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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	**Meditab Specialities Limited**
Corporate address of the manufacturer	Meditab Specialities Limited, Tower A, 1st Floor, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400013. Telephone: +91 22 2482 6000 Facsimile: +91 22 2482 6120
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Meditab Specialties Limited 352 Kundaim Industrial Estate Kundaim, Goa 403 115 India DUNS: 91-621-2889
Unit/block/ workshop number	OSD manufacturing facility (tablets)
Inspection details	
Dates of inspection	24-28 April 2023
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Meditab, Goa is situated in a government-sponsored industrial park in Kundaim (Ponda) at a distance of 25 km from Panjim, the Capital City of Goa. The industrial park consists of Pharmaceutical Industries, light Engineering and Chemical Industries. The manufacturing facility was started in the year 1998. The site manufactures general category tablets (coated and uncoated) only following the wet, dry and direct compressed granulation methods. The site does not manufacture β-lactams, cytotoxics or hormones.
General information about the company and site	Meditab Specialities Limited is a Cipla-associated company that was established in the year 1998. It is managed by a professional board of directors. It manufactures solid dosage form tablets - coated and uncoated. The corporate headquarters of Cipla is located in Mumbai. Senior personnel from Cipla's HQ are available in Mumbai to provide support to the manufacturing units in the areas of Technology, R&D, Manufacturing, Quality Control, Quality Assurance, Regulatory Affairs, and import, export

	and distribution activities.
History	This was the 6th WHO inspection of Meditab Specialties. The manufacturing site was inspected by the WHO PQ inspection team in July 2019, June 2016, November 2013, February 2011, and January 2009. The manufacturing site was inspected by the Goa State Food & Drugs Administration together with the CDSCO.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Document control system - Job descriptions - Training - Change control - Deviation control - Annual product quality review - OOS investigations - Process validation - Cleaning validation - Quality risk management - Batch manufacturing records - Specifications and method of analysis - Stability studies - Electronic data and audit trail **Site areas visited:** - Manufacturing areas covering warehouse, sampling, dispensing, granulation, compression, coating and packaging, analytical laboratory, and microbiological laboratory. - Air handling units - Purified water system
Restrictions	None
Out of scope	The products not in the WHO Prequalification Program were out of the scope of this inspection.
WHO products covered by the inspection	1. HA352 Efavirenz Tablet, Film-coated 600mg 2. HA353 Lamivudine Tablet, Film-coated 150mg 3. HA060 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg
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
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
MR	Management review
NC	Non-conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications

UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	**Summary of the findings and comments (where applicable)**

1. Pharmaceutical quality system

Meditab Specialities Limited has established a quality management system that ensures that pharmaceutical products are consistently manufactured, according to documented specifications and standards, to establish their quality, safety, efficacy, and purity. The personnel involved in carrying out the manufacturing activities, and supervising the activities had the requisite qualifications and were provided with adequate training, in-house as well as external. Resources were provided in the form of suitable premises, equipment, environment, specifications, and procedures to ensure the proper receipt, storage, sampling, dispensing, processing, testing and distribution of pharmaceutical products in conformity with current codes of Good Manufacturing Practices (cGMP).

Major software systems used at the site:

Name of the Software	Vendor Name	Implemented Since	Purpose of Use
SAP (Systems, Applications and Products in data processing)	SAP AG	Nov. 2014	Enterprise software for managing the business operations/transactions across units (BMR / BPR Preparation, Material management, etc.)
CIPDOX	EMC Corporation	Jul. 2015	Document management system for handling change requests, CQA SOPs, QC Specifications, QC SOPs & IOPs.
CHROMELEONE	Thermo Fisher Scientific	Aug. 2005	For chromatography data management with audit trails.
TrackWise	Sparta Systems	Jul. 2017 Jun. 2020	Deviation / CAPA / Complaint / OOS / OOT / Laboratory Incidence records are being handled through TrackWise software.
LIMS	LabWare Inc.	Jan. 2017	For automation of all major Laboratory operations and real-time data availability.
Track and Trace system	Utopia	July 2013	2 D coding and Batch details overprinting on Secondary packing material as per DGFT requirement.
Aggregation System	Utopia	Aug. 2019	Aggregation between Secondary and Tertiary packing material as per DGFT requirement.

The following quality system elements were reviewed:

Annual product quality review (APQR)
The APQR SOP was discussed. The data were provided by the different departments which were compiled and analyzed by the QA team. The APQRs were performed based on the commercialization of the first batch including the calendar year. The annual schedule was prepared at the start of the year and different products were divided into different months. The review included APIs, excipients, packaging materials, qualification, calibration, and other aspects as defined in the WHO GMP Guide. The SOP cross-references another guidance document for statistical analysis.

The schedules for the period between 2019 to 2023 were reviewed and noted that Lamivudine 150mg tablets were manufactured during this review period and no other WHO products were manufactured during this period. A total number of products manufactured and their respective PQRs were prepared during the above-mentioned review period.

Quality risk management (QRM)
Risk management by failure mode, effect and criticality analysis (FMECA) was discussed. A flow chart of FMECA was part of the procedure starting from identifying potential failure mode, Risk Priority Number (RPN) calculation to identify high RPN, action plan and periodic risk review. The procedure did mention communication of risks to the internal team through quality management review (organized once/month). The FMECA logbook for 2023, 2022 and 2021 was reviewed. In addition, an annual periodic schedule for risk assessment by FMECA was reviewed. Several risks related to products, facilities, equipment and others were identified for the year 2023.

Change control
The SOP on change request was discussed which described the procedure to identify, initiate, evaluate, review, approve, implement and regularize the change in conformance with regulatory requirements. The change request was handled through CipDox (a tailor-made solution) which is also used for the management of SOPs and specifications. In general, the procedure was found adequate.

The deviation handling procedure was discussed. The deviations were handled through the TrackWise system. The deviations were of three types, critical, major and minor. A risk scoring was performed based on the severity of the deviation. The procedure stipulated the timeline for handling the deviations, including the trend analysis. A total of 2 deviations were raised in 2023.

Out-of-specification (OOS) and out-of-trend (OOT) investigation procedure
The procedure has provided step-by-step instructions for the handling and investigation of OOS and OOT investigation. A flowchart was part of the procedure, and the investigation was performed in different phases. If an obvious error was identified during the initial investigation, it will be corrected, and the sample will be repeated on the original sample. If an obvious error was not found, experimentation (hypothesis) and manufacturing investigation would run in parallel. The OOT will be raised based on the defined criteria or when the result was reported out of tired specification (e.g., dissolution or content uniformity). The OOS/OOT was handled through TrackWise QMS.

Laboratory incidence investigation and resolution procedure
The procedure was discussed. The laboratory incidents were handled through TrackWise (after running the sample, any incident identified will be logged in TrackWise) and LIMS (before running the sample, e.g., system suitability failure).

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

Basic principles of good manufacturing practices were described and implemented. Manufacturing processes were generally adequately defined and documented in BMRs and BPRs. Required resources were available, including adequate premises, equipment, and utilities. Appropriately qualified personnel were employed. Manufacturing processes were monitored and documented in batch manufacturing and batch packaging records, in hard copies as well as electronic. Testing procedures were also recorded in data sheets and other electronic devices.

Meditab Specialities Limited has a shared/multipurpose manufacturing facility. The facility produces several products of different therapeutic areas in the oral solid dosage form.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

3. Sanitation and hygiene

The SOP for sanitization was discussed. This SOP provided information on all the disinfectants used in the facility by indicating, the manufacturer, the colour, and the composition. The procedure for the preparation of in-house disinfectants was outlined. The procedure for the cleaning and sanitization of washing areas, drain points and other items was provided. For the various items such as the AHU grills, the cleaning aid to be used, the method of cleaning and the cleaning standards were provided. The SOP for cleaning and line clearance of pharma areas was reviewed. It provided procedures for the batch-to-batch changeover, cleaning of areas after major maintenance, and cleaning of critical areas. Cleaning and sanitization during line clearance after sifting, granulation, raw material dispensing, coating and other procedures were in place. The SOP was discussed which provided a procedure for the procurement of items used for cleaning and the washing of protective clothing and linens.

4. Qualification and validation

Qualification, validation, and requalification were conducted according to established protocols in clear and understandable language. Where possible, the local language was used for instructions and procedures.

The validation master plan was discussed. The document guided the validation and qualification activities related to process validation, computer system validation, analytical method validation, air handling units, and water systems including periodic review. The quality assurance department was responsible for coordinating the validation activities and preparing the schedule of various activities. The process validation was executed following three stages. The periodic review was carried out once every

three years by verifying critical process parameters during periodic verification. A validation schedule for the year 2023 was available which included a periodic verification schedule for process validation, cleaning validation, equipment, and utilities. The periodic verification schedule for cleaning validation for all equipment was available. This was tracked following the production schedule received from the manufacturing department.

Process validation and periodic review
The SOP for process validation was reviewed and noted that a three-stage concept was required to validate the process. The procedure also stated how processes have to be validated for legacy products where relevant studies (e.g. pilot and commercial batches) were not available. The SOP for ongoing (continued) process verification was reviewed and noted that Continued Process Verification (CPV) was carried out for finished products manufactured for commercial purposes. A trend limit was established for Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs) from 30 batches. The CQAs were monitored through LIMS whereas CPPs were monitored through the SAP system.

Analytical method validation was performed by Cipla, and the validated method was transferred to Meditab Specialties. The analytical methods related to assay, related substances, and dissolution for Lamivudine 150mg tablets had been validated.

The SOP for cleaning validation and establishment of worst-case products was discussed. It was noted that the worst-case was decided based on solubility, potency, and toxicity. The worst-case was calculated based on dose criteria (maximum daily dose), 10 ppm criteria and PDE criteria.

Validation of computerized systems was discussed and noted that the extent of validation was dependent on the complexity and criticality of the computerized system. The software were broadly categorized into Category 1, 3, 4 and 5 wherein Chromeleon software comes under non-configured products (Category 1), LIMS, SAP (Category 4, configured products) and Category 5 customized applications. Category 5 was required to undergo a rigorous assessment of quality and performance during validation.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

5. Complaints

The company had put in place a robust system to ensure that complaints on their distributed products could be communicated to them, and for investigations to be conducted. Consequently, in the event of a recall, a tested and proven system for an effective recall was in place. The procedure for handling the complaint, SOP was reviewed. The scope of the SOP covered the local market as well as the export market. The procedures for receiving complaints were emails and phone calls. All received complaints were sent to the company's complaint and drug safety mail address. Complaints were divided into critical and non-critical, as determined by a team of quality and technical experts. A rapid alert procedure for complaints of adverse events which were fatal was provided. The procedure accounted for details on how to log complaints into the track-wise software. Complaints dealing with quality, purity and identity issues were termed as technical complaints, those which deal with issues of adverse events such as dizziness, nausea and their likes were termed medical complaints whilst complaints which constitute both were termed as technical and medical complaints. To deal with complaints, a cross-functional investigation

team was formed to evaluate the complaints concerning sterility breaches, patient safety, and field alerts. Root cause analyses were conducted and for critical complaints, a decision should be made within a day.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

6. Product recalls

The procedure for the handling of the recall, SOP was reviewed. The scope covered drug products manufactured by Cipla for both local and export markets. Recalls were initiated based on product complaints, OOS, deviations, batch failure, stability failure, market surveillance and pharmacovigilance reports. Before the decision to perform a recall was made, a quality alignment meeting was held, after the finalization of the investigation. If a recommendation was made for a recall to be considered based on the decision of the quality alignment meeting, a recall committee meeting was called by the coordinator in charge of recall. Recalls were put into three classes, Class I, Class II, and Class III, based on the degree of injury the product can cause to a patient/user. Also, three levels of recall were identified, level I, level II, and level III, based on the extent of the recall. For level one, the recall activity extends to the reach of wholesalers, level two extends as far as the retailers whilst level three extends further to consumers/patients. The procedure for mock recall was guided by a validated mock recall protocol.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

7. Contract production, analysis and other activities

The SOP for contract analysis was discussed. The scope of materials covered for the contract analysis were raw materials (API and excipients), packaging materials (primary and secondary) as well and intermediate materials. A contract analysis request form, annexure SOP and contract laboratory analysis register, annexure SOP were provided. Records captured in the register among others included the name of the contracted laboratory, product details (product name, batch/lot number, AR/sample ID), description of the test, the date the sample was sent, and the name of the analyst who sent the sample. This document was reviewed by the appropriate head of the unit. The date on which the report of analysis was received by Meditab from the contracted laboratory was recorded. These laboratories were audited, and the audit reports were available and reviewed. Quality test agreements were signed by both the contract giver and the contract acceptor, with details of their responsibilities clearly outlined. Validity periods for each contract were indicated.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

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

The SOP for self-inspections with a scope covering manufacturing, testing, packaging, storage, and distribution of products was reviewed. The procedure did not permit any personnel, certified to conduct self-inspections to audit his or her unit or department. Thus, auditors must be independent of those having responsibility for the area being audited. Self-inspections were conducted at least once a year. The planning and scheduling were done based on the risk categorization of operations and processes. Some of the elements considered in the categorization, were the complexity of dosage form, previous compliance level of area to be inspected, and complexity of process involved. A consolidated self-inspection

schedule for Cipla sites including Meditab was reviewed. An audit scheduled for the 27th to 28th of December 2022, covering the six systems of cGMP was carried out as per schedule.

The SOP for vendor audit management was reviewed. The scope covered all raw materials as well as packaging material vendors, including critical consumable items. Vendor selection, evaluation and approval were guided by the SOP. A yearly onsite audit schedule was generated in the track-wise software. The frequency of audit was guided by a risk rating of individual vendors as per SOPs numbers. Personnel who conducted audits on behalf of Meditab were duly qualified. Audits were planned, executed, and reported. CAPA responses from auditee companies were reviewed, with follow-up evaluation before they were closed, and a decision was made on the vendor.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

9. Personnel

The total number of personnel employed at the site was one hundred and fifteen (115). Fifty-one (51) oversaw quality function, forty-five (45) oversaw production, six (6) oversaw stores, eleven oversaw engineering and two (2) oversaw finance. An organogram was in place for the corporate, site, as well as the various functional areas like quality and production. The organogram for the site was prepared, approved, authorized, and signed. The head of the site who reports to the corporate head-Executive Vice President and Cluster Head API/Formulation and Manufacturing, receives reports from the site heads responsible for, engineering, production, quality control, and other functions. They in turn receive reports from the heads of units responsible for, production, quality control, engineering, etc.

The SOP for the organizational chart and job responsibilities was reviewed. It discussed the job responsibilities for the quality function, the manufacturing function, warehousing, engineering, information technology, and various other functions. The job responsibilities of three managers were reviewed.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

10. Training

The training procedure and SOP were discussed. The procedure ensured that new employees were given induction training on the quality policy, company policy, safety and occupational health and environment, data integrity and basic cGMP. Personnel training needs were identified, and training schedules were provided to address those needs. Presentations for training were approved before the conduct of training. Training instructors were certified. Criteria for certification of the instructors was provided and a certified instructor had to attain a minimum score mark of 70% when evaluated. A qualified instructor who had not conducted any training for a period of two or more years had to be re-certified before he or she was added again to the list of qualified instructors.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

11. Personal hygiene

The procedure for handling personnel health and hygiene was guided by SOP. The SOP was reviewed. A pre-employment medical examination was conducted by a certified medical practitioner, whose certificate was available. An annual examination was conducted for all personnel based on the minimum health requirement list, provided in the document. These tests included X-ray, electrocardiogram (ECG), blood group, blood cell count as well as urine and skin. The procedure disallowed personnel with infectious diseases into manufacturing areas and pregnant women were prohibited from areas where materials were exposed. Personnel hygiene directives in pictograms and SOPs were posted at entry and exit areas. Cosmetics, artificial nails, jewellery, rings (nose and ears), bungles, wristwatches, false eyelashes and nail polish were prohibited in the production area. Eating, drinking, and chewing were prohibited in changing rooms, storage areas as well as production areas.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

12. Premises

The premises of Meditab was designed, constructed, and maintained purposely to carry out the manufacturing of pharmaceutical products. The design afforded the logical movement of personnel and materials to avoid contamination and cross-contamination. Pass boxes were in place for the transfer of materials from one processing area to the other. However, no such arrangement was provided for material movement from the granulation area into blending room II. Floors were clean, and smooth and wall-to-floor corners were coved to enhance cleaning.

Dedicated areas were provided for storage, sampling, weighing, and dispensing of materials. Measures were in place to reduce dust. Entry into the manufacturing area was controlled and measures were in place to prevent the ingress of insects and other pests. An area for the storage of rejected materials was provided. Inside the production floor, dedicated areas were provided for the storage of raw materials, processed materials, finished products, packaging materials and equipment spare parts. Areas for the cleaning of equipment and storage of clean equipment were in place. On the production floor, dedicated rooms were allocated for processing operations such as sifting, binder preparation, granulation, blending, compression, coating, and inspections. Processing areas were provided with appropriate conditions of humidity and temperature by means of the AHU system. The differential pressure between processing areas and corridors were monitored by magnehelic gauges and the temperature and humidity condition were monitored by thermohygrometers. However, these thermohygrometers in some areas were old fashion. The area for packaging was designed and divided into seven packaging lines which were appropriately segregated to prevent mix-ups.

The quality laboratory was separated from the manufacturing area. Separate and dedicated areas were provided for training, chemical testing, instrument room, titration room, stability and working standards room, wet zone, hot zone, microbiology, and reserve samples room.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

13. Equipment

The equipment used for manufacturing was of the required material quality and was qualified and maintained by a planned preventive maintenance procedure SOP. The scope of the SOP covered all equipment and instruments related to production, packaging, storage, QC, and service areas. All equipment and instruments were categorized into critical, non-critical and non-critical unclassified based on an assessment matrix for criticality. The elements of assessment included process safety and criticality, usage of the equipment, standby equipment availability, critical spare parts availability, and the availability of service engineers.

The annual plan preventive maintenance schedule for compression and coating equipment for the years, 2022 and 2023 were discussed. The records of maintenance for the compression machine in cubicle IV were available in the document number. The various areas of maintenance were indicated such as oil leakage and vibration noise. Maintenance records for combo de-duster cum metal detector, and neocota were available in the document.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

14. Materials

A receiving bay was provided for the receipt of raw materials as well as packaging materials. The bay was equipped with a weighing balance, and equipment number, which was calibrated on 01/04/2023. Daily verification and monthly calibration were done. A dedusting area had a vacuum cleaner and lint-free material for the cleaning of receipt goods before entry into the storage area. The humidity and temperature of the storage area were monitored. Three areas in a compactor were allocated for the storage of quarantine goods. Materials were stored in an orderly manner.

The SOP in place for the receipt of materials was discussed. A checklist for assessing the integrity and seals of materials received was as per document number. Purchase orders, invoices challans, vehicle identification as well as supplier of goods were verified before receipt of materials. The confirmation of vendors was through SAP. Further checks included the name of the supplier, availability COA and the intactness of the seal which was verified by comparing it with the available seal album.

Storage areas were cleaned and well-maintained. In general, adequate space was provided for the storage of raw materials, in-process materials and finished products. However, some in-process materials were stored in the corridor of the manufacturing area. Materials at the storage areas were segregated into quarantine, under test, sampled for analysis and released. Each material had its name, batch number, manufacturer and or supplier name, number of containers in stock, manufacturing as well as expiry dates indicated on them. The receipt records of the sodium starch batch were reviewed, and the product was received from an approved vendor.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

15. Documentation

Document control procedure SOP was discussed. Documents were classified into four levels. Level I document, comprised of Quality Management and Quality Manual. Level II documents, comprised corporate master documents and others like validation master plans, master study protocol specifications, and SOPs for corporate quality. Level III documents comprised unit-level master documents, SOP for specific operations, cleaning, maintenance, master batch manufacturing records, master batch packaging records, and local language procedures. Level IV documents comprised filled logbooks, and QC test data sheets etc.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

16. Good practices in production

The manufacturing area was located on the ground floor and the following areas were visited:

- Sifting and granulation 1 housed Rapid Mixer Granulator, FBD, sifter and multi-mill
- Blending area
- Storeroom for granules
- Compression and coating area
- Manual inspection of tablets
- Primary packaging area

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

17. Good practices in quality control

An organogram was in place for the management of the quality control laboratory. Reporting lines start with team members of the various sections in the QC laboratory, who report to the sectional heads, the sectional heads report to the unit head, the unit head report to the site head and the site head report to the head of operation quality. The head of operation quality reported to the Head of Global Quality. Head Global Quality reported to the Managing Director and Global CEO. The functions of QC were available and independent of other departments. There was total independence between the QC and production. The benches at the QC were clean and smooth as well as the floor. Dustbins were provided at appropriate places for the collection of waste. Adequate storage areas were provided for the storage of samples and laboratory reagents. The temperature and humidity conditions were controlled and monitored. The facilities provided for carrying out the analysis were adequate. At the instrumentation room a total of 10 HPLCs were provided, two of them were under requalification at the time of the inspection. Other instruments were an automatic potentiometer, IR, UV, and balances. Various other equipment was provided in microbiology and other areas.

Microbiology lab

At the microbiology laboratory the growth promotion test conducted on media, received on 28/03/2022 and first opened on 17/05/2022 was reviewed and found satisfactory.

Stability studies

Two walk-in Stability chambers for 30˚C and 65% RH and 25˚C and 60% RH were available in the stability room.

Retention samples

A dedicated area provided for the storage of reserve samples (finished products and raw materials) was biometric access controlled. A list of authorized persons permitted to access the area was posted at the door. A reserve sample location chart was at the post. The humidity and temperature were controlled and monitored.

The deficiencies were addressed satisfactorily and the same will be verified during future PQ inspections.

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, ***Meditab Specialities Limited***,located at ***352 Kundaim Industrial Estate, Kundaim, Goa 403 115, 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-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   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 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

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

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

5. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

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

7. 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://www.who.int/publications/m/item/Annex-8-trs-1010

8. 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 (WHO Technical Report Series, No. 1019), Annex 2.
   Short name: WHO TRS No. 1019, Annex 2
   https://www.who.int/publications/m/item/trs1019-annex2

9. 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 (WHO Technical Report Series, No. 1044), Annex 4.
   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

10. 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

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://www.who.int/publications/m/item/trs943-annex3

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