## Part 1
### General information

#### Manufacturers Details

<table>
<thead>
<tr>
<th>Company information</th>
<th>Qilu Pharmaceutical Co., Ltd.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of manufacturer</td>
<td>Qilu Pharmaceutical Co., Ltd.</td>
</tr>
<tr>
<td>Corporate address of manufacturer</td>
<td>No. 317, Xinluo Road, High-Tech Zone, Jinan, Shandong Province, China, 250101 Tel: +86-531-83126268 Fax: +86-531-83126002 North latitude: 36.681916 East longitude: 117.144306 D-U-N-S 421279342</td>
</tr>
</tbody>
</table>

#### Inspected site

<table>
<thead>
<tr>
<th>Address of inspected manufacturing site if different from that given above</th>
<th>The same as above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit / block / plant number</td>
<td>Building K002, Workshop No. X Building K004, warehouse Building K02, QA &amp; QC</td>
</tr>
<tr>
<td>Manufacturing license number</td>
<td>Lu 20160001</td>
</tr>
<tr>
<td>Scope of licence: production, packaging, quality control and release of powder for injection, SVP, tablets, granules, hard capsules, eye drops, Inhalants, sterile APIs, psychological drugs</td>
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#### Inspection details

<table>
<thead>
<tr>
<th>Dates of inspection</th>
<th>16 – 20 January 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of inspection</td>
<td>Initial</td>
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#### Introduction

| Brief summary of the manufacturing activities | Production, packaging, quality control and release of powder for injection, small volume parenterals (SVP), tablets, granules, hard capsules, eye drops, Inhalants, sterile APIs, psychological drugs |

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WHOPIR Qilu Pharma (Xinluo Road)  
January 2017  
This inspection report is the property of the WHO  
Contact: prequalinspection@who.int
General information about the company and site

Qilu Pharmaceutical Co., Ltd. was established in 1958 and is a comprehensive large-scale pharmaceutical manufacturing enterprise in China. Qilu has eight manufacturing sites:

Six sites have been inspected and approved by US FDA, EDQM, MHRA (United Kingdom), TGA (Australia), MCC (South Africa), MFDS (Korea), PMDA (Japan).

Seven sites have been inspected and approved by the CFDA (China), and one site was under construction during the inspection.

Qilu Pharmaceutical Co., Ltd., located in High-Tech Zone, is mainly for the production of finished dosage forms and sterile APIs. This site covers an area of 67185 m². During inspection there were seven separate buildings. SVPs were manufactured in the building K 002. The building for finished products manufacturing have been in operation since 2006.

History

This was the first WHO inspection. The site has been inspected by the following regulatory authorities:

<table>
<thead>
<tr>
<th>Date</th>
<th>Approval Type</th>
<th>Product Description</th>
<th>Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb. 2012</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection and Small Volume Parenterals</td>
<td>TGA, Australia</td>
</tr>
<tr>
<td>Mar, 2012</td>
<td>Approved</td>
<td>Capsule and Eye Drops</td>
<td>CFDA, China</td>
</tr>
<tr>
<td>May, 2012</td>
<td>Approved</td>
<td>Powder for Injection (General category) and Small Volume Parental Injection</td>
<td>CFDA, China</td>
</tr>
<tr>
<td>Aug, 2012</td>
<td>Approved</td>
<td>Small Volume Parenteral Injection</td>
<td>CFDA, China</td>
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<tr>
<td>July, 2013</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection, tablets</td>
<td>USFDA</td>
</tr>
<tr>
<td>May, 2014</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection and Small Volume Parenterals</td>
<td>TGA, Australia</td>
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<tr>
<td>May, 2015</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection, tablets</td>
<td>USFDA</td>
</tr>
<tr>
<td>Aug, 2015</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection</td>
<td>MHRA</td>
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<tr>
<td>June, 2016</td>
<td>Approved</td>
<td>Small Volume Parenteral Injection</td>
<td>CFDA</td>
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<tr>
<td>Aug, 2016</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection</td>
<td>CFDA</td>
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<tr>
<td>Nov, 2016</td>
<td>Approved</td>
<td>Cephalosporin Powder for Injection, SVP</td>
<td>MHRA</td>
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Brief report of inspection activities undertaken

Scope and limitations

Areas inspected: See part 2
Restrictions: N/A
Out of scope: N/A
<table>
<thead>
<tr>
<th>WHO product numbers covered by the inspection</th>
<th>TB Amikacin (sulfate) Solution for injection 500mg</th>
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</thead>
<tbody>
<tr>
<td><strong>Abbreviations</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>AHU</td>
<td>air handling unit</td>
</tr>
<tr>
<td>ALCOA</td>
<td>attributable, legible, contemporaneous, original and accurate</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>APQR</td>
<td>annual product quality review</td>
</tr>
<tr>
<td>BDL</td>
<td>below detection limit</td>
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<tr>
<td>BMR</td>
<td>batch manufacturing record</td>
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<tr>
<td>BPR</td>
<td>batch packaging record</td>
</tr>
<tr>
<td>CAPA</td>
<td>corrective actions and preventive actions</td>
</tr>
<tr>
<td>CC</td>
<td>change control</td>
</tr>
<tr>
<td>CFU</td>
<td>colony-forming unit</td>
</tr>
<tr>
<td>CoA</td>
<td>certificate of analysis</td>
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<tr>
<td>CpK</td>
<td>process capability index</td>
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<tr>
<td>DQ</td>
<td>design qualification</td>
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<tr>
<td>EM</td>
<td>environmental monitoring</td>
</tr>
<tr>
<td>FAT</td>
<td>factory acceptance test</td>
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<tr>
<td>FBD</td>
<td>fluid bed dryer</td>
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<tr>
<td>FG</td>
<td>finished goods</td>
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<tr>
<td>FMEA</td>
<td>failure modes and effects analysis</td>
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<td>FPP</td>
<td>finished pharmaceutical product</td>
</tr>
<tr>
<td>FTA</td>
<td>fault tree analysis</td>
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<tr>
<td>FTIR</td>
<td>Fourier transform infrared spectrometer</td>
</tr>
<tr>
<td>GC</td>
<td>gas chromatograph</td>
</tr>
<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>HACCP</td>
<td>hazard analysis and critical control points</td>
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<tr>
<td>HPLC</td>
<td>high-performance liquid chromatograph</td>
</tr>
<tr>
<td>HVAC</td>
<td>heating, ventilation and air conditioning</td>
</tr>
<tr>
<td>ID</td>
<td>identity</td>
</tr>
<tr>
<td>IR</td>
<td>infrared spectrophotometer</td>
</tr>
<tr>
<td>IPC</td>
<td>In process control</td>
</tr>
<tr>
<td>IQ</td>
<td>installation qualification</td>
</tr>
<tr>
<td>KF</td>
<td>Karl Fisher</td>
</tr>
<tr>
<td>LAF</td>
<td>laminar air flow</td>
</tr>
<tr>
<td>LIMS</td>
<td>laboratory information management system</td>
</tr>
<tr>
<td>LoD</td>
<td>limit of detection</td>
</tr>
<tr>
<td>LOD</td>
<td>loss on drying</td>
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<tr>
<td>MB</td>
<td>microbiology</td>
</tr>
<tr>
<td>MBL</td>
<td>microbiology laboratory</td>
</tr>
<tr>
<td>MF</td>
<td>master formulae</td>
</tr>
<tr>
<td>MR</td>
<td>management review</td>
</tr>
<tr>
<td>NIR</td>
<td>near-infrared spectroscopy</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>
</tr>
<tr>
<td>OQ</td>
<td>operational qualification</td>
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WHOPIR Qilu Pharma (Xinluo Road)
January 2017

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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>PHA</td>
<td>preliminary hazard analysis</td>
</tr>
<tr>
<td>PM</td>
<td>preventive maintenance</td>
</tr>
<tr>
<td>PpK</td>
<td>process performance index</td>
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<tr>
<td>PQ</td>
<td>performance qualification</td>
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<tr>
<td>PQR</td>
<td>product quality review</td>
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<tr>
<td>PQS</td>
<td>pharmaceutical quality system</td>
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<tr>
<td>PW</td>
<td>purified water</td>
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<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>
</tr>
<tr>
<td>QMS</td>
<td>Quality management system</td>
</tr>
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<td>QRM</td>
<td>quality risk management</td>
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<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>RH</td>
<td>relative humidity</td>
</tr>
<tr>
<td>RM</td>
<td>raw materials</td>
</tr>
<tr>
<td>RS</td>
<td>reference standard</td>
</tr>
<tr>
<td>SAP</td>
<td>system applications products for data processing</td>
</tr>
<tr>
<td>SFG</td>
<td>semi-finished goods</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>STP</td>
<td>standard test procedure</td>
</tr>
<tr>
<td>T</td>
<td>temperature</td>
</tr>
<tr>
<td>TAMC</td>
<td>total aerobic microbial count</td>
</tr>
<tr>
<td>TFC</td>
<td>total fungal count</td>
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<tr>
<td>TLC</td>
<td>thin layer chromatography</td>
</tr>
<tr>
<td>TMC</td>
<td>total microbial count</td>
</tr>
<tr>
<td>URS</td>
<td>user requirements specifications</td>
</tr>
<tr>
<td>UV</td>
<td>ultraviolet-visible spectrophotometer</td>
</tr>
<tr>
<td>VMP</td>
<td>Validation Master Plan</td>
</tr>
<tr>
<td>WFI</td>
<td>water for injection</td>
</tr>
<tr>
<td>WS</td>
<td>working standard</td>
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</table>
Part 2 | Brief summary of the findings and comments (where applicable)

**Brief summary of the findings and comments**

1. **Pharmaceutical quality system (PQS)**
   **Principle**
   Production and control operations were specified in written form and GMP requirements were generally followed. Managerial responsibilities were specified in job-descriptions. Product and processes were monitored and the results taken into account in batch release; regular reviews of the quality of pharmaceutical products were conducted.

   **Quality Risk Management**
   The SOP “Quality Risk Management” was discussed.

   The following tools were specified:
   - Design of experiments (DoE)
   - Pareto charts
   - Fault tree analysis (FTA)
   - Failure modes and effects analysis (FMEA)
   - Hazard analysis and critical control points (HACCP)

   The register of risk assessments performed in 2016 was presented.

   Risk assessment for computerized systems used in production workshop X was discussed.
   Cross contamination risk assessment for SVP line Y was spot checked.

   RA registers were dedicated to the workshops and laboratories.

   **Product Quality Review (PQR)**
   The SOP “Annual product quality review” was discussed. According to the SOP, PQR should be finished by the first quarter of the next year. In case products were not manufactured during review period PQRs were performed to cover complaints, stability studies, technical agreements etc.
Management review
The SOP “Quality system review” was discussed. According to the SOP quality system review shall be performed quarterly. The SOP was applicable, but not limited to:
- Deviations management
- CC
- Customer requires /complaints
- Returns
- Rejects
- Reprocess and rework
- Inspection
- PQR
- Recall
- Validation /qualification
- Stability program
- Documentation management
- CAPA

Deviations
The SOP “Management of production deviation” and flow chart were discussed. Deviations were classified:
- Critical
- Non-critical

The SOP was applicable for planned deviations to all departments. Deviations classification was carried out by respective departments and approved by QA. Deviations were trended quarterly. Manufacturing process deviations were recorded in respective batch manufacturing records (BMR).

Registers/logs were maintained separately for deviations related to the different departments. QA issued deviation report forms to departments, maintained the registers.

Periodic trending of deviation was in place. Timeline of one month for investigation of the deviation was specified.

Deviation register was presented to the inspectors.

Corrective actions and preventive action (CAPA)
The SOP “Management of Corrective actions” was discussed. This SOP was applicable to all departments. There was a quarterly review of CAPAs related to different quality systems. A risk grade of high, middle and low was outlined in the procedure.
Change control (CC)
The SOP “Change control” and flow chart were discussed. SOP was applicable for any GMP related changes.

Changes were classified:
- Permanent
- Temporary
- Minor
- Moderate
- Major

CC registers were maintained by individual departments.

2. Good manufacturing practices for pharmaceutical products
Manufacturing processes were defined and reviewed. Qualifications and validations were performed. Significant deviations were recorded and investigated, root causes were determined and CAPAs were implemented. Systems were in place for handling complaints and recalling any batch of product from sale or supply.

3. Sanitation and hygiene
The company had an SOP as the basis for its approach to personal hygiene and sanitation in its production facilities. Microbial monitoring was performed.

4. Qualification and validation

Autoclave validation
Autoclave No X, used for product sterilization, and autoclave No Y, used for tools sterilization, validation protocols and reports were discussed.

Autoclave No Z for hard goods qualification report was discussed.

Depyrogenation tunnel qualification
Ampoules depyrogenation tunnel No X qualification report was spot checked.

Temperature mapping
Temperature mapping for warehouses was performed every 2 years in winter and summer periods. The T mapping report for the warehouse X was spot checked.
Clean room qualification
The following tests were performed:
- Particle size
- Air changes per hour
- Velocity
- Air flow pattern
- Pressure differential
- T & Relative humidity (RH)
- Clean up time
- HEPA filter integrity test

Cleaning validation
Cleaning validation report No Y was discussed. Swab and final rinse water samples were tested for bioburden, chemical residuals and total organic carbon (TOC). Recovery studies were performed.

Hold time studies
Amikacin (sulfate) Solution for injection 500 mg/2ml solution hold time studies report was discussed. Hold time studies were performed starting from the dissolution of the API to the end of the filling.

Leak test validation
For leak test, blue dye solution diluted with purified water was used. The leak test validation had been performed by water for injection (WFI). Defective ampoules were detected by the manual visual inspectors. The manual visual inspectors were qualified for this operation.

5. Complaints
The SOP “Complaints management” was discussed. Complaints were classified as:
- Critical
- Major
- Minor

Complaints were trended yearly.

6. Product recalls
The SOP “Product recall management” was discussed. Recalls were classified as:
- Grade I - recall within 24 hours
- Grade II – recall within 48 hours
- Grade III – recall within 72 hours

A person from QA was appointed for dealing with recalls. QP had overall responsibility for dealing with recalls.

Recall effectiveness was evaluated by mock recall.
7. **Contract production, analysis and other activities**

Manufacturing operations, if required, were contracted out to Qilu Hainan site. Technical agreement (TA) with Hainan site was discussed.

Contract laboratory was used for packaging materials analysis. TA with contract laboratory was discussed.

8. **Self-inspection, quality audits and suppliers’ audits and approval**

The SOP “Self inspection” was discussed. Inspection was carried out by team. Self-inspectors were trained annually and qualified after training. Check lists were used to perform self-inspection. Observations were classified as:
- Critical
- Major
- Minor

Inspection report was written by the team and CAPAs addressed by the inspected department.

The SOP “Management of supplier” was discussed. CAPA implementation was checked by the QA. Annual self-inspection schedule was presented to the inspectors.

**Suppliers’ audits and approval:**

The management of the suppliers was performed according to the SOP. The qualifications of the supplier included raw materials, excipients and packaging materials. The SOP for supplier audit was in place. The suppliers of critical materials were audited every two years.

The list of critical materials along with the suppliers and the date of the last audit was spot checked.

9. **Personnel**

There was an adequate number of personnel qualified to perform and supervise the manufacturing and quality control. Steps were taken to prevent unauthorized people from entering production, storage and QC areas.

10. **Training**

The SOP „General training program” was discussed. Several training modules were in place:
- New staff training
- Post training
- External training

Training effectiveness was evaluated.

The qualification of the operators performing the manual visual inspection of the filled products in ampoules was performed every six months. Eyes checks were performed every 6 months.
11. Personal hygiene
All personnel, prior to and during employment, had to undergo health examinations. Regular health examinations were carried out every year. Personnel conducting visual inspections had to undergo periodic eye examinations every six months. Direct contact between the operator’s hands and starting materials, primary packaging materials and intermediate or bulk products were avoided. Smoking, eating, drinking, chewing, and keeping plants, food, drink, smoking material and personal medicines prohibited in production, laboratory and storage areas.

12. Premises
Ancillary areas
Rest and refreshment rooms were separate from manufacturing and control areas.

Storage areas
Storage areas were of sufficient capacity.

Production areas
Exposed surfaces were smooth, impervious and unbroken. Changing rooms were designed as airlocks and used to provide physical separation of the different stages of changing. Changing rooms were flushed with filtered air. Premises were cleaned and disinfected according to written procedures.

Quality control areas
Sufficient space was given to avoid mix ups and cross-contamination. Storage space was provided for samples, reference standards, solvents, reagents and records.

13. Equipment
General
Fixed pipework was labelled to indicate the contents and the direction of flow. Balances and other measuring equipment of an appropriate range and precision were available for production and control operations and were calibrated on a scheduled basis.

14. Materials
Materials were received, sampled and tested according to the written procedures. Acceptable quality level (AQL) was applied for ampoules sampling.

15. Documentation
Documents were available and included SOPs, protocols and records. SOPs were generally followed. Issuing of documents, formats were not always appropriate.
16. Good practices in production

**General**

In general production operations followed defined procedures. Deviations from procedures were recorded and investigated. Access to production premises was restricted to authorized personnel.

The SOP “Environmental monitoring of clean area Workshop No X” was discussed. Environmental monitoring (EM) was performed by settle plates, contact plates and airborne particle counts. Action and alert levels were specified based on historical data. EM monitoring results for 2015 were discussed. The results of the microbial environmental monitoring for 2015 were almost nil for all the sampled locations.

The SOP “Quality monitoring for process water” was discussed. Action and alert levels were specified based on historical data.

17. Good practices in quality control

**General**

The QC function was independent from other departments. Adequate resources were available to ensure that all the QC arrangements were carried out. QC personnel had access to production areas for sampling and investigations as appropriate.

**Out of specification results (OOS)**

The SOP was applicable to investigation results for raw materials and excipients, packaging materials, process water, intermediates, recovered material, APIs and drug products obtained in QC laboratory as well as in stability studies. The sterility test result failure was handled as per the SOP “The investigation procedure of sterility test positive results and necessary action indicated”. Register of OOS for 2015 and 2016 were spot checked.

**Sampling procedures**

The SOP “Sampling procedures of purchased materials” was discussed. For APIs and excipients used for production of finished dosage for exportation to regulated market and first three batches of APIs and excipients provided by new suppliers, each container of the material was sampled for identification. Samples were combined in composite sample for other tests. Sampling rule and procedure for packaging materials was based on AQL principles and was explained in the SOP.

Procedures for sampling of environmental monitoring and for water systems were implemented.

**Stability studies**

The SOP “Stability studies” was discussed. Yearly at least one batch of each strength of each product was placed for on-going stability studies.
Environmental monitoring of clean area of workshop X
The SOP “Environmental monitoring” was discussed. The risk based approach was adopted for location and frequency of sampling points. Alert and action limits for the results of particulates and microbiological monitoring were and quarterly and yearly trends of environmental monitoring were in place. The appropriate corrective actions after the initiated investigation of trends of environmental monitoring were not prescribed in the operating procedure.

Monitoring for water of workshop X
Sampling plan for city water, PW and WFI were in place. Critical sampling points including return and compounding user points for WFI were sampled and tested daily. Alert and action limits were specified. The results for 2015 for WFI were within established limits, no microbial count had been recorded.

Microbiology laboratory
Laboratory premises were spacious and had separate rooms for positive controls, sterility tests, microorganism identification, media preparation and sterilization and other supportive rooms.

PART 3
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, Qilu Pharmaceutical Co., Ltd., located at No. 317, Xinluo Road, High-Tech Zone, Jinan, Shandong Province, China, 250101 (Building K002, Workshop No. 6) was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products.

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 used for assessing compliance
   Short name: WHO TRS No. 986, Annex 2

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

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   **Short name: WHO TRS No. 957, Annex 2**

   **Short name: WHO TRS No. 970, Annex 2**

   **Short name: WHO TRS No. 929, Annex 4**
   [http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1](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](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](http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1)

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

   **Short name: WHO TRS No. 957, Annex 3**
   
   **Short name:** WHO TRS No. 961, Annex 7
   
   [Link](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

   
   **Short name:** WHO TRS No. 961, Annex 9
   
   [Link](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

   
   **Short name:** WHO TRS No. 943, Annex 3
   
   [Link](http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1)

   
   **Short name:** WHO TRS No. 961, Annex 2
   
   [Link](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

   
   **Short name:** WHO TRS No. 981, Annex 2
   
   [Link](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)

   
   **Short name:** WHO TRS No. 981, Annex 3
   
   [Link](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)

   
   **Short name:** WHO TRS No. 961, Annex 14
   
   [Link](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
   Short name: WHO TRS No. 992, Annex 3

   Short name: WHO TRS No. 992, Annex 4

   Short name: WHO TRS No. 992, Annex 5

   Short name: WHO TRS No. 992, Annex 6

   Short name: WHO TRS No. 996, Annex 3
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

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

*Short name: WHO TRS No. 996, Annex 10*