

Prequalification Team Inspection services
WHO PUBLIC REPORT OF DESK-REVIEW OF GMP COMPLIANCE
Active Pharmaceutical Ingredient Manufacturer

Part 1	General information
Company information	
Name of manufacturer	Chongqing Kangle Pharmaceutical Co Ltd
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Chongqing Kangle Pharmaceutical Co Ltd, 4 HuaZhong Road, Congquing (Changshou) Chemical Industrial Park Chongqing, Chongqing, 401 221, China (People's Republic of China)
Unit / block / workshop number	Plant
Manufacturing license number	CFDA No YU20150022, issued by Changqing Food and Drug Authority for manufacture of APIs including Piperazine tetraphosphate, valid till December 21, 2020
Desk assessment details	
Date of review	24 September 2018 – 3 October 2018
List of documents submitted	The following documents copies had been submitted: 1. Manufacturing license List of products manufactured on site 3. FDA Form 483, issued July 26, 2018 4. FDA Establishment Inspection Report 5. Response to the FDA Form 483 6. Annual product review 2017 7. Self-inspection confirmation 8. Site Master File/09/August 2018 9. Piperazine phosphate batch manufacturing record 10. Piperazine phosphate Batch number LPKB-161003B analytical record
Last WHO inspection	26 to 29 January 2016
Introduction	
History of WHO inspections and compliance status (including previous desk assessments)	13 to 16 October 2014 – Initial inspection. 26 to 29 January 2016 – Follow-up inspection.
Brief summary of the manufacturing activities	Manufacture and packaging of intermediates and APIs by chemical synthesis
Areas inspected	WHO inspection from 26 to 29 January 2016 covered the following:

1. Quality Management
 - a. Internal audits
 - b. Product quality review
 - c. Quality Risk Management
2. Personnel
 - a. Personnel qualifications
 - b. Personnel hygiene
3. Buildings and Facilities
 - a. Design and construction
 - b. Utilities
 - c. Water
 - d. Containment
 - e. Lightening
 - f. Sanitation and maintenance
4. Process equipment
 - a. Design and construction
 - b. Equipment maintenance and cleaning
 - c. Calibration
 - d. Computerized systems
5. Documentation and records
 - a. Documentation system and specifications
 - b. Equipment cleaning and use record
 - c. Records of raw materials, intermediates, API labelling and packaging materials
 - d. Master production instructions (master production and control records)
 - e. Batch production records (batch production and control records)
 - f. Laboratory control records
6. Materials management
 - a. General controls
 - b. Receipt and quarantine
 - c. Sampling and testing of incoming production materials
7. Production and in-process controls
 - a. Production operations
 - b. Time limits
 - c. Blending of intermediates or APIs
 - d. Contamination control
8. Packaging and identification labelling on intermediates and APIs
 - a. General
 - b. Packaging materials
 - c. Label issuance and control
 - d. Packaging and labelling operations
9. Storage and distribution

	a. Warehousing procedures b. Distribution procedures 10. Laboratory controls a. General controls b. Testing of intermediates and APIs c. Stability monitoring of APIs d. Reserve/retention samples e. Data Integrity of chromatography systems 11. Validation a. Validation policy b. Qualification c. Cleaning validation d. Validation of analytical methods 12. Deviation and change control 13. Rejection and re-use of materials a. Rejection b. Reprocessing and Reworking c. Recovery of materials and solvents 14. Complaints and recalls 15. Contract manufacturers (including laboratories)
WHO products inspection	Anti-malaria API
Abbreviations	Meaning
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
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
SMF	Site master file
SOP	Standard operating procedure
Part 2	Summary of the assessment of GMP evidence submitted (most recent to oldest)
<i>Inspection Report 1</i>	
<i>Competent authority name</i>	Food and Drug Administration USA
<i>Dates of inspection</i>	23 – 26 July 2018
<i>Inspected areas</i>	• Training program • Manufacturing/design operations • Quality system • Materials system • Production system • Packaging and labelling system • Laboratory control system • Manufacturing codes • Complaints • Recall procedures • Objectionable conditions and managements response
<i>Comments/observations on the scope and comprehensiveness of the report and appropriateness of the CAPAs</i>	FDA EIR was comprehensive and covered 6 systems, CAPAs were acceptable.

Part 3	Review of additional documents
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- a) Manufacturing authorization granted by the local authority
- b) Site master file
- c) List of all the products and dosage forms manufactured on-site
- d) Most recent product quality review (PQR) of the concerned WHO product
- e) Batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant product
- f) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product has been performed and all matters dealt with
- g) Master batch manufacturing and packaging records of the products of interest

Part 4	Desk assessment conclusion
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Based on the previous WHO inspection and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site, ***Chongqing Kangle Pharmaceutical Co Ltd, located at 4 HuaZhong Road, Congquing (Changshou) Chemical Industrial Park, Chongqing, Chongqing, 401 221, China (People's Republic of China)*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines. This compliance status shall be valid until 3 years from the last day onsite of the SRA report (26 July 2021) or when another inspection is conducted by WHO or by a stringent regulatory authority.

Name(s)	Ms Iveta Streipa
Signature(s)	
Approval Date	2 October 2018