# WHO Inspection Report

## Part 1: General Information

<table>
<thead>
<tr>
<th>Laboratory details</th>
<th>Laboratory information</th>
<th>Name of the laboratory</th>
<th>Corporate address of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Shenzhen Institute for Drug Control (Shenzhen Testing Center of Medical Devices)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

## Inspected Laboratory

| Address of inspected Laboratory if different from that given above | No. 28, Gaoxin Central 2nd Avenue, Nanshan District, Shenzhen, Guangdong, China. |

## Summary of activities performed at the laboratory

<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Finished products</th>
<th>Active pharmaceutical Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical / Chemical analysis</td>
<td>pH, density, refractometry, water content, limit tests, disintegration, dissolution, uniformity of dosage units (mass, content), friability</td>
<td>pH, refractometry, optical rotation, loss on drying, water content, heavy metals, acid value, iodine value, limit tests, nitrogen determination</td>
</tr>
<tr>
<td>Identification</td>
<td>HPLC (UV-VIS, RI), GC (FID), TLC, UV-VIS, IR, basic tests</td>
<td>HPLC (UV-VIS, RI), GC (FID), TLC, UV-VIS, IR, basic tests</td>
</tr>
<tr>
<td>Assay, impurities and related substances</td>
<td>HPLC (UV-VIS, RI), GC (FID), TLC, UV-VIS, AAS, IR, volumetric titrations</td>
<td>HPLC (UV-VIS, RI), GC (FID), TLC, UV-VIS, AAS, IR, volumetric titrations</td>
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</tbody>
</table>

## Inspection Details

<table>
<thead>
<tr>
<th>Dates of inspection</th>
<th>14-16 December 2017</th>
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<tbody>
<tr>
<td>Type of inspection</td>
<td>Initial inspection</td>
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</tbody>
</table>

## Introduction

| History | This was the first WHO-PQT inspection of Shenzhen Institute for Drug Control (SZIDC). |

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Contact: prequalinspection@who.int
### Areas inspected

The inspection scope was limited to the drug physico-chemical laboratory and the inspection covered the following sections of the WHO good practices for pharmaceutical quality control laboratories (GPPQCL) text:

- Organization and management
- Quality management system
- Control of documentation
- Records
- Data-processing equipment
- Personnel
- Premises
- Equipment, instruments and other devices
- Contract
- Reagents
- Reference substances and reference materials
- Calibration, verification of performance and qualification of equipment, instruments and other devices
- Traceability
- Incoming samples
- Analytical worksheet
- Validation of analytical procedures
- Testing
- Evaluation of test results
- Certificate of analysis
- Retained samples
- Safety

### Restrictions

None

### Out of scope

Microbiology section was outside the scope of this inspection

### Key persons met

- Xiangyu Wang, Division Director, CFDA
- Xinhua Xiang, Department Deputy Director, NIFDC
- Mingzhe Xu, Department Deputy Director, NIFDC
- Xiana Wang, Inspector, SZQMS
- Yi Lu, Director General, SZIDC
- Tiejie Wang, Deputy Director/Technical Manager, SZIDC
- Xiaowei Wang, Deputy Director/Quality Manager, SZIDC
- Liang Xu, Deputy Director, SZIDC
- Jun Li, Assistant Director, SZIDC
- Min Yang, Department Director, SZIDC (Names and job titles)

For more detail, refer attendance records.

### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHU</td>
<td>air handling unit</td>
</tr>
<tr>
<td>ALCOA</td>
<td>attributable, legible, contemporaneous, original and accurate</td>
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<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<td>--------------</td>
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</tr>
<tr>
<td>BDL</td>
<td>below detection limit</td>
</tr>
<tr>
<td>CAPA</td>
<td>corrective actions and preventive actions</td>
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<td>CC</td>
<td>change control</td>
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<tr>
<td>CFU</td>
<td>colony-forming unit</td>
</tr>
<tr>
<td>CoA</td>
<td>certificate of analysis</td>
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<td>DQ</td>
<td>design qualification</td>
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<td>EM</td>
<td>environmental monitoring</td>
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<td>FAT</td>
<td>factory acceptance test</td>
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<td>FMEA</td>
<td>failure modes and effects analysis</td>
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<td>FPP</td>
<td>finished pharmaceutical product</td>
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<tr>
<td>FTA</td>
<td>fault tree analysis</td>
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<tr>
<td>FTIR</td>
<td>Fourier transform infrared spectrometer</td>
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<tr>
<td>GC</td>
<td>gas chromatograph</td>
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<td>GMP</td>
<td>good manufacturing practice</td>
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<td>HACCP</td>
<td>hazard analysis and critical control points</td>
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<td>HPLC</td>
<td>high-performance liquid chromatograph</td>
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<td>HVAC</td>
<td>heating, ventilation and air conditioning</td>
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<tr>
<td>IR</td>
<td>infrared spectrophotometer</td>
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<tr>
<td>IQ</td>
<td>installation qualification</td>
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<tr>
<td>KF</td>
<td>Karl Fisher</td>
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<tr>
<td>LAF</td>
<td>laminar air flow</td>
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<tr>
<td>LIMS</td>
<td>laboratory information management system</td>
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<tr>
<td>LoD</td>
<td>limit of detection</td>
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<tr>
<td>LOD</td>
<td>loss on drying</td>
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<tr>
<td>MB</td>
<td>microbiology</td>
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<td>MBL</td>
<td>microbiology laboratory</td>
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<td>MR</td>
<td>management review</td>
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<tr>
<td>NMR</td>
<td>nuclear magnetic resonance spectroscopy</td>
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<td>NRA</td>
<td>national regulatory agency</td>
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<tr>
<td>OQ</td>
<td>operational qualification</td>
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<td>PHA</td>
<td>process hazard analysis</td>
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<tr>
<td>PM</td>
<td>preventive maintenance</td>
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<tr>
<td>PQ</td>
<td>performance qualification</td>
</tr>
<tr>
<td>QA</td>
<td>quality assurance</td>
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<tr>
<td>QC</td>
<td>quality control</td>
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<tr>
<td>QCL</td>
<td>quality control laboratory</td>
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<td>QRM</td>
<td>quality risk management</td>
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<tr>
<td>RA</td>
<td>risk assessment</td>
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<td>RCA</td>
<td>root cause analysis</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>TAMC</td>
<td>total aerobic microbial count</td>
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</tbody>
</table>

WHO Public Inspection Report:
Shenzhen Institute for Drug Control (Shenzhen Testing Center of Medical Devices)
14-16 December 2017

This inspection report is the property of the WHO
Contact: prequalinspection@who.int
1. Organization and management

The Shenzhen Institute for Drug Control (SZIDC (STCMD)) (Shenzhen Testing Center of Medical Devices) is a legally authorized institute established by Shenzhen Municipal Government in accordance with related laws and regulations (Drug Administration Law, etc.), which implements quality supervision and inspection on Drugs, Health Food, Cosmetics and Medical Devices. The SZIDC (STCMD) was accredited by the China National Accreditation Service for Conformity Assessment (CNAS), certificate valid up to May 20\textsuperscript{th}, 2018; and by the China Metrology Accreditation (CMA), certificate valid up to 26\textsuperscript{th} November 2023.

The SZIDC (STCMD) is headed by Director who, together with the Deputy Director, Technical Manager and Quality Manager, constitutes top management. SZIDC (STCMD) has 16 departments, including 7 functional departments and 8 testing departments in the home office, and 1 testing department in the division office. Each department has 1 - 3 leader(s), all of whom constitute the executing management of the SZIDC (STCMD). There were a total of 192 employees of whom 61 were related to the prequalification.

The SZIDC (STCMD) is divided into home office and division office, managed by institute director and deputy director. The home office has seven functional departments namely: Executive Office, Business and Technology Department, Quality Management Department, Equipment Purchasing and Maintenance Department, Supervision Management Office, Information Technology Department, Medical Devices General Business Department, and eight testing laboratories for: Chemical Drug, Traditional Chinese Medicine, Health Food and Cosmetics, Pharmacology and Toxicology, Microbiology, Analysis and Testing Research, Non-active Medical Devices, and In-vitro Diagnostic Reagents; the division office has one testing laboratory for: Active Medical Devices.

The home office is responsible for the testing for drugs, biological products, health food, cosmetics, non-active medical devices and pharmaceutical packaging materials; the division office is for active medical devices testing.

There are also technical and managerial positions, such as authorized signatories, biological safety managers, internal auditors, supervisors and biological safety supervisors, testers (including testers, checkers, re-testers and reviewers) and assistant testers, samplers and assistant samplers, metrological controllers, equipment controllers, chromatographic column controllers, reference material controllers, reagent
controllers, waste and disposal controllers, experimental animal controllers and assistant workers, business acceptors, sample controllers, business administrators, scientific research administrators, quality controllers, information system administrators, network administrators, documents/standards controllers, archives controllers, librarians, purchasers, warehouse keepers, support administrators, safety supervisors, experimental animal keepers, and assistant workers.

According to the presentation, SZIDC (STCMD) has drafted 12 monographs for International Pharmacopeia, 6 of which have been adopted; and drafting and revising over 700 national standards for drugs, cosmetics and medical devices.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

### 2. Quality management system

The quality management system of SZIDC (STCMD) was described in the Management Manual SZIDC. The Manual was written to address the requirements of WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL), China National Accreditation Service for Conformity Assessment (CNAS) for ISO/IEC 17025 international standard, and the CMA. A clause comparison (correspondence) table of the Manual and each of the above three requirements was annexed.

The manual had six chapters namely: Laboratory Overview, Notes of Manual, Statement and Commitment, Management Requirements, Technical Requirements and Administrative Requirements, and nine annexes. The manual described various elements including, but not limited to, impartiality statement, quality policy, quality objectives, and service commitment.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

### 3. Control of documentation

Regarding document control system, the SZIDC (STCMD) had changed from a four-tier system (i.e. Management manual; high level SOPs; SOPs; and Forms) to a two-tier system (Management manual; and SOPs (Forms)). The documents were reviewed once every three years for SOPs and forms and five years for quality manual. The five-year review period for the Management manual was however, considered too long a period for a living-controlled document. There was no statement made to indicate that a controlled document may be revised whenever necessary.

The quality management system documents were divided into controlled and uncontrolled documents, but these two terms were not defined as there was no general section for definition of various terms used in the manual.
Document control procedures were adequately described in two SOPs namely: “Preparation and Numbering Guidelines for management System Documents,” and the “Files and Document Control Procedure.”.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

4. **Records**

Original observations, calculations and derived data, calibration, validation and verification records and final results, were retained. The records included the data recorded in analytical worksheets and/or in STAR LIMS system. The records included the identity of the personnel involved in the sampling, preparation and testing of the samples.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

5. **Data processing equipment**

The Data Control Procedure described the ALCOA principle but there was no data integrity policy available. The controls on data integrity and audit trail were inadequate.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

6. **Personnel**

Job descriptions for managerial, technical and key support personnel involved in tests are maintained; defining the responsibilities of tests (with respect to performing test, evaluation of results, reporting opinions and interpretations, method modification, development and validation of new methods, and managerial duties), expertise and experience required, qualifications and training programs. There were 20 scientists in the physical chemical laboratory. A competence matrix with 16 names was available. Up to 15 competencies were possible for a scientist.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

7. **Premises**

Generally, laboratory facilities were of suitable size, construction and location. Rest and refreshment rooms were separate from laboratory areas. Access to the laboratory premises was controlled by biometric system. Laboratory had storage facilities for storage of samples, reagents and glassware. Reference substances and reference materials were stored in locked cabinets and locked fridge. Temperature and relative humidity in
sample storage, reference substances and reference materials storage units and stability chambers were monitored online.

SZIDC (STCMD) is located on cover area of 15,000m² with building area of 14,813m². The premises were spacious, modern and suitable for the testing of drug samples.

Different laboratories included the P&C laboratory, Sample room, Instrument laboratory, Balance room, Reagent room, Animal house and Microbiological laboratory.

The sample reception, temporary storage and retention sample store areas were located on Level I whereas instrumentation laboratory (HPLC, dissolution, weighing balances) was located on Level IV.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

8. Equipment, instrument and other devices

There were adequate number of laboratory equipment and instruments which included pH meters, water content testing apparatus, melting point, loss on drying testing, friability, disintegration time, tablet hardness, dissolution testers, AA spectrophotometry, viscosity, density, dimensions, IR, TLC, HPLCs (with UV-VIS, DAD, and RI detectors), GC, UV Vis spectrophotometers, and FT-IR spectrophotometer, polarimeter, volumetric titrations.

According to the presentation made during the opening meeting, there were over 3,000 sets of advanced test instruments (LC-MS, GC-MS, ICP-MS, HPLC, GC, AAS, IR, UV, etc.) of which 117 sets were related to the prequalification.

The following procedures were available: SOP for network software chromatographic data management, SOP for Waters HPLCs (Empower-3) system management procedure and SOP for Dionex (Chromeleon) system management procedure.

There were three servers for the major equipment: the 6 Agilent and 15 Waters HPLCs had connectivity to one server while the 8 Dionex HPLCs and 7 Shimadzu HPLCs were connected to two separate servers.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

9. Contracts

The agreement between Shenzhen Academy of Metrology & Quality (SMQ) Inspection National Hi-Tech Metrology Station and SZIDC (STCMD) was discussed. It was noted that agreement did not describe and agree on technical requirements such as methods, standards, specifications, retention of raw data, audit of laboratory if required etc.
SOP for Purchasing Control Procedure for services and supplies was available and it applied to the SMQ.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

10. Reagents

The SOP for reagents and testing solutions management SOP was discussed. Other procedures used included Operation Procedure for Module of Management for Reagents in LIMS SOP, Operation Procedure for Module of Preparation of Test Solutions in LIMS SOP.

There were two water generating systems for water used for analysis; the purified water generating system and the Ultra-Pure Millipore water generating system with a 0.45µ terminal filter. The purified water was distributed to the physico-chemical laboratory via pipes and was used for general physical/chemical testing, glassware cleaning and source of Ultra-Pure water generating unit. The ultrapure water generated was used for AAS, HPLC, GC and other precision analysis.

The purified water was periodically tested (partial testing on daily basis and full testing on weekly basis) against the Chinese pharmacopoeia. The partial testing included pH, conductivity and oxidizable substances on daily basis. The full testing of the purified water was done as per the Chinese pharmacopoeia, once a week for the following tests: appearance, pH, Nitrate, sub-nitrate, amino and electronic conductivity, oxidized substances, non-volatile substances, heavy metals, microbial limits.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

11. Reference substances and reference materials

Reference standards were procured from NIFDC, China. In addition, laboratory procures chemical reference substances (reference standards) from USP and Ph. Eur, The Operation Procedure for Module of Management for Reference Materials in LIMS SOP and the STAR LIMS were used for maintaining list of all reference standards received and their usage (total number of vials received, used and balance in stock).

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

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

Equipment management procedure described some elements of equipment qualification. A separate procedure described the responsibility and scheduling. STAR LIMS was used to generate equipment
calibration schedules. Annual schedule for the calibration was prepared and different equipment had different calibration frequency.

The STAR LIMS v10 R4 system generates the calibration schedule automatically. Schedule for 2017, prepared on 28th December 2016 and approved on 2nd January 2017 was available. A full set of records of calibration records were available. Calibration was done twice a year.

HPLCs were calibrated every 6 months. The Waters HPLC in the Chemical drugs testing department had been calibrated on 7th September 2017 by SMQ, a government institution accredited by CNAS. The worst case results were within limits; e.g. for the flow rate test the results were: 0.5, 1.0, 1.5, and 2.0ml/min for the quaternary pump, total results were 1.6, the worst RSD was 1.1% (Specs ≤5% RSD).

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

13. Traceability

The results of an analysis were traceable to reference substances, to calibrated equipment and instruments used for analysis and the weights traceable to standard weights as noted during the review of laboratory data. All traceability records about a sample that was tested were maintained by the laboratory.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

14. Incoming samples

The incoming samples were received at the reception of the laboratory. The reception area was divided into pharmaceutical sample area, health & food sample area, cosmetics and medical devices. The samples were received through online registration and by the walk-in customers. It was indicated that guidance documents were available on the laboratory website for the sample submission requirements. Also, hotline facility was provided for the walk-in customers. LIMS was used to enter details of the incoming samples whereas verification was done by another person. The labels were printed and affixed on these incoming samples. It was noted by the inspectors that temporary storage area was not temperature mapped and only one probe was used (ambient storage condition 10-30ºC). It was indicated by the laboratory that incoming samples were stored for not more than 1 to 2 days and were moved to another area for further distribution.

Although sample management procedure (SZIDC (STCMD)/SOP-5.8-001-13) required login of incoming samples using STAR LIMS system before sample acceptance, a number of samples were stored in the temporary storage room without having sample contract form (standard test request form) and without logging them into the STAR LIMS system.

The inspectors also visited the sample retention room. It had 12 metallic storage drawers for storage under room temperature, freezing and cold storage units for -24ºC, -18ºC, -11ºC, 2.4ºC, and 6ºC. The samples...
were stored for one year after they received by the laboratory. The objective of retaining these samples was to perform out of specification, if required and for the arbitration purposes (post marketing samples). It was indicated that the sample retention room was temperature mapped using 13 probes and room was maintained between 10 and 30ºC.

On the fourth floor, another sample storage room was provided for the samples distributed for the testing. This room was not temperature mapped. The temperature and humidity at the time of the inspection was 19.5ºC and 62.3%.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

15. Analytical worksheet

Analytical worksheets were generated within the STAR LIMS system. They were used by the laboratory analysts to record all information about the sample, reagent preparation, testing procedure, calculations and results. They were signed by the responsible analysts, verified and checked by the supervisor.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

16. Validation of analytical procedures

There was no laboratory validation master plan available with the institute which described laboratory’ philosophy on validation approach for analytical method validation, verification, personnel qualification, facility qualification, computer system validation.

There was no specific procedure available on the verification of pharmacopoeial and manufacturers’ analytical test methods. Although the procedure on control of test method procedure SOP described some aspects of validation, verification and transfer of analytical methods, there was no description of the analytical performance characteristics to be verified for the various types of analytical procedures.

Upon review of analytical method for finished products, it was noted that verification was not performed before an analytical method was used for the first time in the SZIDC (STCMD) laboratory. For example, the analytical method for Fosinopril Sodium tablet was used without verification. It was used directly from the Chinese Pharmacopoeia monograph. It was noted that method was modified (e.g. column oven temperature set 35ºC against no temperature requirement). This modification was not approved and authorized for consistent use.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.
17. Testing

The physico-chemical and instrumentation laboratory had 20 analysts (16 analysts, 2 students and 2 director/deputy director for chemical control lab). The competency matrix was available. The laboratory was equipped with a total of 36 HPLC systems, out of which 29 HPLCs (12 Waters, 8 Dionex, 3 Shimadzu, and 6 Agilent) were used for the pharmaceutical analysis. A total of three servers were used for all HPLC and GC systems. Empower-3 software was used with Waters and Agilent HPLC systems. Chromeleon and VP Station software’s were used for Dionex and Shimadzu system respectively. A total of 4 GCs were (3 Agilent and 1 Shimadzu) used by the laboratory. The administrator rights were given to IT personnel named as network manager who in turn reported to the IT director.

The laboratory was also equipped with 4 UV Spectroscopy, 10 analytical balances and 14 dissolution apparatus.

Instructions for testing were available in electronic form and as paper print-outs. Samples were tested in accordance with the work plan of the laboratory and agreements with customers. Test results were reviewed and evaluated. OOS results were investigated.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

18. Evaluation of test results

Test results were reviewed and evaluated before issuance of the certificate of analysis (COA). Test results were entered to the LIMS by analysts who performed the test, after which the test results in LIMS were checked by the reviewer.

The SOP for the investigation of out of specification results was available.

The issues related to this section have been adequately addressed by the laboratory, and the same shall be verified during future inspections.

19. Certificate of analysis

Certificate of analysis (CoA) was generated by LIMS. The CoA contained the information as described under section 19, Certificate of analysis, WHO GPPQCL.

20. Retained samples

Retained samples were kept in a separate room as incoming samples.

For more details, refer to the section 17, incoming samples.
21. Safety

In general, this section was found satisfactory as appropriate facilities were provided to the personnel for safe handling of chemicals such as safety eye and body showers were provided in the laboratory.

PART 3

Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken the Shenzhen Institute of Drug Control, SZIDC, located at No. 28, Gaoxin Central 2nd Avenue, Nanshan District, Shenzhen, Guangdong, China was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories.

All the non-compliances observed during the inspection that were listed in the full report 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 GMP guidelines referenced in the inspection

   *Short name: WHO TRS No. 961, 957), Annex 1*

   *Short name: WHO TRS No. 986, Annex 2*

   *Short name: WHO TRS No. 961, Annex 2*
   [http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

   Short name: WHO TRS No. 961, Annex 5
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

   Short name: WHO TRS No. 957, Annex 2

   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

    Short name: WHO TRS No. 961, Annex 7
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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Shenzhen Institute for Drug Control (Shenzhen Testing Center of Medical Devices)
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Short name: WHO TRS No. 961, Annex 9
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1


Short name: WHO TRS No. 943, Annex 3
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1


Short name: WHO TRS No. 981, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/


Short name: WHO TRS No. 992, Annex 5


Short name: WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf