

**Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
WHO PIR
of the Quality Control laboratory**

Part 1		General information	
Laboratory Details			
Name of the laboratory	SGS India Pvt. Ltd-Life science		
Address of inspected laboratory	2 nd , 3 rd , and 4 th Floor, TICEL Bio Park Ltd. CSIR Road, Chennai-600113 Tamil Nadu India		
GPS Coordinates	Latitude: 12.9880 Longitude: 80.2513		
Address of corporate office, telephone number and fax number	SGS India Private Limited 4B, Adishankaracharya Marg Vikhroli (West) Mumbai - 4000 083, Maharashtra India		
Inspection Details			
Dates of inspection	09-12 December 2019		
Type of inspection	Routine		
Introduction			
Brief description of testing activities	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
	Physical/ Chemical analysis	pH, refractive index, water content, Loss on drying, density, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content), Particulate matter test, Osmolality test	pH, density, refractive index, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests, particle size
	Identification	HPLC (UV-Vis, RI, DAD detector), GC(FID), TLC,	HPLC (UV-Vis, RI, DAD detector), GC (FID), TLC,

SGS India Pvt. Ltd-Life science, Chennai India-QCL

09-12 December 2019

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		UV-Vis spectrophotometry, FTIR, basic tests	UV-Vis spectrophotometry, FTIR, basic tests
	Assay, impurities and related substances	HPLC (UV-Vis, RI, DAD detector, UPLC (UV-Vis, PDA detector), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, potentiometry, volumetric titrations	HPLC (UV-Vis, RI, DAD detector), UPLC (UV-Vis, PDA, detector), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, potentiometry, volumetric titrations
	Micro-biological tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics
	Stability studies	N/A	N/A
General information	SGS was originally founded in 1878 in Rouen as a French grain shipment inspection house. The company was registered in Geneva, Switzerland as Société Générale de Surveillance (SGS) in 1919. SGS' activities encompassed inspection, verification, testing and certification company. SGS operates a network of more than 2,600 offices and laboratories around the world with about 97,000 employees. SGS India has two laboratories in India, one in Chennai and the other one in Navi Mumbai. SGS Chennai started its operations in February 2005. SGS lab Chennai is a contract testing laboratory. This laboratory is not involved in activities of production, importation or distribution of pharmaceutical products. SGS lab Chennai is involved in testing of pharmaceutical products (raw materials and finished products) according to the applicable pharmacopoeia monographs, or according to specific client test methods.		
History	The laboratory was inspected/accredited by: - Tamil Nadu Drug control authority-India - ISO/IEC 17025:2017 by NABL		

	- US FDA – The respective EIR dated 23 Nov 2018 was provided and reviewed.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Quality Management System Personnel Training and Safety Documentation and Records Premises and Equipment Validation – Qualification – Calibration Laboratory Practices Reference standards – Reagents - Water
Restrictions	Not applicable
Out of Scope	Stability testing was carried out at Mumbai laboratory.
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
Ph.Int.	International Pharmacopoeia
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 (where applicable)
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1. Organization and management

The organization and management structure of the laboratory; i.e. responsibility, authority and interrelationship of the personnel, was specified in an organisational chart signed and dated 22 Nov 2019. The total number of staff accounted to 78 at the time of inspection. The laboratory was headed by Mr. Cresenciano Maramot / Mr. Sathananthan Sangaran and comprised of the following sections:

- Chemical
- Microbiology
- QA
- Management
- Support staff and others

The laboratory had arrangements to ensure that its management and personnel were not subjected to commercial, political, financial and other pressures or conflicts of interest that might adversely affect the quality of their work. The laboratory had a policy in place to ensure the confidentiality of information contained in marketing authorizations and test reports. Self-Declaration on Data integrity and code of integrity template was an appendix of the SOP for Orientation on training.

The laboratory layout was signed and dated on 14 Aug 2018. 2nd, 3rd and 4th floors partially belonged to SGS.

A paperless project with intention to manage documentation without any paper was in process, using TrackWise software system for handling of OOS, deviations and CAPA. The project was planned to be carried out phase by phase to be extended to Document Management and Training Management System. The objective was to operate paperless by the end of 2020. The project has been postponed due to COVID-19 pandemic situation.

Performance assessment of the organization was done in accordance with the SOP for Measurement and monitoring of key performance indicators (KPI).

NABL accreditation was granted in accordance with ISO/IEC 17025:2017 in the disciplines of Chemical & Biological testing as per the scope recommended by the assessment team. (Method assessment).

The identified deficiencies related to the organization and management were adequately addressed in the Laboratory's CAPA plan.

2. Quality management system

A quality manual, defining the quality management system was available.

The QMS consisted of the following quality chapters:

- Management
- Quality Management
- Personnel
- Facilities
- Equipment
- Testing
- Documentation
- Validation

The Quality policy statement covered management's intention with respect to standard of service, management's commitment towards the establishment and implementation of a QMS, management's commitment to professional practice, management's commitment to compliance with WHO GPPQCL and included the requirement that all staff concerned with testing & calibration activities should familiarize themselves with the QMS and applicable procedures.

The structure of the quality manual was found to be in accordance with current expectations of WHO GPPQCL.

Management review (MR)

SOP for Management review meeting was reviewed. An MR meeting should take place at least once a year. Indicator parameters such as OOS, deviation, customer complaint, CAPA, change control, calibration (external/internal), method transfer, and SOPs were trended to be presented for the management review. Agenda items were also listed in the respective SOP.

Internal audits:

The scope of internal audit was to ensure compliance as per GMP requirements. Internal audits were carried out by applicable schedule and procedure. Audit plan was provided in the beginning of each year and documented on the template for Internal audit schedule. The audit plan for year 2019 was provided. Area to be audited, time and execution of audit were recorded. Premises, facility and safety, laboratory logbooks, and analytical worksheets, Control of documentation, RS management, reagent and culture media were audited. As the audit report was not presented to the inspection team, the implementation of CAPA, if any could not be investigated.

CAPA handling

SGS LS Chennai had a CAPA system and procedure in place for the management of corrective and preventive actions. An investigation report was provided for the deviations identified during the inspection, such as deviation for gauge functionality, which was reviewed.

Complaints

SGS LS Chennai had a customer complaint system and procedure in place for handling of complaints. Complaints were registered based on the expression of dissatisfaction of the services provided by SGS LS Chennai. Complaints were investigated to find out the root cause and appropriate corrective, preventive actions were proposed and implemented.

Change control

Changes in the systems and procedure were addressed through change management with approval by concern department and Quality assurance before implementation.

Disaster recovery

A disaster recovery plan, i.e. Business continuity plan was available for review. The disaster recovery plan was risk based and included action plans for the continuity of the laboratory testing activities and IT infrastructure.

The identified deficiencies related to the QMS were adequately addressed in the respective Laboratory's CAPA plan.

3. Control of documentation

The laboratory had established and maintained a system of procedures to control all documents (preparation, revision, distribution, return, archiving) through SOP for SOP Management. A master list, identifying the current version status, was available. The distribution of controlled copies was adequately described in the SOP. Each controlled document had a unique identifier, version number, date of implementation, reference to the previous version. The documents were released by the person initiating the change, applicable technical manager and QA manager, and available at the relevant location. An SOP was in place comprising the authorization for copying and the identification of copies from official and controlled documents. Relevant staff was trained on new and revised SOPs in accordance with the applicable SOP. The personnel acknowledged by signature that they were aware of applicable changes. SOPs were revised every three years (or earlier if needed) and were approved by Quality Assurance department.

The identified deficiencies related to the Control of documentation were adequately addressed in the Laboratory's CAPA plan.

4. Records

Record were made of analytical tests, including calculation and derived data, method validations/verifications, instrument use, calibrations and maintenance and sample receipt in logbooks containing consecutively numbered pages. The records were signed, alterations were commented. Records were kept in an archive for a defined period. Access to the archive was restricted to authorized personnel.

The issuance of templates and forms were managed by SOP for GMP documentation. The logbooks and analytical sheets used in the laboratory were controlled and logged in a logbook.

The identified deficiencies related to the records were adequately addressed.

5. Data processing equipment

An inventory of all computerised systems was available with the information such as software system category, supplier's name, description, application/use, current status, year of last review, review status and year of next review.

Records on hardware configuration, installation and changes (incl. software updates) were kept for computerised systems which were components of test equipment. Electronic data was protected from unauthorized access.

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 as part of the decision-making steps.

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. Calculation algorithms were tested in accordance with the respective SOP. The sheets were made available in computer Drive and protected from any modification.

LIMS (Laboratory Information Management system) software used for sample management was 21 CFR part 11 compliant, which was controlled by global team. Unique identification number was generated during Sample registration and approved by Technical leader. Results were entered by Analyst upon completion of analysis. Analytical document was reviewed by Data reviewer and released CoA by QA.

Access to the network was controlled by the user ID and protected by a password. Backups of electronic data were performed as per the applicable SOP.

Workstation connected to HPLC system was checked for security.

The URS and qualification documentation of chromatography software EMPOWER 3 was provided.

The protocol of Operation and Performance Qualification of the was available. The security elements such as verification of Full-audit trail, projects access features, back up restoration and operational user privileges etc. were reviewed to ensure that those features were tested.

The identified deficiencies related to the computerized systems were sufficiently addressed.

6. Personnel

SGS Lab had the qualified personnel, the facilities and equipment necessary to carry out the following activities:

- Physical-chemical tests
- Microbiological tests
- Development and validation of analytical methods of pharmaceutical products

A Competence Matrix was provided with the name of employee, employee number, qualification, DOJ (Date of Joining) and areas of activities for:

- Physico-Chemical laboratory
- Microbiology laboratory

All new employees including temporary should undergo orientation and technical training during the first month of employment. New employee was allowed to perform GMP activities upon completion of training.

Training for specific job duties was the responsibility of the department head or the designee. Training must be conducted by qualified individuals with experience and knowledge of the subject matter being instructed. The department head predetermined training requirements based on job descriptions and develop a training outline for each employee by using the Technical Training Needs form. All employees should receive GMP and data integrity training annually.

Retraining might be conducted in response to trends in deviations, OOS investigations, and audit observations (internal or external) or after an extended absence. This training was documented in the Training Form.

The identified deficiencies related to the training of personnel were adequately addressed.

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 facility and instruments/equipment e.g. climatic chambers were connected to online monitoring system for Temperature and humidity. Access to the laboratory facilities was restricted to designated personnel.

Procedures for environmental conditions control and cleaning of the analytical laboratories were available and reviewed. Thermohydrometers used were calibrated over the intended range of use and calibration certificates were reviewed by the laboratory using a check-list to ensure accuracy and completeness of the issued calibration certificate.

Microbiological testing was performed in a contained laboratory unit. Three separate Air handling unit (AHU) were installed in Microbiology laboratory and Air handling unit was required to be validated annually and Preventive Maintenance was required to be performed once six months. The Area in microbiology was categorized in Grade A, B, C and D. Environmental monitoring was carried out as per schedule described in the respective SOP. The trend analysis report was evaluated for any positive or negative trends in the results. The laboratory performed several microbiological tests under pharmacopoeia guidelines. The tests were composed of total viable aerobic microbial count by membrane filtration or pour plate count methods, tests for specified micro-organisms, microbial identification and microbial assay of antibiotics by cylinder plate method. Viable count was performed daily for class A & B and recorded in a logbook with required information about the air-sampler and start and end time. Air sampler was not equipped with a printer. The procedure was described in SOP for Environment monitoring.

The agreement for collection, transportation, treatment and disposal of biomedical wastes between the laboratory and the service provider was available. Disposal of chemical waste was adequately described in SOP for Waste disposal. The chemical liquid waste was processed by TICEL ETP plant.

Based on the MSDS, the toxicity or any associated risk of a product or reagent was evaluated. The chemist was informed by the Department Head if special precautions were needed for the handling of the sample.

The identified deficiencies related to the training of premises were adequately addressed.

8. Equipment, instrument and other devices

The equipment, instruments and other devices used for the performance of tests, calibrations, validations and verifications were required to be suitable for use as they met relevant standard specifications.

The laboratory had a documented Validation Master Plan available which provided an overview of the validation approach for operation of equipment, validation activities performed on-site, personnel training and qualification, computerized systems validation and user access roles on various systems, cleaning validation, analytical method validation, supplier qualification and a policy on revalidation / re-qualification.

The following equipment and/or related qualification documentation were reviewed to verify the adequacy of their calibration/validation certificates:

- Calibration certificate of pass-boxes including downflow velocity and filter integrity.
- BOD incubator. The temperature mapping and temperature monitoring of the equipment was properly recorded. The expanded uncertainty was measured, and it was considered in the temperature setting of the equipment.
- The calibration certification of autoclave. The calibration was performed by external service provider Equation, considering vacuum leak test, Bowie Dick test, Heat distribution study empty chamber and fully loaded, in different numbers of consecutive cycles, including the chemical indicator and the pertaining CoA.
- Temperature mapping of -65 °C Deep Freezer was issued by MSIR INDIA in accordance with the requirements.
- The calibration certificate of Thermo-hygrometer.
- Weight certificates used for daily verification of balances dated 30 Jul 2019. Where they had two weights with the same mass, one of them was marked with * sign. The Accuracy was mentioned as E2.
- Daily calibration of a randomly selected balance was reviewed and confirmed.
- Balances were calibrated in accordance with the applicable SOP.
- The performance verification of a randomly selected Micropipette was demonstrated. The entire process was properly followed up. The percentage of inaccuracy was measured to be out of the limit, although the average of values and % CV was within the acceptable limits. Hence, the calibration was reported as “Not Satisfactory”. Deviation was raised to address the problem on 11 Dec 2019 (same day of performance verification).
- Calibration certificate of Milli-Q system; issued by Merck Life science.
- IQ/OQ/PQ records of the Perkin Elmer Frontier IR Spectrophotometer were reviewed and found to be in order. The instrument was calibrated every six (6) months using a certified and traceable Perkin Elmer polystyrene film. Examples of six-monthly calibration records were reviewed. Software access controls were defined and implemented.
- IQ/OQ/PQ records of the Labindia Dissolution Tester DS8000+ were reviewed and found to be in order. Dissolution testers were calibrated every six (6) months. Record of calibration performed on 09 Nov 2019 was presented and reviewed. Calibration checks performed included level check, RPM check, wobble check, depth check, centring, temperature checks, timer check and auto sampler deliver volume calibration. The USP calibrator tablet check was also performed and found to be compliant.
- The verification of analytical balance was presented and reviewed.
- IQ/OQ/PQ records of the Metrohm auto-titrator with Tiamo 2.5 Software were reviewed and found to be in order.

SOP for Operation, calibration and cleaning for BOD incubator (MAKE-NEWTRONIC) was reviewed. The equipment was associated with a data-system for monitoring of the temperature.

The identified deficiencies related to the equipment and other devices were adequately addressed.

9. Contracts

The laboratory had a procedure in place for the selection and purchasing of services and supplies.

The laboratory had subcontracted a few testing only to SGS Mumbai in accordance with SOP for Internal subcontracting SGS LSS Laboratories.

Suppliers/vendors responsible for activities such as laboratory service calibration, preventive maintenance, supply of instruments, chemicals etc. were required to be evaluated as per the applicable before signing a contract. There were three different type of levels for evaluating the vendor i.e. Level-1, Level-2 and Level-3. The level was determined using a qualification report for all the level of vendor and upon the compliance to the SGS criteria. Questionnaires were sent to the suppliers to assess their activities and qualification of services and the necessity for an onsite audit.

A pest control contract was signed with the service provider to remove the general pest like Bugs, Silverfish, Crickets, cockroach and rodents in accordance with SOP for Pest control management was available. The last visit invoice was provided.

The identified deficiencies related to the contracts were sufficiently addressed.

10. Reagents

The reagents used were of appropriate quality and correctly labelled, once upon the receipt and once they were opened with new expiry date in accordance with the applicable SOP. 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 were prepared in the laboratory and labelled with pre-printed labels affixed to the glassware with name of the reagent, date of preparations and initials of technician or analyst, expiry date or retest date, as justified and concentration, if applicable. Volumetric solutions prepared in the laboratory were also properly handled.

The quality of water, i.e. TOC, conductivity and pH was regularly verified to ensure that the various grades of water met the appropriate specifications as per SOP for Operation, Monitoring and Preventive Maintenance of Milli-Q Water and Rios Ro Water System. Microbial limit test was performed once in a month for RO and Purified water.

Two types of water were used in the facility.

- Reverse Osmosis (RO) Water
- Purified Water

Preventive Maintenance of the equipment was performed once in six month and calibration once in a year.

Culture media were received along with the COA from the approved qualified vendor. Growth promotion test passed dehydrated powder media and Ready to use sterilized media were used for Testing. Positive and negative controls were performed for each autoclaved media lot with one environmental isolate in addition to testing organisms.

Following types of Medias were used and recorded:

- Soya bean Casein Digest agar
- Soya bean Casein Digest Medium
- Fluid Thioglycolate Medium
- Sabourauds dextrose agar
- R2A

The identified deficiencies related to the reagents were adequately addressed.

11. Reference substances and reference materials

Reference substances stored and periodically monitored in accordance with applicable procedures. Unique identification numbers were assigned to reference substances used. A nominated person was identified for the management of reference substances. Official, pharmacopoeial standards were used for the purposes described in the corresponding monographs.

The following information was kept on the labels of reference substances and/or the accompanying documentation (as appropriate): name and description of the material, batch or control/identification number, source, date of receipt or preparation, date the closure is first opened, expiry date or retest date, location of storage and storage conditions, certificate/batch validity statement of compendial reference substances, testing results (CoA) and assigned content, safety data sheets.

The identification number was quoted on the analytical worksheets whenever the reference substance was used. When pharmacopoeial standards were used the batch validity statement was verified by the analyst prior to use. A register of all reference substances was also available.

CoAs and MSDS were available for reference substances used by the laboratory.

A list of Reference cultures supplied by BioBall and the logbook for usage were available and reviewed.

The identified deficiencies related to the Reference standards and materials were adequately addressed.

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 annually using certified reference weights.

Records/log books 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.

Procedures were available for the qualification, safe handling and maintenance of equipment used in the laboratory.

For details, refer to section 8 of this report.

13. Traceability

Traceability of the test reports to track the usage of reagents, media cultures and microorganisms were inspected.

All calibrations or qualification of instruments were traceable to certified reference materials and to SI units (metrological traceability).

The identified deficiencies related to the traceability were adequately addressed.

14. Incoming samples

The laboratory was not responsible for sampling of materials/product. Samples were received and acknowledged by security / sample Receipt personnel to the courier and moved to sample registration section.

Samples were inspected on receipt using a sample receipt check list. A test request accompanied each sample submitted to the laboratory and contained the following information:

- description of the sample,
- specification to be used for testing,
- required storage conditions.

The test requests were required to be reviewed by the laboratory to ensure that the laboratory had the resources to meet them and that the selected tests/methods were capable to meet the customers' requirements.

All delivered samples and accompanying documents were assigned a registration number. An electronic register was kept in which the following information was recorded:

- registration number of the sample
- date of receipts
- unit to which the sample was forwarded

Prior to testing, samples were stored in the sample storage room, taking into account the storage conditions for the sample. The samples were sent for testing to the specific unit together with the test request by the responsible person.

Visual inspection of samples was carried out by the laboratory staff to ensure that labelling conformed to the information contained in the test request.

All samples were managed in accordance with SOP for sample management and tests were performed after receipt of test request.

The identified deficiencies related to 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.

The worksheets contained the following information:

- registration number of the sample (i.e. sample code)
- 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 the test equipment used
- identification of reagents and solvents employed
- interpretation of the results
- the conclusion whether the sample was found to comply with the specifications

Values obtained from each test, including blank results, were 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 old information should be deleted by putting a single line through it; it should not be erased or made illegible. Alterations were signed by the person making the corrections the date for the changes inserted. The reason for the change was given.

16. Validation of analytical procedures

Non-standard methods, in-house methods and standards used beyond their intended scope were validated to confirm their effectiveness as per SOP for Analytical & for Microbiology validating test methods, as well as regulatory guidelines related to method validation. The data concerning this validation was required to be maintained.

Verification of compendial analytical methods, used for testing Pharmaceutical raw materials drug products and microbiology analysis was performed as per the applicable SOP. Other statistical tools, as well as regulatory guidelines related to Method verification were also applied.

Method Transfers exercise was applicable for new Method of analysis between the labs. This was based on predetermined acceptance criteria for transfer of method, in accordance with agreements with the customer. Method Transfer was the documented process that qualified the laboratory to use an analytical test procedure that originated in another laboratory, thus ensuring that the receiving unit had the procedural knowledge and ability to perform the transferred analytical procedure as intended. Method transfer was required to be performed as per SOP for Method Transfer Guidelines, as well as regulatory guidelines related to Method Transfer.

The identified deficiencies related to the validation and verification of analytical procedures were sufficiently addressed.

17. Testing

Test procedures were described in detail which could allow analysts to perform the analysis in a proper manner. However, applicable pharmacopeial methods were not consistently used and deviation from the procedures were not identified. Specific tests were carried out by another unit or by specialized external laboratory, refer to section 9 of this report.

The LAL test, using GEL clot method, was performed to detect or quantify bacterial endotoxins that might be present in or on samples.

Testing documentation related to the five randomly selected samples were reviewed and discussed.

The identified deficiencies related to the testing were adequately addressed.

18. Evaluation of test results and OOS investigation

The handling of OOS-results was described in the applicable.

Out-of-Specification results (OOS) detected was logged in and documented on a specific form. An investigation was started to determine the root cause of the OOS results and to define corrective and preventive actions (if applicable). If no laboratory error was identified the OOS-result was considered as valid and customer was informed of this result, and it was up to the customer to indicate if any specific (re)testing was required. If the lab error occurred, then the sample would be retested by the same analyst followed by invalidation of OOS result.

The current analytical practices (i.e. failure to prepare- and test replicate samples for quantitative analyses and not applying other validated testing methods for confirmatory purposes) did not support the laboratory in reporting a final reportable value in the instance where an inconclusive outcome was reached during phase I. However, the issue was properly addressed in the Laboratory's CAPA plan.

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

The analytical test reports further 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 complies with the requirements

The identified deficiencies related to the evaluation of results and OOS investigation were adequately addressed.

19. Certificate of analysis

A certificate of analysis was prepared for each sample/batch of a substance or product and contained series of information, among others:

- registration number & description of the sample
- date of receipt
- name and address of the testing laboratory
- reference to the specification and/or analytical method used for testing of the product / sample
- the results of the tests performed with the prescribed limits
- 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.

CoAs were signed using electronic signatures.

The identified deficiencies related to the Certificate of analysis were appropriately addressed.

20. Retained samples

Retained samples were kept in their final pack and retained as required by the legislation. For more details, refer to section 14 of this report.

21. Safety

Staff was wearing laboratory coats, including eye protection. However, special care was not taken in handling highly potent, infectious or volatile substances. Safety showers were installed. Rubber suction bulbs were used on manual pipettes. Safety data sheets were available before testing was carried out.

Two fumes cupboards were in use in the chemical laboratory.

The identified deficiencies related to the safety were properly addressed in the Laboratory's CAPA plan.

Miscellaneous	
Assessment of the Laboratory Information File	The Laboratory Information File (LIF) approved 22 Nov 2019 was provided. The following statement regarding subcontracting of testing to other SGS laboratories was ambiguous and was revised: <i>“As per SGS policy, SGS do not subcontract any testing to SGS labs Before subcontracting we get approval from the client and we ensure the compliance status of the lab.”</i>
Annexes attached	N/A

Part 3 – Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, including the CAPA plan provided for the observations listed in the Inspection Report, **SGS India Pvt. Ltd-Life science**, located at **TICEL Bio Park Ltd., CSIR Road, Chennai-600113, Tamil Nadu, India** is 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 4	List of WHO Guidelines referenced in the inspection report
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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
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