World Health Organization

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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
of the Quality Control laboratory
WHOPIR

Part 1	**General information**		
Laboratory Details			
Name of the Laboratory	SIFDC-Drug Quality Control Center (Shanghai Institute for Food and Drug Control)		
Address of inspected Laboratory	No.479, Futexi 1st Road, Pudong New Area Shanghai 200131 P. R. China		
GPS Coordinates	Latitude N 31° 20’ 8” Longitude E 121° 35’ 34"		
Address of corporate office, telephone number, and fax number	Headquarter: No.1500, Zhangheng Road, Zhangjiang High-Tech Park Pudong New Area Shanghai P. R. China		
Dates of inspection	22-25 July 2024		
Type of inspection	Initial		
Introduction			
Brief description of testing activities	*Type of analysis*	*Finished products*	*Active pharmaceutical ingredients*
	Physical/ Chemical analysis	pH, Disintegration, Dissolution, Loss on drying, Uniformity of dosage units (mass, content), Colour of solution, Clarity of solution, Water content (semi-micro method, Karl Fischer), Visible particles, Subvisible particles, Density, Refractometry, Friability	pH, Specific rotation(Optical rotation), Melting point(Melting range), Loss on drying, Sulfated ash, Limit tests, Colour of solution, Clarity of solution, Water content (semi-micro method, Karl Fischer), Nitrogen determination
	Identification	HPLC (UV, DAD, RI, FLD), GC (FID), TLC,	HPLC (UV, DAD, RI, FLD), GC (FID), TLC,

		UV-VIS, IR, Specific rotation (Optical rotation), Melting point (Melting range), Basic tests	UV-VIS, IR, Specific rotation (Optical rotation), Melting point (Melting range), Basic tests
	Assay, impurities, and related substances	HPLC（UV, DAD, RI, FLD), GC(FID), TLC, UV-VIS, IR, AAS, Volumetric titrations, Potentiometric titrations	HPLC（UV, DAD, RI, FLD), GC(FID), TLC, UV-VIS, IR, AAS, Volumetric titrations, Potentiometric titrations
	Microbiological tests	Sterility, Microbial limits	Sterility, Microbial limits
	Bacterial Endotoxin Testing (BET)	Bacterial endotoxins (Gel-clot method: limit test)	Bacterial endotoxins (Gel-clot method: limit test)
General information	The Shanghai Institute for Food and Drug Control (SIFDC), also known as the Shanghai Coastal Institute for Drug Control, is a government laboratory affiliated with the Shanghai Medical Products Administration. It is primarily responsible for testing drugs (including biological products), food (including special food products), and cosmetics within the jurisdiction of Shanghai. SIFDC operates several laboratory divisions, including the Drug Quality Control Center. All divisions are overseen by the Zhangjiang Headquarters, which manages business operations, personnel, and capital allocation. The Laboratory's main operations/activities include: • Testing of imported drugs • Post-market drug surveillance and evaluation testing • Entrusted testing, technical consultation, and research for drugs and biological products • Enhancement of quality standards and revision of pharmacopeial standards • Review testing for new drug registration • Lot release of biological products • Registration, sampling, and contract testing for food and cosmetics		
History	The Shanghai Institute for Drug Control (SIFDC) was established in 1953 through the merger of the drug inspection departments of the former Shanghai Health Inspection Institute and the Eastern China Drug and Food Inspection Institute. Originally it was named “the Drug Inspection Institute of the Shanghai Health Bureau”, it was later renamed several times, including the "Shanghai Institute for Drug Control" in 1990, "Shanghai		

	Institute for Food and Drug Control" in 2005, and once more in 2021. Over its 70-year history, SIFDC has been relocated three times, with the most recent move occurring in September 2006 to its current location. Since 2021, SIFDC has undergone one WHO PQT peer audit, four CNAS (China National Accreditation Service for Conformity Assessment) accreditations, and 17 reviews and expansion reviews of CMA (China Metrology Accreditation) accreditation, all of which were recognized and approved. Additionally, SIFDC has received 15 on-site inspections, all of which have either met the inspection requirements or completed the necessary rectifications. Details of external audits, inspections, and current certificates were provided in Annex 4 of the respective LIF.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Organization and management including: - Structure - QMS - Documentation and records - Computerized systems Planning and strategic management including: - Service providers and suppliers - Performance management - Quality Risk management Resources including: - Personnel - Premises - Equipment qualification - Reagents, RS Technical activities including - Handling of samples - Validation, verification and transfer of analytical methods - Testing, evaluation and reporting of results & OOS - Safety
Restrictions	The QCL was advised to remove 'PQ' from its name and to refer to the WHO list for prequalified laboratories where applicable. Additionally, the inspection was conducted in Chinese, with the assistance of interpreters to ensure accurate communication and understanding throughout the process.
Out of Scope	Not applicable
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
CAPA	Corrective action & Preventive action

DQ	Design qualification
eLN	Electronic laboratory note
EQ	Equipment qualification
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)
IQ	Installation qualification
IR	Infrared spectrophotometry
KF	Karl Fischer titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
N	Normality
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
OQ	Operation qualification
Ph.Eur.	European Pharmacopoeia
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PT	Proficiency testing
PTS	Proficiency testing scheme
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QM	Quality manual
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
TLC	Thin layer chromatography

TOC	Total organic carbon
URS	User requirements specifications
USP	United Stated Pharmacopoeia
UV	Ultraviolet-visible spectrophotometry or spectrophotometer
VMP	Validation master plan
VS	Volumetric solution

Part 2	**Summary of findings and recommendations**

1. Organization and management

1.1. Structural and general requirements

The laboratory was legally authorized by the Top Manager Director to operate and be accountable for test results, certificates of analysis, and other work it performed.

SIFDC's management comprised six individuals, including the Director, Deputy Director, Technical Manager, and Quality Manager. For more details, refer to the list of participants. The organization consisted of 17 departments: 10 functional departments and 7 testing departments. The executive management included 26 department-level managers (1 to 2 per department). SIFDC employed a high-quality laboratory team of 413 staff members, including 70 employees related to the SIFDC-Drug Quality Control Center.

Management ensured that both managerial and technical staff possessed the necessary authority and resources (financial, human, infrastructure) to fulfil their duties.

Procedures were established to prevent any influences that could compromise impartiality. These included declaring conflicts of interest and maintaining the confidentiality of all laboratory information. The confidentiality statement and policy were also included in the Quality Manual. These measures were randomly checked and verified for selected employees.

Organizational charts defined the laboratory's organizational and management structure, its position within the parent organization, and the relationships between management, and technical operations.

The responsibilities, authority, and interrelationships of all personnel were specified in the respective job descriptions. The laboratory had a Quality Manager who reported directly to the Laboratory Director and led the QA department. On the organizational chart, the QA department was named as Quality Management (QM) department.

A list of deputies was available and reviewed. Adequate information flow and communication were maintained between staff at all levels through conferences, meetings, point-to-point communication, and social media, ensuring awareness of notifications, instructions, and operational priorities.

1.2. Quality management system

The quality manager ensured the establishment, implementation, and maintenance of a QMS appropriate to the laboratory's activities.

Before implementation, the QMS was communicated and understood by appropriate personnel. All system elements were documented electronically or on paper.

The quality manual contained:

- A quality policy statement addressing service standards, commitment to QMS effectiveness and compliance with guidelines, and access to management system documentation.
- Organizational structure.
- Operational and functional activities related to quality, with clear responsibilities.
- Documentation structure within the QMS.
- Internal quality management procedures and standard operating procedures.
- Personnel qualification, experience, and training policies.
- Policies

Systematic and periodic internal and external audits verified compliance with QMS requirements.

1.3. Control of documentation

A master list, available both electronically and on paper, was established to identify the current version and distribution of documents. The SOPs were managed according to the SOP for SOPs. The laboratory used a database for managing the SOPs. The list of SOPs was reviewed annually, as part of the internal audit to determine if any revisions were necessary. The valid versions of SOPs were available in the database, on paper, and in LIMS (for analysis purposes). The document administrator was responsible for keeping them updated.

Procedures for controlling and reviewing documents ensured that:

- Each document had a unique identifier, version number, and implementation date.
- Authorized standard operating procedures were readily accessible.
- Documents were regularly reviewed and updated as needed.
- Invalid documents were immediately replaced with authorized, revised versions.
- Revised documents referenced previous versions retained in archives for traceability.
- Staff were trained on new and revised procedures.
- Documentation, including records, was retained according to SOP for Archiving. The retention period depended on the type of sample.

Upon the implementation of new and revised procedures, notifications were disseminated via the database for document management. Following receipt of these notifications, the quality specialist for each group coordinated and conducted training sessions. An SOP for training was in place to guide these activities.

The Quality Management documents were prepared in accordance with the applicable guidelines, including the WHO Guideline on data integrity, i.e., WHO TRS 1033-Annex 4.

1.4. Change Control

The laboratory implemented the SOP for managing changes. Change requests were reviewed and implemented only after management approval, with comprehensive records maintained.

For critical changes, such as enhancements to existing procedures or the introduction of new methods, approval, and oversight were provided by senior management.

Change processes were also addressed in management reviews, facilitating monitoring by senior management.

The Quality Manager ensured that changes were documented in controlled templates, approved, planned, implemented, and reviewed. Each request was assigned a specific number, and the description, classification, date of closure, and follow-up evaluation were recorded in the Change Control registry.

Staff acknowledged their awareness of changes and their implementation dates through signatures.

1.5. Control of Records

The applicable SOPs comprehensively detailed the identification, collection, indexing, retrieval, storage, access, maintenance, and disposal of all quality and technical or scientific records, whether paper, electronic, or hybrid. Records could be maintained in electronic format (eLN) or on paper, contingent upon the testing deadline for the sample. For manufacturer samples, eLN was used, as the laboratory had adequate time to process the analysis electronically. For other samples, such as post-market surveillance samples, paper templates were employed to expedite analysis and reporting. However, the laboratory was in the process of transitioning as many records as possible to eLN for analytical documentation.

All original observations, including calculations and derived data, calibration, validation, verification records, and final results were retained for a minimum of six years, as mandated by national legislation or contractual agreements. Calculations could also be performed using validated Excel sheets, which were stored in a designated folder with restricted access, in accordance with the SOP for Calculation Model Management.

Records included data documented in analytical worksheets on consecutively numbered pages, with references to pertinent recordings in appendices, whether on paper or electronically. For the issuance of templates, the specifications of the blank pages were communicated to the supplier. Each department requisitioned the quantity required. The process was explained by the staff responsible for procuring the blank pages (from Business group), including the presentation of the records. Therefore, procedures were in place to control the issuance of blank paper templates for data recording, with reconciliation and authenticity controls where required.

Records of samples for legal proceedings were maintained according to applicable legal requirements.

A Laboratory Information Management System (LIMS) ensured the traceability of operations, with access to stored electronic data restricted to authorized personnel.

All quality, technical, and scientific records were legible, readily retrievable, stored, and retained in a secure environment to prevent damage, deterioration, or loss. Original records were stored under secure and confidential conditions, with access limited to authorized personnel. Electronic storage and signatures conformed to electronic record requirements.

Quality management records included reports from internal and external audits, inspections, management reviews, risk assessments, and records of complaints and their investigations, as well as corrective and preventive actions.

1.6. Control of Data / Computerized Systems

The validation of the computerized system was carried out in accordance with SOPs for computerized system life-cycle management, for periodic review of computerized systems, for computerized system validation, and for the retirement of computerized systems. Validation reports demonstrating suitability for use were prepared and verified by the Quality Manager or designated personnel and made available to staff after approval by the Laboratory Director or a designated person.

An SOP for the LIMS system described the use of the Laboratory's electronic Laboratory Information Management System (LIMS), including access rules. A statement from the service provider indicated that the audit timestamp field of the LIMS system is always displayed in GMT and cannot be altered. This uniformity in audit timestamps is a standard setting in the software systems, designed to accommodate multi-site implementations across different time zones.

Commercial off-the-shelf software was applied within its designed application range, and was deemed sufficiently validated, to the extent that could be verified during the inspection.

The suitability and validation of the randomly selected systems were investigated.

For test data in computerized systems:
- Electronic data were protected from unauthorized access, with an audit trail enabled and periodically checked in accordance with the respective SOP.
- Computers and automated equipment were properly maintained and provided with necessary environmental and operating conditions for data integrity.
- Electronic data were backed up at regular intervals, retrievable, and stored suitably to prevent data loss in accordance with the SOP for computerized systems and electronic data backup.

The laboratory used both networked and standalone computerized systems. However, the current list of software systems did not clearly indicate which systems were networked and which were web-based, nor did it specify the purpose of each system. Therefore, it is recommended that the software system list be revised to ensure that all relevant information is accurately documented.

1.7. Corrective and preventive actions

Any deviation or nonconformity reported by staff or otherwise identified was investigated through root cause analysis with the analyst to identify and rectify the problem in accordance with applicable SOPs for the Deviation Control Procedure. It was noted that there was no clear distinction between planned/unplanned deviations and non-conformities.

The laboratory identified responsible persons for necessary actions and established timelines for implementation. Additionally, the effectiveness of the corrective actions taken was reviewed.

Depending on their potential impact, preventive actions were managed as per SOP for Preventive Actions.

1.8. Internal audits

The Quality Manager was responsible for organizing annual internal audits, including planning, establishing, implementing, and maintaining an audit program, in accordance with SOP. The internal audits covered the entire scope of the laboratory's activities, along with the quality control measures implemented for more frequent supervision of these activities. The audit plan for 2024 was available, and the results of the most recent internal audit, along with the names of the external auditors were presented during the opening meeting.

The applicable SOP required planning and performing audits periodically by the Quality Manager (at least once a year) to enable systematic assessments. It ensured audits were conducted by trained personnel independent of the activity being audited. Audit results were reported to relevant management, discussed during management review, and communicated to staff. Appropriate corrections and corrective actions were implemented promptly upon identifying nonconformities.

The effectiveness of implemented corrective actions was monitored, and records were retained as evidence of the audit program implementation and results.

1.9. Complaints

The laboratory had an SOP for the management of complaints. However, no complaints had been registered with the laboratory.

1.10. Management Review

Laboratory management reviews were organized at planned intervals, at least annually, to monitor the management system's effectiveness in accordance with the applicable SOP.

Senior management, including the board director, laboratory director, and quality manager, confirmed previous decisions and their impact on the laboratory's activities and resources.

Outcomes of management reviews were recorded, documenting all decisions and actions related to QMS effectiveness, improvement of laboratory activities, required resources, and necessary improvements.

Records of management reviews included information on, but not limited to, the suitability of policies and procedures, performance management, status of actions from previous reviews, changes in internal and external factors impacting the laboratory, results of internal and external audits or inspections and any required follow-up actions, changes in laboratory activities, adequacy of resources, training programs, feedback from customers and staff, trend analysis results, and atypical and out-of-specification results.

1.11. Improvement

Provisions for improvement were included in the Quality Manual. The laboratory identified and selected opportunities for improvement, implementing necessary actions. These opportunities were identified through the review of policies, procedures, and objectives, audit and inspection results, corrective and preventive actions, risk assessment, management review, staff and customer suggestions, and analysis of data, trends, and proficiency testing results.

The laboratory requested feedback from customers through methods such as customer satisfaction surveys, face-to-face conversations, and report reviews. This feedback was used as an improvement tool.

A trend analysis was performed following the respective SOP, using established key indicators for ongoing monitoring. If the analysis revealed results outside predefined criteria, appropriate actions were taken to prevent the reporting of incorrect results. At the beginning of each year, laboratory quality control items, such as proficiency testing activities and the involved laboratory/personnel, were stipulated, reviewed, and approved by the Quality Manager. The Quality Management Department recorded the completion of SIFDC quality control activities in a timely manner and summarized the annual proficiency testing results at the end of each year.

SIFDC prioritized proficiency testing schemes that operated in accordance with ISO/IEC 17043, such as those run by CNAS-accredited providers and internationally recognized organizations like APLAC. The minimum requirements for SIFDC's participation in proficiency testing activities each year were implemented according to CNAS RL02 Rule for Proficiency Testing. If proficiency testing results were "unsatisfactory," SIFDC initiated the Nonconformities Control Procedure within 180 days of the final report's release to identify causes, implement corrective actions, and participate in similar proficiency testing programs promptly. Due to the absence of an unsatisfactory result among the records reviewed during the inspection, this activity could not be verified.

In addition, SIFDC obtained the Certificate of Proficiency Testing Provider from the China National Accreditation Service for Conformity Assessment in February 2017 and complied with ISO/IEC 17043: 2010 requirements for proficiency testing providers.

2. Planning and strategic management

2.1. Externally provided services and supplies

The process for selecting and purchasing products and services required by the laboratory was described in the applicable SOP.

The laboratory communicated its requirements to external providers, specifying:

- The products and services to be provided and their acceptance criteria.
- Competence, including any required qualification of personnel (if applicable).
- Activities that the laboratory or its customer intended to perform at the external provider’s premises.

A master list of suitable external suppliers for essential products and services was prepared by the laboratory. The process for purchasing blank papers for controlled templates was reviewed and discussed.

2.2. Review of tenders and contracts

The Laboratory did not use any contracted laboratory.

2.3. Performance Management

Refer to section 1.11.

2.4. Quality Risk Management

The laboratory adopted a well-established approach to risk management in accordance with SOPs for Quality Risk Management and for Testing Risk Control. All types of risks associated with processes, activities, stakeholders, products, and services were considered, with procedures and methodologies defined to minimize, monitor, and control the probability or impact of adverse events and potential failures. While the laboratory did not perform proactive risk analysis, risks were identified during internal audits and addressed accordingly.

A team led by the Quality Manager, including experts from various areas, was established to coordinate and facilitate science-based risk decision-making. The quality risk management process involved defining the risk, gathering background information, and setting timelines and decision-making levels.

The process of identifying and treating risks and opportunities was recorded and monitored by senior management during management reviews.

The related to QRM was sufficiently addressed in the respective CAPA plan.

2.5. Crisis Management

The facility was equipped with energy supplies, i.e., UPS, to ensure business continuity. Business continuity planning enabled effective measures to be taken during issues or incidents, managing them and ensuring uninterrupted operations.

The recovery plan included inputs from key stakeholders and personnel and the formation of a continuity team. Recovery strategies for IT, including manual workflows and an IT disaster recovery plan, were managed in accordance with another SOP.

2.6. Communication management

Refer to section 1.1.

3. Resources

3.1. Personnel

Personnel with the necessary education, training, technical knowledge and experience for their assigned functions, were employed either permanently or under contract. The competence requirements for each function were documented. The laboratory had procedures and criteria for selecting and assessing personnel competence in accordance with the QMS.

Staff undergoing training were appropriately supervised and assessed upon completion, with assessments fully documented.

The laboratory director or designated person authorized personnel to perform specific laboratory activities, ensuring only sufficiently qualified and trained personnel were allowed to perform them.

Procedures and criteria for the continuous assessment of personnel competence were documented, and training or requalification of personnel was provided as necessary.

A matrix of the competencies of each staff member, along with documented procedures and criteria for continuous assessment, was maintained.

The laboratory director or designated person was responsible for consigning samples to specific units and approving analytical test reports and certificates of analysis. Designated qualified personnel were responsible for reviewing all analytical data to ensure the validity of test results and for performing specific tests or analytical techniques requiring advanced technical training and knowledge.

3.2. Premises

The laboratory's layout, encompassing both Physicochemical and Microbiological areas, was documented, and the facility was of suitable size, construction, and location. The premises accommodated the requirements of a pharmaceutical testing laboratory, minimizing risks to staff health and the quality of analytical results. Emergency exits were available. The layout of the microbiology laboratory was revised during the inspection to exclude irrelevant areas and include relevant areas, such as the glassware cleaning station.

Appropriate entrance and sample reception areas were provided for staff, visitors, and samples. Rest and refreshment rooms and toilets were separate from laboratory areas. Changing areas were easily accessible and appropriate for the number of users.

Storage facilities were organized for the storage of samples, reagents, and equipment. Separate storage facilities were maintained for secure storage, ensuring appropriate temperature and humidity conditions and being securely locked. Controlled substances were marked and kept separately, with access restricted to designated personnel. An appropriate spill kit to be used in the storage facility was provided at the time of inspection.

The laboratory was equipped with adequate instruments and equipment, including workbenches, workstations, and fume hoods. Separate instrument rooms for different measurement techniques were available as required. Adequate safety equipment was appropriately located, and measures were in place to ensure good housekeeping and cleaning routines. Weighing areas were situated in locations where environmental conditions of temperature and humidity were controlled.

Preparation and analysis of cytotoxic and genotoxic substances were performed according to the respective SOP. Archive facilities were provided to ensure secure storage and retrieval of all documents, with records kept in secure rooms and electronic records retained with duplicate copies in an external facility.

Environmental conditions, including lighting, energy sources, temperature, humidity, and air pressure, were appropriate to the functions and operations performed, with relevant conditions monitored, controlled, and documented. The storage facilities for cold temperatures were equipped with alarms, which were subject to random checks during the inspection.

Procedures were in place for the safe removal of waste according to local policy, conforming to local environmental standards and laboratory policy. Solid-, liquid-, and biowaste were discarded by the service provider. Training on how to handle the neutralization of acids and bases was provided to the staff following the respective procedure.

Microbiological testing was performed in a contained unit, with sterility testing conducted in an isolator with a separate air supply. The microbiology unit areas had dedicated air-handling units and other provisions, including temperature and humidity controls, managed by the Temperature and Humidity Recording System. The air supplied to the controlled areas was regularly tested according to the SOP for the Operation of the HVAC System to ensure it was of appropriate quality to avoid contamination. Personnel were aware of the proper entry and exit procedures, including gowning.

Laboratory activities, such as sample preparation, media, and equipment preparation, and enumeration of microorganisms, were segregated by space to minimize the risks of cross-contamination, false-positive results, and false-negative results. Sterility testing was performed in a dedicated isolator following the SOP for Sterile Isolators, effective 15 July 2024. The laboratory was equipped with two isolators. The SOP included an environmental monitoring program that covered active air monitoring, air settling or contact plates, and temperature and pressure differentials of the classified areas.

Pressure gauges used for the isolators were labelled. For other controlled areas, the same system used for temperature and humidity control was used. Alert and action limits were defined.

Environmental control complied with testing of non-viable and viable particle verification of HEPA filter integrity and airflow. Mapping locations for sample points for routine monitoring during sterility testing and exposure duration were defined and documented. Microbiological environmental monitoring was continuously executed during routine and validation testing through air sampling and settle plate methods.

A documented cleaning and disinfection plan for the Microbiology unit, including procedures for dealing with spillage, was available. The same plan was also applicable to the isolators.

Entry to the controlled rooms occurred via a system of airlocks and a change room where operators were required to wear suitable clean-room garments. The controlled rooms, classified as Grade C, were used for microbial limit testing including the storage of the respective sterilized materials and utensils. The changing rooms were of adequate size to facilitate ease of changing.

3.3. Equipment, instruments, and other devices

All equipment, modules, and accessories were uniquely identified, including manufacturer details, identification numbers, and location. Specifications were captured in qualification documents.

The frequency of calibration and performance verification was determined by the manufacturer or applicable guidelines, in accordance with the SOP for Instrument Verification Management.

The documentation of the selected equipment was reviewed to verify whether the analytical equipment was adequately qualified, demonstrated fitness for its intended purpose, complied with pharmacopeial requirements, and/or followed manufacturer recommendations, with the laboratory being ultimately responsible for equipment qualification

- Isolator
- Incubator
- Autoclave
- Balance
- HPLC (and the associated audit trail)
- UV-Vis (and the associated audit trail)
- Dissolution apparatus
- GC
- Friability
- Disintegration apparatus
- Pass Box
- pH meter
- Leakage tester (for Isolators' gloves)
- Optical Rotation

During purchasing, an equipment qualification (EQ) plan was available for each piece of equipment, ensuring supplier support for EQ processes. This support included testing, training, maintenance, and repair, as specified in the contract/package, including the price.

A preventive maintenance schedule and EQ plan were established for analytical equipment, to be performed either by the laboratory or a competent external service provider. All calibrations and equipment qualifications were traceable to appropriate references, and a change control process was required for any modifications to analytical equipment. Requalification was mandated after certain changes, in accordance with the SOP.

Defective or out-of-specification equipment had to be taken out of service, repaired, requalified, and clearly labeled before reuse.

Documentation for equipment qualification had to define responsible personnel, specify tests and criteria, provide procedures and material details, record test dates and results, state reasons for qualification, specify actions for failures, and include signatures of the personnel involved.

Equipment logbooks were maintained to document equipment history, including maintenance.

The stability of temperature, uniformity of temperature distribution, and time required to achieve equilibrium conditions in incubators were initially established and documented, particularly with respect to typical uses.

Sensors used for controlling or monitoring the operating cycles of autoclaves required calibration, and the performance of timers was verified. In addition to directly monitoring the autoclave's temperature, the effectiveness of each cycle was verified using chemical and biological indicators to ensure proper sterilization or decontamination. The laboratory had a separate autoclave for decontamination.

When centrifuges were used in test procedures, an initial assessment of the rotations per minute (RPM) was conducted, although it was not part of regular testing.

The Temperature and Humidity Monitoring System monitored and recorded temperature, humidity, and differential pressure (where applicable) in controlled areas, refrigerators, and incubators. The system was designed to generate alarms if predefined limits were exceeded. The operation of the system was detailed in the respective SOP, while the alarm limits were specified in another applicable SOP. The system was validated by the supplier, with the last revalidation performed on 15 Jul 2024.

3.4. Reagents and materials

Reagents and chemicals, including solvents and materials used in tests and assays, were required to meet appropriate quality standards and be suitable for their intended use. Commercial reagents were sourced from verified and approved qualified providers, accompanied by certificates of analysis and safety data sheets. Reagent management covered their entire life cycle, from receipt and preparation to use and disposal, following standard operating procedures, specifically the SOP for Reagent and Test Solution Management.

The expiry date of opened reagents was restricted to one year, with retesting conducted annually. Retesting could not extend beyond the original expiry date. The inventory of critical chemicals, reagents, and other materials was managed by the LIMS system.

Labelling requirements included essential information such as the substance name, receipt and opening dates, expiry dates, storage conditions, concentration, manufacturer details, batch numbers, and personnel identifiers.

In-house reagents and water manufactured by the laboratory also had specific labelling requirements. Regular verification of water quality and appropriate storage conditions for reagents were necessary, with expiry date policies documented and justified by the laboratory.

Organism resuscitation was performed in accordance with the respective SOP. Although the laboratory did not currently require organism resuscitation methods, provisions were defined in the SOP.

LAL testing was performed as part of Physico-Chemical activities, in room 222, following specifications in the established procedures.

Culture Media

Media was supplied by approved and qualified vendors. Growth promotion and, if appropriate, other suitable performance tests were conducted on all media for every batch and every shipment.

The performance of culture media, diluents, and other suspension fluids was checked in accordance with the relevant SOPs: for the management of storage, sub-cultivation, and passage of strains for testing; for culture media and reagent quality testing for microbial analysis; and for lab culture media management.

The shelf-life of prepared media under defined storage conditions was determined and verified.

3.5. Reference substances and reference materials

Reference substances from reputable commercial sources or those supplied by the pharmaceutical product manufacturer were used.

The control of reference substances and materials was overseen by a designated staff member through the LIMS.

All reference substances and materials were assigned an identification number. Each batch received a new identification number, marked on individual vials, and referenced in analytical worksheets.

A register was maintained for all reference substances and materials, containing detailed information such as the identification number, description, source, receipt date, batch designation, intended use, storage location, expiry or retest date, certificates, and safety data sheets.

Before use, the intended use and expiry or retest date of reference substances were confirmed, with corresponding information included in test reports.

Reference cultures were required to establish the acceptable performance of media (including test kits), validate methods, verify the suitability of test methods, and assess or evaluate ongoing performance.

Traceability was ensured using reference strains of microorganisms obtained directly from a recognized national or international collection.

Reference strains were subcultured once to provide reference stocks. Purity and biochemical checks were conducted in parallel, as appropriate, according to the Chinese Pharmacopeia. Reference stocks were stored in aliquots and deep-frozen. Working cultures for routine use were primary subcultures from the reference stock. Once the reference stocks were thawed, they were not to be refrozen or reused.

No more than five generations (or passages) from the original reference strain were subcultured.

SOP for Handling of Reference Cultures was available and reviewed.

4. Technical activities

4.1. Incoming samples

When submitting the samples to the laboratory, they were divided into three approximately equal portions: one for immediate testing, another for confirmation of testing, and a third for retention in case of dispute. Providing a separate container for microbiological testing if needed, was applicable.

A standard test request form had to be completed for every sample sent to the laboratory.

The test request form included the following details:
- Name and date of receipt of the provider.
- Material source.
- Detailed sample description, including composition, international nonproprietary name, and brand names.
- Packaging details.
- Dosage form, concentration or strength, manufacturer's name, and batch or lot number.
- Sample size.
- Reason for analysis request.
- Sampling date.
- Consignment size (if applicable).
- Expiry date or retest date (if known).
- Reference documents and testing specifications. It could be the Chinese or any other pharmacopeia, as available.
- Additional comments or discrepancies found.

Before commencing testing, the laboratory was required to review the test request to ensure:
- Adequate sample amount for requested tests.
- Possession of necessary capability and resources for conducting tests.
- Ability to meet customer requirements with available tests or methods.

Each sample and its accompanying documentation were assigned a unique registration number in the LIMS system. Different codes were used based on the samples' origin.

Each sample container was affixed with a label bearing the unique registration number without obscuring any other markings or inscriptions.

A register was maintained recording:
- Sample registration number.
- Receipt date.
- Specific unit(s) designated for analysis.

Upon receipt, the sample underwent visual inspection by laboratory staff to ensure conformity with the test request information. Any discrepancies or damages were recorded on the test request form and queries were directed back to the sample provider.

Samples, retained before testing and after completing required tests, were stored appropriately.

The specific unit responsible for testing was determined by the Head of the Laboratory or designated person.

All documentation accompanying each numbered sample sent to the specific unit was ensured to have the correct identification number, origin, purpose, and additional information for receipt and testing activities.

The observation related to Incoming samples was adequately addressed in the respective CAPA plan.

4.2. Selection, validation, and verification of analytical procedures

The analytical procedures to be used for testing were defined in the test request. An SOP was available for Analytical method verification, transfer, and validation.

All analytical procedures employed for testing were ensured to be suitable for their intended use. Additionally, the laboratory had an SOP that described the method validation process for analysing non-pharmacopeial substances or products.

Validation was performed in accordance with an approved validation protocol, which outlined the analytical performance characteristics to be verified for various types of analytical procedures. The results were documented in the validation report.

Pharmacopeial procedures and those approved by the licensing authority were considered validated for the use described in the monograph. If validation was not required, method verification was performed according to an approved protocol or procedure to demonstrate that the laboratory could execute the method and that the pharmacopeial procedure used was suitable for the sample being tested. The laboratory specifically confirmed parameters such as specificity, accuracy, precision, repeatability, limit of detection, and/or limit of quantification.

System suitability tests were conducted prior to and throughout the analysis of samples to ensure that the complete analytical system—including instruments, reagents, columns, and analysts—remained continuously suitable for the intended application.

For microbiology testing, the laboratory demonstrated that the performance criteria of the standard test method were met through method verification, ensuring the test method's suitability for the specific product.

The laboratory maintained an overview of method verifications and had conducted only one method validation, specifically assigned by the National Authority, as they typically received samples accompanied by compendial methods.

4.3. Technical records

The analytical worksheet, or an equivalent document such as an eLN, served as an internal record for the analyst to document information about the sample, test procedure, reagents, standards, materials, calculations, and test results. It included all raw data obtained during the analysis and provided documentary evidence to confirm whether the sample met the required specifications or to support an out-of-specification result.

A unique analytical worksheet was used for each numbered sample or group of samples.

The analytical worksheet provided the following information:
- Sample registration number
- Page numbering, including total pages (with annexes)
- Date of the test request
- Dates of analysis start and completion
- Name and signature of the analyst
- Identification of test equipment used
- Reference substances used (provider, lot number, potency/content)
- System suitability test results and analytical acceptance criteria, if applicable
- Identification of reagents, solvents, and columns used
- Results obtained, including from internal or external sources, if applicable
- Interpretation of results and conclusions (compliance with specifications), approved and signed by qualified personnel
- Further comments, such as deviations from prescribed procedures, nonconforming work, or sample transfers to other units or contract laboratories, including dates

All test values, including blank results, were immediately entered on the analytical worksheet, with all graphical data attached or traceable to an electronic record file.

The completed analytical worksheet was signed by the responsible analyst and reviewed and approved by designated qualified personnel, either in paper format or electronically. Calculations and data transfers were systematically checked or controlled.

Any changes made to original records, either in paper or electronic format, were traceable to what was changed, who was responsible when it was performed, and why. The deletion of data was not acceptable.

The analytical worksheet and any attachments, including calculations and recordings of instrumental analyses, were archived together with the specification.

4.4. Testing

Testing methods for compliance with specifications were provided by the appropriate pharmacopeial monograph or the medicine licensing authority. Detailed guidance on pharmacopeial requirements was usually found in the specific monographs of the pharmacopeia. Test procedures were described in detail, providing sufficient information for trained analysts to perform the analysis reliably and reproducibly.

Compliance with internal quality control criteria was ensured. SOP for Management of the sample testing deadline was also available.

The documentation for the following randomly selected samples, from receipt to the issuance of their CoA, was reviewed:

- (Lamivudine)
- (Camphor)
- (Levothyroxine)
- (Dapagliflozin)
- (Gadoteric Acid Meglumine Salt Injection)
- (Tacrolimus ointment)

4.5. Evaluation of test results

For compliance testing, the product had to meet all acceptance criteria of the analytical tests specified in the approved specification. Test results were compared with specification limits to determine if the sample met the requirements, and a conclusion was drawn regarding its conformity with the specification.

4.6. Measurement uncertainty

The requirements for measurement uncertainty applied to the applicable quantitative tests. The process followed the SOP for the Measurement Uncertainty Evaluation Procedure. This SOP defined situations where measurement uncertainty was or was not required.

A proficiency testing on osmolality was arranged, with the attestation for participation dated 22 Aug 2023 available. In these tests, the use of measurement uncertainty was correctly considered.

4.7. Validity of test results

The validity of results, including OOS invalidation investigations, was ensured by the laboratory through a procedure encompassing the review of various activities, including:

- Reference substances or reference materials
- Verification of measuring and testing equipment
- Appropriate quality control checks

- Data analysis methodologies that do not necessitate additional experiments (such as the use of control charts, trend analysis, and various types of correlation of results of the sample being tested)
- Replicate tests or calibrations using the same or different methods.
- Retesting of retained samples.
- Review of all raw data and reported results.
- Review of measurement uncertainty results, if required.

The performance of the laboratory underwent regular assessment through participation in proficiency testing schemes, organized both internally and externally, in accordance with SOP. The laboratory prepared an annual plan for proficiency testing. However, it was recommended that the laboratory develop a plan for at least the next three years to ensure that all essential testing methods were included and to maintain an overview.

4.8. Out-of-specification (OOS) results

When a suspected out-of-specification result was identified, a review of the different procedures applied during the testing process was undertaken by the supervisor with the analyst or technician, using a checklist before any retesting was performed. The investigation ensured that:

- If stable, original sample preparations were not discarded until the investigation was complete.
- The appropriate procedures were applied and followed correctly, including requirements for validation and verification, and internal quality control tools.
- Examination of the raw data was undertaken to identify possible discrepancies.
- All calculations were checked.
- The equipment used was qualified and calibrated, and acceptable system suitability tests were performed.
- The appropriate reagents, solvents, and reference substances were used.

The identification of an error that caused an aberrant result invalidated the result, necessitating a retest of the sample by the same technician or analyst.

Suspected OOS results could only be rejected if they were clearly due to an identified error. In cases where an investigation was inconclusive, a confirmatory test was to be performed by another trained analyst. A similar result would indicate a confirmed OOS result. If comparable results were not obtained by the second analyst, the lack of consistency was investigated. Further confirmation using another validated method, if available, was advised and, if performed, fully documented.

If available, hypothesis testing was considered to define the root cause better.

An SOP was established to investigate suspected OOX test results. All investigations and their conclusions were documented and reported by the analyst to the investigator. The investigators comprised senior chemists (four in the physico-chemical laboratory and one in the Microbiological laboratory).

In cases of error, a root cause analysis was conducted, and any corrective actions were documented, implemented, and recognized as opportunities for improvement.

The OOS which pertained to related substances (analyzed using HPLC), was reviewed and discussed. The OOS was reported on 12 Apr 2023 and closed on 21 Apr 2023. The investigation validated the OOS result, leading to the issuance of a non-compliance report to the applicant.

4.9. Reporting of results

The study supervisor compiled the analytical test report, whether in hard copy or electronically, containing the analytical test results for approval by the Head of the laboratory. Subsequently, the dossier containing all information related to the sample-such as its origin, chain of custody, and analytical data-was archived.

The laboratory determined when to report the uncertainty of a result and how conformance to specifications was evaluated.

The laboratory determined when to report the uncertainty of a result and how conformance to specifications was evaluated. The test report, which also served as the Certificate of Analysis (CoA), provided the following information:

- A title (e.g., "test report", "analytical test report", or another suitable title).
- The laboratory registration number of the sample.
- The laboratory test report number.
- The name and address of the laboratory testing the sample.
- The name of the originator of the request for analysis.
- The name, description, and batch number of the sample, where appropriate.
- An introduction giving the background to and the purpose of the investigation, if applicable.
- A reference to the specifications used for testing the sample or a detailed description of the procedures employed (sample for investigative testing), including the limits.
- The results of all the tests performed or the numerical results, with the standard deviation of all the tests performed (if applicable).
- When applicable, the expanded measurement uncertainty of the reportable result with reference to its assessment and an explanation of how it was used in making the compliance decision.
- A conclusion as to whether or not the samples were found to be within the limits of the specifications used, or, for a sample for investigative testing, the substances or ingredients identified.
- A statement to the effect that the results relate only to the items tested, calibrated, or sampled.
- The date on which the tests were completed.
- The signature of the laboratory director or other authorized person reviewing and authorizing the report.
- Whether or not the samples comply with the requirements.
- The date on which the sample was received.

- The expiry date or retest date, if applicable.
- A statement indicating that the analytical test report, or any portion thereof, cannot be reproduced without the authorization of the laboratory.

4.10. Nonconforming work
Refer to section 1.7.

4.11. Retained samples
There had to be a sufficient amount of retained sample to allow at least two re-analyses, with the retained sample contained in its original packaging. Sample disposal criteria were established according to national legislation, applicable international recommendations, or, if required, by the originator of the request for analysis.

5. Safety rules

Each staff member was provided with general and specific safety procedures reflecting identified risks. Training on safety-related issues was held at predefined intervals, as specified in the QMS documentation. General rules for safe working included the following requirements:

- Safety data sheets were available to staff before testing.
- Smoking, eating, and drinking in the laboratory were prohibited.
- Staff were familiar with firefighting equipment, including fire extinguishers, fire blankets, and gas masks.
- Laboratory coats or suitable protective clothing, including eye protection, were mandatory.
- Special care was taken when handling highly potent, infectious, or volatile substances.
- Highly toxic or genotoxic samples were handled in specially designed facilities to prevent contamination.
- Chemical containers were appropriately labeled with prominent warnings (e.g., “poison,” “flammable”).
- Electrical wiring and equipment, including refrigerators, had adequate insulation and spark-proofing.
- Rules for handling compressed gas cylinders were observed, with staff familiar with relevant color codes.
- Staff were not permitted to work alone in the laboratory.
- First-aid materials were provided, and staff were instructed in first-aid techniques, emergency care, and the use of antidotes.

Protective clothing, including eye protection, masks, and gloves, was available and fit for purpose. Safety showers (for eyes and full body) were installed. Staff were instructed in the safe handling of glassware, corrosive reagents, and solvents. Warnings, precautions, and instructions were incorporated.

Hazardous products were identified, labeled appropriately, and kept separately from other products.

Miscellaneous	
Assessment of the Laboratory Information File	The Laboratory Information File for the Shanghai Institute for Food and Drug Control was submitted on 15 Jan 2024 and reviewed.
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 of ***SIFDC-Drug Quality Control Center***, located at ***No.479, Futexi 1st Road, Pudong New Area, Shanghai, 200131; P.R. China*** 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**

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report, Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   Short name: WHO GPPQCL Guidelines, TRS No 1052, Annex 4
   https://www.who.int/publications/i/item/9789240091030

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
   https://www.who.int/publications/m/item/trs961-annex2

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report, Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://www.who.int/publications/m/item/annex-4-trs-929

4. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report, Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
https://www.who.int/publications/m/item/annex-4-trs-

5. 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***
https://www.who.int/publications/m/item/trs986-

6. 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

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report, Geneva, World Health Organization, 2010 (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

8. 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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex6-gmp-sterile-pharmaceutical-products.pdf

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report, Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex7-transfer-technology-pharmaceutical-manufacturing.pdf?sfvrsn=2e302838_0

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report, Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 96, Annex 9)
    Short name: WHO TRS No. 961, Annex 9
    https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

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

12. 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
    Short name: WHO TRS No. 1010, Annex 8
    https://www.who.int/publications/m/item/Annex-8-trs-1010

13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report, Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
    Short name: WHO TRS No. 981, Annex 2
    https://www.who.int/publications/m/item/trs981-annex2

14. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report, Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
    Short name: WHO TRS No. 981, Annex 3
    https://www.who.int/publications/m/item/annex-3-trs-981

15. WHO guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report, Geneva. WHO Technical Report Series, No. 961, 2011, Annex 13.
    Short name: WHO TRS No. 961, Annex 13
    https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs961-annex13-guidelines-preparing-laboratory-information-file.pdf?sfvrsn=54d1f397_2 -
    https://www.who.int/publications/i/item/9789241209922

16. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report, Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4.
Short name: WHO TRS No. 992, Annex 4
https://www.who.int/publications/m/item/trs992-annex4

17. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature–sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report, Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5.
Short name: WHO TRS No. 992, Annex 5
https://www.who.int/publications/m/item/trs992-annex5

18. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report, Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
https://www.who.int/publications/m/item/trs1010-annex10

19. Good chromatography practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report, Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO Good chromatography practices
https://www.who.int/publications/m/item/trs1025-annex4

20. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third report, Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

21. WHO model certificate of analysis. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second report, Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 4.
Short name: WHO TRS No. 1010, Annex 4
https://www.who.int/publications/m/item/trs1010-annex4

22. 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

23. Guidelines on pre-approval inspections. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report, Geneva, World Health Organization, 2002 (WHO Technical Report Series, No. 902), Annex 7
Short name: WHO TRS No 902, Annex 7
https://www.who.int/publications/m/item/trs902-annex7

24. Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-first report, Geneva, World Health Organization, 2017 (WHO Technical Report Series, No. 1003), Annex 3
Short name: WHO TRS No 1003, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1003