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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Guilin Pharmaceutical Co Ltd – OSD**
Corporate address of the manufacturer	Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd Building A, No. 1289, Yishan Road, Shanghai, 200233, China
Name & address of inspected manufacturing site if different from that given above	Oral solid dosage (OSD) manufacturing Center No. 43 Qilidian Road Guilin, Guangxi 541 004
Unit/block/workshop number	Building 7 (OSD)
Dates of inspection	14 – 16 April 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Guilin Pharmaceutical Co., Ltd. is located at No.43 Qilidian Road, Guilin, Guangxi, 541004, China. It manufactures APIs, tablets, soft capsules, hard capsules, powder for injections, small volume parenteral (SVP) injections, and films. The manufacturing site has the following manufacturing activities:

Name of manufacturing center	Workshop name	Production line	Abbreviation
API manufacturing center	Multi-purpose workshop	Production line of artemisinin-derived APIs	API- I
		Multi-purpose production line	API- II
	Levamisole hydrochloride workshop	Levamisole hydrochloride production line	API- III
OSD manufacturing center	OSD- I workshop	General production line for dosage forms/ preparations	OSD- I
	OSD- II workshop	Lactasin production line	OSD- II
	OSD- III workshop	Soft capsules production line	OSD- III
	OSD- IV workshop	General production line for dosage forms/ preparations (domestic)	OSD- IV
	OSD- V workshop	Films production line	OSD- V
INJ manufacturing center	INJ- I workshop	Production line for Artesunate for injection	INJ- I
	INJ- II workshop	SVP production line	INJ- II
	INJ- VI workshop	SVP production line	INJ- VI
	INJ packaging workshop	Co-package center for Artesunate for injection	INJ-PA
		INJ-VI packaging line	
		Packaging area for Injections of FPP Building (Labelling area of powder for injection and large strength injection)	

The scope of this inspection was limited to the OSD Manufacturing Center.

General information about the company and site	Guilin Pharma is a comprehensive pharmaceutical company engaged in R&D, production, and marketing of chemical drugs. Guilin Pharmaceutical Co., Ltd is located in Guilin. Since 2003, Shanghai Fosun Pharmaceutical (Group) Co., Ltd. has become the holding enterprise of Guilin Pharma.
History	The WHO PQ Inspection Services regularly inspect the Guilin Pharmaceutical's non-sterile manufacturing site. The last PQ inspection was conducted on 11-15 September 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management system - Personnel, hygiene, and training - Qualification and validation - Production activities - Quality control laboratory - Warehouse, material management, and supplier qualification - Premises, equipment, and air handling units
Restrictions	The inspection was restricted to products relevant to the WHO prequalification programme, as listed in the inspection scope.
Out of scope	All other products and workshops are not relevant to the WHO prequalification programme and are not included in the inspection scope.

WHO products covered by the inspection

#	ePQS no.	Product
1.	MA083	Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg
2.	MA084	Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg
3.	MA085	Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg
4.	MA113	Pyrimethamine/Sulfadoxine Tablet 25mg/500mg
5.	MA116	Pyrimethamine/Sulfadoxine Tablet, Dispersible + Amodiaquine (hydrochloride) Tablet, Dispersible 12.5mg/250mg + 76.5mg
6.	MA117	Pyrimethamine/Sulfadoxine Tablet, Dispersible + Amodiaquine (hydrochloride) Tablet, Dispersible 25mg/500mg + 153mg
7.	MA131	Dihydroartemisinin/Piperaquine phosphate Tablet, Film-coated 40mg/320mg
8.	MA139	Dihydroartemisinin/Piperaquine phosphate Tablet, Dispersible 40mg/320mg
9.	MA140	Dihydroartemisinin/Piperaquine phosphate Tablet, Film-coated 80mg/640mg
10.	MA141	Dihydroartemisinin/Piperaquine phosphate Tablet, Dispersible 20mg/160mg

	11.	MA151	Dihydroartemisinin/Piperaquine phosphate Tablet, Film-coated 60mg/480mg
	12.	MA157	Dihydroartemisinin/Piperaquine phosphate Tablet, Dispersible 30mg/240mg
	13.	MA178	Pyrimethamine/Sulfadoxine Tablet, Dispersible 12.50mg/250mg
	14.	MA179	Pyrimethamine/Sulfadoxine Tablet, Dispersible 25mg/500mg
	15.	CV023	Molnupiravir Capsules, hard 200mg
	16.	MA202	Primaquine (phosphate) Tablet, Dispersible 5mg (Under assessment)

Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
GPT	Growth promotion test
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media Fill Test
MR	Management review
NC	Non conformity

NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

Part 2	**Summary of the findings and comments**

1. Pharmaceutical quality system

The quality management system was divided into quality assurance and quality control. The QA and QC departments were independent from manufacturing. The person responsible for quality (vice president) managed the overall product quality. The QA had oversight of all document control processes. The QA department conducted a product release in accordance with the material and product release procedure. Detailed descriptions of the Standard Management Procedures (SMPs) and SOPs formed part of the quality system. The QA was responsible for documents (analytical control procedures, specification sheets, manufacturing instructions, master batch records, manufacturing and batch control records, analytical methods, process validation protocols and reports, stability reports, and review of audit trails).

Product quality review/PQR

The PQR deadline for all products (OSD, API, and INJ) was by the end of March of the following year, with a periodic review from January to December of the preceding year. Approximately 40 OSD products were manufactured on-site; the PQRs for these products were also available. The PQR of Amodiaquine dispersible tablets was spot-checked. In 2024, 200 batches were manufactured and released. No OOS, OOT, deviation, return, complaint, or recall for the product in 2024. There was one change to the analytical method, three changes to the facility, 12 changes to the equipment, seven changes to the material and supplier, and seven others. One major change was related to the layout of

the facility, particularly the changes in the granulation and coating room, as well as the relocation of equipment from one packaging line to another. The review of the mentioned PQR did not reveal any non-conformities.

Quality risk management (QRM)

The risk assessment/RA report of the OSD-I workshop for product manufacturing in shared facilities was discussed, which was prepared in accordance with the guidelines of the WHO, PIC/S, EMA, NMPA, and ISPE. The RA included the list of products manufactured (31 products) on-site for commercial purposes. Before commercialization, when a new product was introduced for small-scale manufacturing and exhibited in batches, risk assessment was performed as part of the change control process. If the product has not been manufactured for over 3 years, it would not be included in the RA. The RA included assessment of the material of construction of the equipment (SS316L), a dust-free charging system, the use of the closed system, including lifting/positioning devices, CIP for the granulator, de-duster connected to compression machines, negatively pressurized core processing areas, dedicated filter bags and hose pipes, cleaning procedure for each equipment, cleaning validation of products manufactured in OSD-I, separate personnel/material entry, gowning of personnel, and assessment of other elements. The risk assessment to determine the potential risk of contamination and cross-contamination was found adequate.

Change control management

The change control procedure was in place, detailing the process of initiating, evaluating, approving, implementing, reviewing, and closing changes. The generic classification of changes included temporary and permanent changes. Following the impact evaluation, permanent changes were classified into three categories: major, moderate, and minor. In terms of investigation and impact assessment, the changes were treated equally. The concerned heads conducted an impact and risk assessment for all the changes before approval. The change controls were logged in a validated spreadsheet, and manual forms were used to assess the change controls.

Deviations management

Deviations were managed through the deviation procedure. The deviations were classified as planned and unplanned, which were further classified into critical, major, and minor. The procedure defined the term "deviation," providing examples for guidance. The procedure involved setting up a cross-functional team for investigation and impact assessment, CAPA review, and monitoring within 90 days of implementation. There was provision for annual deviation trending. Failure/Root cause investigation was executed according to the respective SOPs.

Corrective action and preventive action (CAPA) management

The CAPA procedure was reviewed. CAPA system was established to investigate and take corrective actions and preventive actions for observation arising from deviations, recalls, OOS/OOT, complaints, PQR, risk assessment, rejection, self-inspections or external inspections (including domestic and international GMP inspections, and customers audit, etc.), process performance (CpK) and quality monitoring trends, etc.

The SOP for product clearance was reviewed and applied to OSD products. The line clearance involved removing materials and records, and the waste was handled in accordance with the waste treatment procedure. The equipment was dismantled, packed into a plastic bag, and transferred to the cleaning station. The components that could not be dismantled were cleaned, as were the equipment surfaces. In addition, cleaning of the area followed a top-down clean approach (tools, chairs, walls, doors, windows, and floor drain). This step was repeated using disinfectant (phenol acid/alkaline for areas and 75% ethanol for equipment surfaces). Finally, the dismantled equipment was cleaned and reassembled.

Batch release

The SOP for product release was discussed, and it was noted that the procedure was common for OSD, sterile, and API products. The qualified person had a team of 16 personnel responsible for the batch release of APIs (3), OSD (7), injectable (5), and contract manufacturing product release (1). These personnel worked in the QA department and were responsible for the QA and batch release activities. The production team first reviewed production records, QC reviewed QC-related documents, and QA/QP performed the final review. A total of 19 items were verified as part of the batch release by the QA team. Once QA has reviewed all 19 items, the batch record documents will proceed with the final review by the QP (22 items).

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

Guilin Pharmaceutical Co., Ltd manufactures oral solid dosage forms in the OSD Manufacturing Center. The OSD workshop was divided into OSD-I, II, III, IV, and V. The WHO-prequalified and under-assessed products were manufactured in OSD-I. It is a shared and multi-product facility where products from different therapeutic areas are manufactured.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

3. Sanitation and hygiene

The hygiene master plan defined the relevant company's entire plant hygiene control and hygiene management requirements to ensure effective management and control of plant personnel, pest control, factory hygiene, clean rooms, QC laboratories, warehouses, clearance of production areas, and water supply and cleaning of production areas. The company had SOPs for cleaning and disinfection/ sterilization for different production areas, equipment, containers, and tools. Relevant checking methods and the cleaning and disinfection/ sterilization expiry dates were established. Generally, the manufacturing areas were neat.

4. Qualification and validation

The Validation Master Plan was prepared following the local GMP, national regulations, WHO guidelines, and references from other regulatory agencies. The VMP described the validation philosophy, confirming that qualification and validation activities should be performed before commercializing the products. The roles and responsibilities were also described in the VMP. The VMP covered HVAC, water, pure steam, compressed air systems, and other areas.

Process validation

The manufacturing process validation protocol for Primaquine (as phosphate) dispersible tablets (new product introduction), 5mg Base, batch size: 150,000 tablets, was discussed. The protocol referred to change control, which was raised to introduce a new product. The risk assessment was performed as part of change control before introducing Primaquine tablets. In general, the process validation was adequately performed.

Cleaning validation

A risk assessment for cleaning validation of OSD-I was performed to determine the number of cleaning methods that require validation, select the product as a worst-case scenario for cleaning validation, and calculate the Maximum Allowable Carryover (MACO) and Maximum Safe Surface Residue (MSSR). Based on the initial RA, seven (7) groups containing more than one product were identified, and the cleaning method for the worst-case product was validated. This was based on the difficulty of cleaning, the solubility of the API in the cleaning media, potency (ADE/PDE values), and the minimum daily dose. Based on this assessment, a score was calculated, and the high-score product was selected as the worst case. Cleaning validation was adequately performed.

Analytical method validation

The SOP for testing Primaquine Phosphate dispersible 5mg tablets was reviewed, and it was noted that Guilin had validated test methods, including dissolution by HPLC, related substance by HPLC, nitrosamine impurity by LC-MS, microbial limit test, and assay by HPLC. The analytical methods were validated by the R&D team within the QA department using the same quality control laboratory.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

5. Complaints

The SOP for handling customer complaints was available, and complaints were recorded in QA-COM 2023. The SMP outlined that QA personnel were responsible for logging complaints from the marketing department or customers. The complaints were received either verbally, in writing, or via email. QA acknowledged receipt of the complaint within 7 days for critical complaints, 15 days for major, and 30 working days for minor complaints. Classified complaints were defined in the procedure. The root cause was established, and an investigation was instituted. Complaints were closed within 30 days after the final investigation report was issued. Extension was allowed upon approval by QA. At the end of the calendar year, trend analysis of received complaints was carried out and recorded.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Product recalls

Recalls were managed using SOP for product recall management. The recall could be initiated for voluntary or compulsory reasons. It was classified as Class 1, 2, and 3. The SOP has been revised to address the WHO's previous observations. The CAPA was designed to limit the number of extensions to a maximum of twice, and extensions could only be conducted when the product had been under the company's control. A Class 1 recall was for products with a serious health hazard. It should only take one day to prepare the recall plan and send notifications through formal notices and emails to the relevant parties. Recalls should be conducted at hospitals, pharmacies, distributors, and with clients/customers. The administrative center should issue a public notice on its website, and the Regulatory Affairs Department should also notify relevant drug regulatory authorities, including those from foreign countries. All the recall processes for Class 1 should be closed within 1 month. Recall Class 2 was conducted when the products may cause temporary or reversible health hazards, and Recall Class 3 was conducted for any other quality issues that do not pose health hazards. The process for recalling classes 2 and 3 was the same as that of class 1; the difference was only in the timeline. The notification time limits were 3 days for Class 2 and 7 days for Class 3, and the timelines for closing the recall process were 2 months and 3 months, respectively.

7. Contract production, analysis, and other activities

The company previously had a technical agreement with Fosun Pharma to manufacture Molnupiravir Capsules, but the agreement was dissolved as of October 14, 2024. Guilin Pharmaceutical is the marketing holder of all the WHO PQ Products, including the Molnupiravir Capsule.

The manufacturer confirmed that no contracted manufacturing activities were used for WHO prequalified products. The company has outsourced several of its testing activities, including tests for asbestos and aluminium in the talc excipient, as well as some tests for packaging materials. Some of these tests were contracted to Shanghai Instrument Testing.

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

A review was conducted of the SOP for self-inspection of the QA system and the implementation schedule for self-inspection to OSD-I, II, and III in 2024. Based on the SOP, before the start of self-inspection, a risk assessment should be conducted to determine the number of days for inspection. The determination was based on the risk associated with the dosage form and areas, considering factors such as batch size, number of batches manufactured, and number of products manufactured, among others. The self-inspection was organized by the QA team, and it consisted of up to 20 people from various units. The latest self-inspection for OSD-I, II, and III was conducted from June 11 to 13, 2024. It resulted in 11 CAPAs, all of which have been handled.

<u>Supplier Qualification</u>

The supplier qualification process and supplier quality audit were reviewed. Materials were classified as critical, major, and general. For critical material sourced from China every 2 years, the company conducts an on-site audit. Overseas critical material is audited on-site every 4 years, with a desktop audit conducted between on-site audits. The qualification of the supplier of Amodiaquine HCl, Artemether, DHA, Lumefantrine, Piperaquine Phosphate, Tenofovir Disoproxil Fumarate,

Sulfadoxine, and Pyrimethamine was reviewed. The company has a long-standing relationship with this supplier. There has been a history of routine audits conducted at the site, whether onsite, desk, or virtual. The addition of a new product from the site also prompted inspection.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

9. Personnel

According to the company's presentation, the total number of employees was 1063, which consisted of 12 senior engineers, 62 engineers, 170 assistant engineers, and 30 licensed pharmacists. There were 507 people in production-relevant departments (OSD/API/INJ), 63 in QA, 109 in QC, and 49 in the warehouse. Others included management staff and personnel from supporting departments. The organogram displayed different reporting levels, beginning with the president reporting to the company chairman, vice presidents (e.g., Head of Production, Head of Quality) reporting to the president, and responsible persons reporting to the respective vice president. All the senior QA, QC, and Production directors reported to the Enterprise Head. There was a fully-fledged QA department with qualified, competent, and technically skilled personnel.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

10. Training

The SOP for GMP training was discussed. Training included induction on the quality management system and good manufacturing practices. Training was implemented according to the annual training plan, with each department responsible for providing technical training and evaluating the effectiveness of the training provided. On-the-job training was provided to all employees according to the annual training schedule established by department heads. The effectiveness of the training was assessed through a written examination and/or an oral assessment, with a pass rate of 80%. Those who scored less than 80% underwent retraining.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

11. Personal hygiene

Personnel had to go through the first common change rooms. The second change room had a crossover bench, shoe covers, a hairnet, a facemask, a handwashing area, and a dryer. Before entering the production area (classified as Grade D), personnel had to undergo another round of gowning and hand sanitization.

12. Premises

Layout plans for the site, which included man and material movement, area classification, pressure zoning, and differential pressure, were reviewed. The premises were laid out in a way that allowed production to take place in areas connected in a logical order, corresponding to the sequence of operations and the requisite cleanliness levels. Interior surfaces (walls, floors, and ceilings) were smooth and free from cracks and open joints.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

13. Equipment

Generally, the equipment used in manufacturing, including processing and packaging, was of appropriate design and construction for the required processes. The equipment was placed in a suitable location to facilitate operations for use, cleaning, and maintenance. All production equipment was labelled with a unique identity number, and the appropriate cleanliness status was identified. Instruments were calibrated and maintained according to the written procedure and schedule. Status labels were assigned to each instrument, and records were maintained. Major production equipment, including a granulating machine, a blender, and tablet compression equipment, was available, along with the equipment's name, manufacturer, and identification number.

The equipment's preventive maintenance was managed in accordance with the procedure. The preventive maintenance schedule was required to be prepared for a year, covering two six-month schedules. The engineering section managed the process of preventive maintenance. There were separate teams dedicated to OSD and the injection line. The plan was based on the criticality of equipment and its impact on the product. Trends in scheduled preventive maintenance and equipment breakdowns were analyzed quarterly, and the results were submitted for review.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

14. Materials

The facility had three warehouses: an automated warehouse (storage of excipients and APIs) with temperature-controlled areas according to product storage requirements, Warehouse No. 3 for printed labels (labels with product name and code), and Packaging Warehouse Nos. 1-7: for packaging materials (primary and secondary packaging). The company also has one warehouse facility off-site, which is reportedly used for storing finished pharmaceutical products for the domestic market. The inspection team conducted a walkthrough primarily of Warehouse Building 2, which was used to store APIs, Excipients, and FPPs, and was equipped with a sampling area. This warehouse catered to all workshops, including INJ, OSD, and API. Material received in the receiving bay was checked to ensure that the goods were received in accordance with the purchase order, including verification that the material came from an approved supplier. An SOP specific to each manufactured product had information on the approved supplier. Upon arrival, the purchased order was checked against the information in the SAP system. Data on the material was managed through the SAP system, and a separate application was used to operate the automated warehouse.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

15. Documentation

The SOP for Documentation detailed the management of drafting, revision, review, approval, issuance/ return, expiration, and filing of documents to ensure that the generation, approval, issuance, and storage of documents were accurate and adhered to data integrity and ALCOA+ principles. The QA was responsible for reviewing, approving, distributing, retrieving, archiving, and destroying master documents. Controlled master documents included BMR, BPR, specifications (raw materials, in-process, Finished Product, stability), packing material specifications, testing procedures, SOPs, general test procedures, sampling protocols, and approved vendor list. Documents were approved, signed, and dated by the appropriate responsible persons. Documents were regularly reviewed and kept up to date. The company used four levels of documents. The Class 1 documents included a quality manual, SMF, job description, department responsibility, and organization chart. The Class 2 documents included quality system management documents, process procedures, and specifications. The Class 3 documents included operating procedures in QC and production, equipment verification and maintenance procedures, and batch records. The Class 4 documents included records, confirmation/ verification protocols, and reports. New documents and proposals for change or revision were partially managed using the Document Management System (DMS). Proposals for a new document or a revision were submitted to the DMS.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

16. Good practices in production

The inspector visited Workshop-1, which manufactures products for the WHO PQ and domestic markets. The workshop had three OSD areas: OSD-I, OSD-II, and OSD-III. The PQ products and products for domestic markets were manufactured in OSD-I, whereas OSD-II and OSD-III were dedicated to the domestic market. The OSD-I occupied two floors, floor 1 for primary and secondary packaging activities and floor 2 for production activities. It was noted that eight granulation suites were divided into various activities (1, 4, 6 used for wet granulation, 8 for dry granulation, 2 for domestic pilot, 3 was a new area for future expansion, and 5 and 7 used for domestic products). Pre-blending 1 and 2 were used for Piperaquine dispersible tablets, as well as for domestic products. Three blending rooms were used for the PQ and domestic markets. A total of 11 compression rooms were available, wherein 10 compression machines were installed. Compression machines 1, 2, 3, and 4 (Fette) were mainly used for PQ products but also for the domestic market. Compression machines 6, 7, 8, 9, and 10 were new machines intended for PQ and domestic products, whereas machines 5 and 11 were used solely for domestic products. There were six coating rooms, each containing four coating machines. Machines 1, 3, and 5 were used for film coating, while the fourth was used for sugar coating. Coating area 2 was empty, and area 6 was used for coating granules. There were 14 primary packaging lines (3 bottles and 11 blisters), whereas a few (5, 6, 7, and 8) were used solely for PQ products, and the rest for both PQ and domestic products.

The manufacturing and primary packaging areas were classified as Grade D, which was supported by the Controlled Non-Classified (CNC) area. Before transferring the materials received from the warehouse through the escalator, external packing was removed, cleaned using 75% ethanol, and stored under UV light for 20 minutes. The temperature and relative humidity were set at 18-26°C and 45-65% relative humidity. Temperature and relative humidity were monitored/recorded manually

using a min/max thermohygrometer. Three dispensing areas were provided. After dispensing, the powder charging system was used to transfer materials for sieving, milling, and finally to the IBC through vacuum. The inspector visited the granulation suite, compression machine, and coating machine area during the visit. No manufacturing activities were carried out. The equipment and facilities were generally well-maintained, clean, and tidy during the inspection. The compression machine was verified for Primaquine phosphate 5mg dispersible tablets. It was a single rotary and B tooling machine connected with a de-duster and a metal detector. The material was charged through the IBC using a lifting/positioning device. The compression area housed a balance, a hardness tester, and a friability test, whereas the disintegration test was performed in the IPQC lab. No testing activity was carried out in the IPQC lab at the time of the inspection.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

17. Good practices in quality control

The quality control department was responsible for testing and assessing the quality of incoming raw materials, packing material, semi-finished products, finished products, stability samples, and IPQC using approved specifications, and assigning an appropriate status to the products before further processing. The analytical processes, from testing request to sample receiving and distribution, testing task assignment, and test result entry, were governed by well-established procedures. The quality control laboratory (including all sections under quality control) was well equipped and had adequate and competent staff to carry out the quality control functions. The QC function was independent of other departments. Sufficient resources were available to ensure all the QC arrangements were effectively and reliably carried out. The QC personnel had access to production areas for sampling and investigation as appropriate. Columns used for HPLC tests were dedicated to each product and were logged in the logbooks. System suitability was performed for all new columns, and documentation confirmed that only standard substances were used during the test run, and no product samples were used. Reagents were well-maintained with labels indicating the date received, the person who received them, the in-house batch number, the use-by date, the vendor's batch and code, the person who opened them, and the date of opening. Receiving samples, allocating analytical reports, testing methods, checking, and releasing different materials were described in laboratory procedures. The handling of dry chemicals and reference standards, as well as the preparation of solutions and working standards, were done according to approved procedures. Working and primary standards were available and mainly stored separately, locked according to their storage conditions, e.g., refrigerators at 2-8°C. Hygroscopic standards for which storage conditions were specified as room temperature were stored in desiccators. Working Standards were adequately labelled.

There were 22 HPLC instruments, 3 UV-Vis spectrometers, a GC, an AA, an ACP Mass spectrometer, and an IR spectrometer; the list is not exhaustive. The HPLCs were connected to the Empower 3 software. Validation and verification of analytical methods were managed through a standard operating procedure. It was applicable for validation/ verification of quantitative and semi-quantitative analytical tests for drug products, raw materials, API, intermediates, and excipients. Validation was performed for non-pharmacopoeial chemical test methods and modified pharmacopoeial methods. In contrast, verification was applicable for verifying pharmacopoeial

methods, validated non-pharmacopoeial methods, modified methods, and changes to analytical instruments that employed different mechanisms that would impact the method.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***Guilin Pharmaceutical Co., Ltd*****,** located at ***No. 43, Qildian Road, Guilin, Guangxi, 541004, China,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

All the non-compliances observed during the inspection that were listed in the full report, as well as those reflected in the WHOPIR, were addressed by the manufacturer to a satisfactory level prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	**List of WHO Guidelines referenced in the inspection report**

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***

   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf
2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   untitled (digicollections.net)

3. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report. Geneva, World Health Organization, 2022 ***(WHO Technical Report Series, No. 1044), Annex 2.***
   TRS 1044 - Annex 2: WHO good manufacturing practices for sterile pharmaceutical products

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

5. 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://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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