World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
of the Quality Control laboratory

Part 1	**General information**		
Laboratory Details			
Name	Vimta Labs Ltd, Life Sciences Facility		
Address	MN Park (Formerly Alexandria Knowledge Park) Plot No 5, Genome Valley, Shamirpet Mandal Hyderabad, Medchal-Malkajgiri District, Telangana 500 101, India		
Inspection details			
Date of inspection	13-15 March 2019		
Type of inspection	Routine		
Introduction			
Brief description of testing activities	*Type of analysis*	*Finished products*	*Active pharmaceutical ingredients*
	Physical/ Chemical analysis	pH, Color test, Polarimeter, Density, Loss on Drying, Water Content, Disintegration, Dissolution, Uniformity of dosage units (mass content), Friability, Tablet Hardness, Particulate matter test, melting point, XRD, DSC, FT Raman, TGA, PSA, AAS, Particulate count, Water activity, Osmolality, Viscosity	pH, Density, specific optical rotation, viscosity, Loss on drying, Melting Point, Water Content, Heavy metals, Sulphated ash, Acid insoluble ash, Acid value, Iodine value, Ester value, Acetyl value, Peroxide value, XRD, DSC, FT Raman, Particle Size Analyzer, AAS, TGA
	Identification	HPLC (UV Vis), GC, (FID, ECD) GC/MS, TLC, UV-VIS Spectrophotometry, IR, AAS, XRD, DSC, FT Raman, LCMS, IC, SDSPAGE, Western blot, Iso-electric focusing, Intact mass, Charge variant analysis, Glycan profiling,	HPLC (UV Vis), GC (FID, ECD), TLC, UV-VIS Spectrophotometry, IR, FTIR, AAS, Chemical reaction, XRD, DSC, FT Raman, LCMS, IC, SDS-PAGE, Western blot, Isoelectric focusing, Intact mass, Charge variant analysis, Glycan profiling,

		Disulphide mapping, Bioassays	Disulphide mapping, Bioassays
	Assay, impurities and related substances	HPLC (PDA, Fluorescence, RI, light scattering detector), GC (FID, ECD), TLC, HPTLC, UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC.	HPLC (Fluorescence, PDA, RI, light scattering detector),), GC (FID, ECD), TLC,UV-VIS Spectrophotometry, AAS, Volumetric titrations, Potentiometry, Nitrogen Assay, UPLC.
	Content	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, DSC, RP-HPLC (PDA, RI and FLD), SECHPLC (GPC), ELISA	FT Raman, XRD, TGA, DSC, LCMS, IC, ICPMS, ICPOES, GCMS, RP-HPLC (PDA, RI and FLD), SEC-HPLC (GPC), ELISA
	Micro-biological tests	Sterility test, Microbial Limit Test, Bacterial Endotoxin Test (gel clot), Microbial Assay, Anti-Microbial Effectiveness Testing	Microbial Assay, Microbial Limit Test, Bacterial Endotoxin Testing and Sterility
	Stability studies	Storage and testing as per client's Protocol based on ICH Guidelines	Storage and testing as per client's protocol based on ICH Guidelines.
	Others	Growth Promotion Testing of Media, Disinfectant Efficacy Evaluation, Invitro Microbial Kill Rate Study	
General information	Vimta Labs Limited (hereafter Vimta) was established in 1984 as a Partnership Firm and then converted to a Limited Company in 1991. Vimta Ltd consists of 18 sites, including Headquarters, Life science facility, 8 Food Testing Branch labs, 7 Clinical Diagnostic Branch Labs and one Environment Branch Lab, with total of 1083 employees at the time of inspection.		
History	A list of regulatory inspections since 2014 was provided. The facility was inspected by various authorities, including CDSCO, EMA, USFDA, MoH Ukraine, NGCMA. The laboratory was inspected by WHO as part of Pre-qualification of Medicines Program – Inspection of Quality Control Laboratory on August 2013, December 2010 and April 2008.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	Management & Quality Management System Documentation and Records, including data processing and archiving Personnel & training		

	Premises and Equipment including Validation, Qualification and Calibration Contracts Method validation and verification Laboratory Practices, including evaluation of test results Safety Reference standards – Reagents - Water
Restrictions	Not applicable
Out of Scope	Only divisions involved in quality control of pharmaceutical products were in the scope of inspection.

Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GC	Gas chromatography or Gas chromatography equipment
GMP	Good manufacturing practices
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
KF	Karl Fisher titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
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
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometry or spectrophotometer

Part 2	Summary of findings and recommendations

1. Organization and management

The laboratory had defined the organization and management structure of the laboratory; responsibility, authority and interrelationship of the personnel in the laboratory's organogram with issue no 17, approved on 17 Oct 2018. The part which was in the scope of inspection consisted of AVP-Drug & Pharma and AVP-AL (Trace). The QA unit independently reported to the Managing Director.

The total number of Quality Control Laboratory staff accounted to 578 at the time of inspection. The laboratory was since 2013 headed by Mrs. Harita Vasireddi and comprised of 4 levels, divided in the following sections:

- Samples accession
- Archives
- Ultra-Trace Laboratory
- Physical Characterization
- Trace Analysis Laboratory
- Industrial Chemistry
- Food and Water Laboratory
- Drug Laboratory
- Contract Laboratory
- Biopharma
- Microbiology Laboratory

The laboratory was accredited by NABL, India (National Accreditation Board for Testing and Calibration Laboratories) as per ISO/IEC 17025/2005 on January 2019 in the areas of Chemical, Biological and Mechanical Testing. Chemical Testing, Biological Testing and Mechanical Testing bearing Accreditation Certificate No. TC-5418. The laboratory was also licensed to test Drugs and Pharmaceuticals by the Drug Control Administration, Govt. of Telangana, India.

The laboratory ensured that its management and personnel were not subjected to commercial, political, financial and other pressures or conflicts of interest that may adversely affect the quality of their work and had a policy in place to ensure the confidentiality of information contained in the analytical and relevant reports.

Laboratory working hours were established between 9:00 – 18:00, including the 2nd, 4th and 5th Saturday, i.e. not the 1st and 3rd of every month.

2. Quality management system

A comprehensive Quality Management System was documented in three levels: QM/MSD (Management System documents) Level 1; Management System Procedures (including policies) Level 2; and SOPs/forms/formats Level 3. These defined the quality management system including change control and trending analysis and was appropriate for the scope of activities, complying with the requirements stipulated for a Quality manual.

The activities of the laboratory were systematically and periodically audited internally. Management reviews were performed annually, covering audit reports, complaints, and non-conforming work. Amongst others, a detailed trending analysis in accordance with SOP for OOX and trending and tracking of laboratory investigations and unplanned deviations, including Trend Report dated 12 Mar 2019 were available and reviewed. Trend analyses were addressed in SOP for Deviations and investigations.

The laboratory participated in proficiency testing schemes. The necessity of external laboratory quality control (PT) was mentioned in the Management System Procedure for Assuring quality and further elaborated in SOP for Assuring quality of test results. Allocation of PT samples was in accordance with SOP for Sample pre-registration and registration. Furthermore, a proficiency testing plan (PT plan) (2017-2020) for both physico/chemical and microbiological testing was available which was arranged by topics. The laboratory was required to ensure that the PT plan would cover the major parameters in each group under the relevant discipline. Nevertheless, a detailed scheme for participation in appropriate proficiency testing was not provided.

The Change control procedure was inspected by review of the change control documentation provided for the Change control event regarding restructuring of the sterility facility located in level 4, in accordance with the proposed layout. An evaluation was carried out on 1 Oct 2014 to verify the adequate completion of changes/modifications. Each change control was assigned a number in the logbook for chronological registration of the event.

SOP for Handling of complaints was established and implemented to deal with complaints. A logbook was used to record the complaints in a chronological order. Errors in final reports were also recorded in the same logbook.

The deficiencies identified on the quality management were adequately addressed in the QCL's CAPA plan.

3. Control of documentation

The laboratory incorporated the SOPs in the DMS data-system to control all QCL related documents, i.e. preparation, revision, distribution, return and archiving. Some of the common SOPs, applicable to the entire organization were still in paper format. Currently, an Excel sheet was used to keep the overview of the SOPs and their revision date. Control of documentation was managed by SOP for Development and Management of procedural documents. Issuance of logbooks and forms was managed by QA based on a request from the respective department in accordance with SOP for Controlled issue of logbook and forms.

A master list identifying the current issue no. status and distribution of documents was available. Each controlled document had a unique identifier, issue number, date of implementation and reference to the previous issue number. The documents were authorized by the QA-Head. Once authorized, two copies were provided, i.e. a controlled and a master copy which were kept by the QA unit. A Work copy was available at the relevant location based on a distribution list. An SOP was in place comprising the authorization for copying and the identification of copies from official and controlled documents. A notification was sent to the relevant staff once the SOP was issued/revised and a training session was organized in case of major changes which were identified by a new issue number. The personnel recorded their attendance by signature, in accordance with SOP for Training.

The compliance of the issuance of forms by QA was verified by random review of templates used for laboratory activities.

4. Records

Records of analytical tests were properly documented, including calculation and derived data, method validations/verifications, instrument use, calibrations and maintenance and sample receipt in bound logbooks containing consecutively numbered pages from 1-50. The records were complete and signed, alterations were commented on, and references were made to the appendices containing the relevant recordings, e.g. chromatograms and spectra.

Records were kept as comprehensively described in the applicable SOP in an archive consisting of multiple rooms on both sides of a corridor, with fire resistant doors and automated fire or smoke detection systems and subjected to fortnightly pest control and housekeeping. Access to the archive was restricted to authorized personnel, and keys were kept by only the archivist and the chairman.

5. Data processing equipment

An inventory of all computerized systems dated 14 Mar 2019 was available with name, issue no, and purpose of the software.

Records on hardware configuration, installation and changes (incl. software updates) were kept for computerized systems which were components of test equipment. Performance Qualification was generally done jointly by vendor and the laboratory. Electronic data was protected from unauthorized access.

EMPOWER chromatography data software which was a component of HPLC equipment was randomly selected to verify the software's user specific access and audit trail option. Access rights were described in SOP with four user groups. Privileges were allocated based on each category's designated activities. The privileges for Analyst® were also verified. The Audit trail was reviewed after each run by QA-designated staff. Manual integration was allowed but were required to be investigated and approved by QA unit, in accordance with SOP for Procedure for Manual integration, and a logbook was assigned to record the respective data. Manual integrations were infrequent. The most recent one took place on 22 Jan 2018. The record displayed that the respective manual integration for a base to base integration was requested by the customer.

Procedures were established and implemented for making, documenting and controlling changes to information stored in computerized systems. Computer generated, time-stamped audit trails for electronic records were maintained and reviewed.

Electronic data was backed up at appropriate regular intervals according to a documented procedure. Backups were carried out every 15 days or upon completion of projects, on tapes in accordance with the respective SOP. Automated backup was carried out when the system was connected to the HP storage through server, e.g. backup for LIMS. Suitable tapes were deployed for backup purposes. Restoration of backed up data was performed once a year based on a IT service request form, and was supported by restoration evidence.

Concerning spreadsheets (e.g. Excel®), all cells including calculations were locked so that formulas could not accidentally overwritten. Free access was only given to cells to be filled in with data. Project specific Excel sheets were prepared by the QCL and generated/implemented in the respective system application. However, a new project was initiated to prepare the Excel sheets which were applicable to the laboratory activities, in cooperation with the organization's SAS-team to validate the Excel sheets by using SAS program. A report for the preparation, qualification and usage of Excel sheets for different Excel sheets was approved by QA on 12 Mar 2019 and Excel sheets were stored in a folder accessible to the intended users. Preparation of other necessary Excel sheets was in process.

SOP for Master validation plan; Vimta Life Science (Analytical division) was available and reviewed, including plans for validations in 2019, calibration schedule and list of software with date of re-evaluations.

The deficiencies identified on the data processing were adequately addressed in the provided CAPA.

6. Personnel

The laboratory had sufficient personnel with the necessary education, training, technical knowledge and experiences for their assigned functions. Training of Staff was assessed on completion of the training, with an acceptable score of 80 %. The Laboratory maintained current job descriptions (JDs) for all personnel involved in tests and/or calibrations, validations and verifications. Records of all technical personnel, describing their qualifications, training and experience were maintained in their own folder. Randomly selected CVs and JDs of personnel were reviewed.

Training in good data and record management in evaluating the configuration settings and reviewing electronic data and metadata, such as audit trails, for individual computerized systems used in the generation, processing and reporting of data was performed for relevant staff. Generally training was appropriate for personnel and well documented.

7. Premises

The laboratory facilities were of suitable size and design to suit the functions and to perform the operations to be conducted in them. Separate storage facilities were maintained for the secure storage of samples, retained samples, reagents, laboratory accessories and reference substances, if necessary under refrigeration (2-8 °C) and frozen (-20 °C). The environmental conditions of these rooms were monitored and controlled. The temperature of all rooms was monitored by using hygro-thermometer devices. The laboratory provided separate rooms for storing flammable substances, fuming and concentrated acids and bases.

Microbiological testing was performed in a contained laboratory unit. Access to the laboratory facilities was restricted to the designated personnel by individual key cards. The Microbiology laboratory was redesigned in 2013- 2014 to be divided in two sections:

- Analytical Microbiological laboratory for microbiological testing (NE Block)
- Analytical Microbiological laboratory for Sterility testing (NE Block)

The sterility testing facility was totally renovated/redesigned to accommodate the observations from the previous WHO-inspection:

- A third change room was added
- Deferential pressure was monitored
- The facility's layout was modified to give it a logic flow/pass-through

The environmental conditions of the Microbiology laboratory were manually controlled using hygro-thermometers. However, temperature, humidity and pressure were displayed on a digital monitor installed in every room. Reference cultures were stored in a cold room (2-8 °C).

The deficiencies identified on the premises were adequately addressed in the provided CAPA plan.

8. Equipment, instrument and other devices

The equipment, instruments and other devices used for the performance of tests, calibrations, validations and verifications were generally suitable for use as they met relevant standard specifications. They were regularly qualified and/or calibrated. Calibration/validation certificates of equipment were randomly selected to verify their adequacy.

The deficiencies identified on the equipment were adequately addressed in the QCLs CAPA plan.

9. Contracts

The laboratory had a procedure for the selection and purchasing of services and supplies it used. A list of approved vendors for purchase of supplies and a list of service providers were presented. A new procedure for the audit of service providers was implemented and the QA audit schedule was prepared on 25 Feb 2019.

The laboratory did not subcontract any specific testing.

The deficiency identified on the contracts was adequately addressed.

10. Reagents

The reagents used were of appropriate quality and correctly labelled. Labels of reagent contained: content, manufacturer, date received and date of opening of the container, concentration, if applicable, storage conditions, expiry date and retest date, as justified.

Reagent solutions prepared in the laboratory were labelled with name of the reagent, date of preparations, expiry date, concentration, if applicable.

Culture media were stored in the room designated for the preparation of media. The Media preparation process was recorded in the respective module in LIMS data-system. Media containers were labelled by QA-department with the date of opening, date of expiry and date of growth promotion test (GPT) completion. Media were assigned an inhouse expiry date which would be renewed after completion of a new GPT, if applicable. Media preparation was performed in accordance with SOP for Microbiological pharma media: Procurement, performance verification, storage and use. Culture media were procured from either HiMedia or Sriman Diagno Plast India.

The quality of water produced by using Milli-Q was regularly verified to ensure that the purified water met the appropriate specifications in accordance with SOP for Water quality for laboratory use. A batch number was assigned to the produced water in a logbook and the containers were labelled accordingly. Reverse Osmosis (RO) water was provided using the main water supply and monitored daily for pH and conductivity preferably in the first hour, and monthly for microbiological count.

The deficiencies identified on the reagents were adequately addressed in the QCL's CAPA plan.

11. Reference substances and reference materials

a. Reference substances and reference materials

Reference substances were either purchased from approved vendors or supplied by clients, initially tested, released, and stored in the required condition either in a desiccator or a refrigerator, and periodically monitored according to the following provisions:

- Instructed by manufacturer
- Verification of USP Reference standards retest date on the USP website before each use.

Official, pharmacopoeia standards were used for the purposes described in the corresponding monographs. Reference standards received from clients were returned after completion of test. Adequate information was kept on the labels of reference substances. CoAs of Reference standards were available. The identification number was quoted on the analytical worksheets whenever the reference substance was used. A usage log was also available.

b. Reference cultures

Reference cultures were used for establishing the acceptable performance of media, for validating methods, for verifying the suitability of test methods and for assessing or evaluation of ongoing performance. Reference strains were generally sub-cultured between three to five generations from the original reference strain, in accordance with SOP for Reference cultures use and maintenance. Reference cultures were procured from the vendor M/S Chromachemie Lab Pvt Ltd which was evaluated by Vimta on 7 Dec 2016. Documentation for preparation and usage of randomly selected reference and working stocks was reviewed.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Each instrument was uniquely identified. Labels indicated the status of the calibration and the date when recalibration was due. Equipment underwent DQ, IQ, OQ and PQ, following a plan established by the laboratory. Balances were checked daily using internal calibration and regularly using suitable test weights. Requalification was performed every 3 months using certified reference weights.

Records/logbooks were kept for items of equipment with information to identify the device, current location, maintenance carried out, history of damage, malfunction, modification or repair. Use of the instrument was also recorded.

13. Traceability

Test results were traceable, were appropriate, ultimately to primary reference substances.

All calibrations or qualification of instruments were traceable to certified reference materials.

The entire workflow of viable monitoring performed on 28 Feb 2019 for room 4340, from purchase of media to preparation, also usage of reference culture, autoclave logbooks was verified to be adequately traceable.

14. Incoming samples

Incoming samples were delivered in parcels to the post office area located at the first level where the parcel was checked for physical intactness and assigned an inward-registration number. Incoming samples were immediately transferred to the CRM unit where they were controlled for further physical conditions and correctness of quantities. Samples were initially stored safely in the sample rooms, taking into account the storage conditions for the sample and registered in the LIMS system with adequate information. Samples were assigned a serial number in addition to the registration number. Later, the samples were distributed to the respective departments (Drugs & Pharma and Microbiology) for analysis as per the test request.

Shipment condition for temperature sensitive samples was verified by both delivery office and CRM officer. The Data-logger identification no was recorded on the Sample receipt acknowledge form. Supporting documentation was uploaded into the LIMS. Samples were accompanied by MSDS.

The test requests were reviewed by the laboratory to ensure that the laboratory had the resources to meet the specifications and that the selected tests/methods were capable to meet the customers' requirements. A barcode with information including the registration number and the name of designated laboratory unit was affixed to the samples. The consignment was also checked by the custodian to verify that the package was submitted in accordance with the test request. Samples were transferred to the respective laboratory by the laboratory assistant. Visual inspection of samples was carried out by the laboratory staff to ensure that labelling conformed with the information contained in the test request.

The samples were stored safely, considering the storage conditions, either in Contract Lab, Drug Lab or Physical Characterization laboratory based on the test requests and the respective specifications. Delivery of samples to the laboratory unit took place through a window which was opened to the storage area, where the samples were segregated in three groups:

- Validation samples (If Method development was required)
- Routine samples (for compendial samples)
- Unspent samples (Returned samples from the laboratory unit

An accountability log of used samples was recorded to be verified after completion of the tests.

The deficiencies identified on the incoming samples were adequately addressed.

15. Analytical worksheet

The analysts recorded information about samples, test procedures, calculations and results in analytical worksheets, which were completed by raw data. Analytical worksheets from different units related to the same sample were assembled together as appropriate for the particular client order.

The worksheets contained the relevant information as required by the order, such as:

- the date on which the analysis was started and completed;
- reference to specifications and full description of the test methods, by which the sample were tested, including the limits; identification of test equipment used; reference substances, reagents and solvents employed;

- interpretation of the results and
- the conclusion whether or not the sample was found to comply with the specifications;
- any deviation from the prescribed procedures (which were approved and reported).

All values obtained from each test, including blank results, were immediately entered on the analytical worksheet and all graphical data, whether obtained from recording instruments or plotted by hand, were attached or were traceable to the electronic record file or document where the data was available.

The completed analytical worksheets were signed by the responsible analyst and verified, approved and signed by the supervisor. For corrections the incorrect information was deleted by strike through with a single line and clearly legible. Alterations were signed by the person making the corrections the date and reason for the changes inserted.

16. Validation of analytical procedures

The procedures employed for testing were suitable for the intended use, as demonstrated by validation, if appropriate.

Analytical procedures were verified in accordance with SOP 02/96 issue no. 6.0 for Verification of compendial and customer methods/procedures. A verification was requested for all compendial/customer methods before execution of the method for the first time. Verification was raised based on an assessment and logged in the respective logbook. The Verification of a randomly selected protocol was reviewed. Specificity, precision & accuracy and other processes, including sample preparation and acceptance criteria were described in the protocol.

Full validation of the analytical procedure took place in absence of a compendial and validated method from the client in accordance with the respective SOP. The date of execution, the sample and its registration number, protocol number, analyst, report number and remarks were recorded in a logbook for “Full validation methods”. The protocol and validation report for the determination of preservative content in a randomly selected sample was provided. System suitability, specificity, precision, linearity, accuracy, range, stability of analytical solution, robustness parameters were described and tested.

Method development could be carried out by Vimta in a designated department for method development.

In order to keep track on executed validations and verifications, an Excel sheet was used by the units with a large number of validations and verifications. However, the Contract laboratory unit with only one client used a logbook.

Appropriate system suitability tests were employed prior to the analytical tests for verification of pharmacopoeia methods and/or validated analytical procedures.

The full/complete validation protocol and report for a randomly selected sample (500 mg/vial) dated 26 Feb 2019 was reviewed.

17. Testing

Test procedures were described in detail and allowed analysts to perform the analysis in a reliable manner. Deviations from the test procedures were approved and documented.

Specific tests were carried out by the Physical Characteristic laboratory unit where XRD, FT Raman, TGA and DSC were performed. The stability test was performed in the Contract laboratory unit.

The drug contract laboratory on the 2nd level was used for testing of samples according to the compendial and clients' methods and the drug contract laboratory on the 3rd level was used for development of analytical methods, method validation protocols and report preparation.

The deadline for test performance, from the day of receipt of sample to the date of dispatch of the report depended on the type of sample and test(s) required and it was monitored by review of a report generated in LIMS.

The deficiencies identified on the testing were adequately addressed.

18. Evaluation of test results and OOS investigation

SOP for investigation of OOX results was in place describing the conduct of investigations of OOS test results, addressing different scenarios and repeats. When a doubtful result (suspected OOS result) was identified, a systematic review of the procedures and calculations applied during the testing process, was undertaken by the supervisor and the analyst. OOSs were assigned an ID number in a logbook in a chronological order.

Doubtful results were rejected only if an error could clearly be identified. In the case that Phase 1 testing could not confirm the root cause, the customer would be notified within one business day. Phase 1b investigation was comprehensively described and included a decision tree and permutations, to confirm or rule out possible cause. If the initial result was confirmed but the root cause not identified this would lead to Phase II which included additional testing and re-testing and if relevant evaluation of other batches to be considered.

If the investigation was inconclusive, the SOP gave clear guidance on the number of retests allowed (based on statistical principles). Once an error was identified, corrective and preventive measures were recorded and implemented. All individual results (all test data) with acceptance criteria were reported. The repeat of tests was done by a second analyst, as experienced and competent as the first one.

Analytical test reports were issued by the laboratory based on information recorded in analytical worksheets.

The test reports also included the following information:

- the background and the purpose of the testing;
- reference to the specifications and methods used;
- the results of all tests performed;
- the statement whether the sample complied with the requirements.

Randomly selected OOS investigations were reviewed.

19. Certificate of analysis

A certificate of analysis was prepared for each sample/batch of a substance or product and contained the required information, among others the results of the tests performed with the prescribed limits and a conclusion as to whether the sample was found to be within the limits of the specification. The date on which the tests were completed was also recorded on the certificate.

20. Retained samples

Refer to section 14 in this report.

21. Safety

Staff were wearing laboratory coats, including eye protection. Special care was taken in handling highly potent, infectious or volatile substances. Highly toxic and/or genotoxic samples were handled in safety cabinets. Safety showers were installed. Rubber suction bulbs were used on manual pipettes. Safety data sheets were available before testing was carried out.

Disposal of chemicals was managed in accordance with SOP for Safe disposal of laboratory chemicals.

Business Continuity Plan was presented. A mock drill was carried out by the Safety Group. In addition, SOP for Onsite Emergency Plan was available, and an evacuation simulated plan was performed as described in the procedure.

The deficiency identified on the safety was adequately addressed.

Miscellaneous	
Assessment of the Laboratory Information File	The Laboratory Information File revision no 13 (2018) contained specific information about the operations being carried out at Vimta Labs Ltd. Policy or essential steps for each activity were described and where appropriate, supportive documentation was appended. All modifications to the previous issue no. were highlighted in blue font.
Annexes attached	N/A

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 ***Vimta Labs Ltd, Life Sciences Facility,*** located at ***MN Park (Formerly Alexandria Knowledge Park) Plot No 5, Genome Valley, Shamirpet Mandal Hyderabad, Medchal-Malkajgiri District, Telangana 500 101, India*** was considered to be operating at an acceptable level of compliance with WHO GPPQCL 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 laboratory, 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 5	List of WHO Guidelines referenced in the inspection report

1. 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 GPPQCL Guidelines or ***TRS No. 957, Annex 1***
   http://www.who.int/medicines/publications/44threport/en/

2. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/
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
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
   Short name: WHO GDRMP guidance or ***WHO TRS No. 996, Annex 5***
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

6. 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 GMP guidelines*** or ***TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

7. 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***
   http://www.who.int/medicines/publications/44threport/en/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
    Short name: WHO TRS No. 961, Annex 7
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