fermentation, inactivation, concentration, and diafiltration was sterilized prior to use, and aseptic connections were made using sterile welding techniques.

Seed lots were managed through a master and working seed lot system, with storage maintained at controlled temperatures. Cleaning validation was performed using swab and rinse sampling methods, and cleaning procedures included both manual and automated approaches. Reprocessing was not permitted unless specified in the master formula.

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Process validation for drug substance manufacturing was completed for all strains, and validation for drug product manufacturing was ongoing at the time of inspection. Aseptic process simulations were conducted biannually for both drug substance and drug product operations. Time Out of Refrigeration (TOR) limits were defined and monitored, although documentation practices required improvement.
Corrective and preventive actions were implemented to address risks related to recontamination, filtration integrity, aseptic connection validation, and documentation of TOR and cleaning procedures.

3. Facilities and Equipment System

The manufacturing site was equipped with dedicated production suites for drug substance, formulation, filling, and packaging activities. Cleanrooms were classified and maintained under controlled conditions, with appropriate airlocks, pressure differentials, and environmental monitoring systems in place. Facility layouts supported segregation of personnel and material flow.

Equipment used in production and quality control was qualified and maintained according to a site-wide validation master plan. Preventive maintenance and calibration programmes were implemented, and records were available for review. Utilities, including purified water, water for injection, and pure steam systems, were validated and monitored. HVAC systems were designed and qualified to support cleanroom classifications and included HEPA filtration and pressure zoning.

Compressed air systems were in place and monitored for microbial contamination. Autoclaves and depyrogenation tunnel were qualified for sterilization processes. Cleaning validation was conducted using swab and rinse sampling methods, and disinfectant efficacy studies were performed for various surface types.

Corrective actions were implemented to address deficiencies in pressure cascade design, cleaning validation coverage, and documentation of equipment reuse cycles and disinfectant validation.

4. Laboratory Control System

The site maintained dedicated laboratories for chemical and microbiological testing, equipped with appropriate facilities for sample handling, reagent preparation, and analysis. Procedures were in place to ensure that materials were not released until their quality was confirmed through testing. Analytical methods for identity, potency, sterility, and other critical parameters were validated and supported by documented protocols.

Reference standards were qualified and stored under controlled conditions. Stability studies were initiated for bulk validation batches, with samples stored under real-time and accelerated conditions. Retention samples for previously manufactured batches were transferred to the previous manufacturer in accordance with the business agreement.

Environmental monitoring was conducted routinely, with defined sampling frequencies and trend analysis. Microorganism identification was performed using automated systems, and personnel monitoring was included in the programme. Out-of-specification and out-of-trend results were investigated according to documented procedures, with defined timelines and root cause analysis.
Corrective actions were implemented to address gaps in sample traceability, reagent management, and alignment of environmental monitoring locations with documented layouts.

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5 Materials Management

Procedures were in place for the selection, receipt, sampling, approval, and control of raw materials, packaging components, and reagents. Materials were managed through an electronic system that tracked status, expiration, and retest dates. Sampling was conducted by Quality Control personnel using a statistical plan, and retest procedures were defined for materials within their shelf life.

The international packing and shipping was validated. The packing and dispatch area was inspected and found fit for purpose.

Storage areas were monitored for temperature, though humidity control required improvement. Corrective actions were implemented.

6 Packaging and Labeling System

Vials were printed with batch-specific information during sealing, and labelling was performed using a high-speed labelling machine. Challenge tests were implemented to verify label accuracy and sensor functionality at key stages of production, including batch changes and equipment interventions.
Secondary packaging was performed manually. Qualification of the labelling equipment was ongoing at the time of inspection. Corrective actions were initiated to ensure completion of equipment qualification and to strengthen operational controls during labelling activities.

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, **GCBC Vaccines Pvt Ltd**, located at **Survey No. 274, Athvelli Village, Medchal Mandal-501 401, Medchal, Malkajgiri District, Hyderabad, Telangana, 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.

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Part 4	List of WHO Guidelines referenced in the inspection report

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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***
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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***
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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***
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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***
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http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

16. 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***
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18. 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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21. 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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