### Part 1  General information

#### Manufacturers Details

<table>
<thead>
<tr>
<th>Company information</th>
<th>Zhuhai Rundu Pharmaceutical Co Ltd</th>
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</thead>
<tbody>
<tr>
<td>Name of manufacturer</td>
<td>Zhuhai Rundu Pharmaceutical Co Ltd</td>
</tr>
<tr>
<td>Address</td>
<td>No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041 P.R. China</td>
</tr>
<tr>
<td>GPS coordinate</td>
<td>22°3' 50.0N, 113°21' 13.5E D-U-N-S: 42-114-7133</td>
</tr>
<tr>
<td>Corporate address of manufacturer</td>
<td>No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041 P.R. China</td>
</tr>
<tr>
<td>Tel</td>
<td>+86-756 7637768</td>
</tr>
<tr>
<td>Fax</td>
<td>+86-756 7630123</td>
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</tbody>
</table>

#### Inspected site

| Address of inspected manufacturing site if different from that given above | As above |
| Unit / block / plant number | Building#26, Zone II |
| Zone III: Warehouse for API storage |
| Manufacturing license number | No 20160246 |
| Type: Drug manufacture certificate |
| Scope of the license: APIs, Small volume injection, Tablets, Hard capsules, Pharmaceuticals intermediate (pellet), excipients (Sugar spheres) |

#### Inspection details

| Dates of inspection | 15 – 19 October 2018 |
| Type of inspection  | Routine API + addition of the new workshop (API) |

#### Introduction

| Brief summary of the manufacturing activities | Manufacture of API and intermediates by chemical synthesis and small volume injection, tablets, hard capsules, pharmaceuticals intermediate (pellet) and excipients (sugar spheres) |
| General information about the company and site | History: |
| 1997: Zhuhai Mintong Pharmaceutical Research Institute was established; |
| 2000: Zhuhai SEZ Mintong Pharmaceutical Factory was established; |
| 2002: Zhuhai Sanxin Fine Chemical Co. Ltd. was established; |
2007: Rundu and Mintong was merged and renamed as Rundu Mintong Pharmaceutical Company;
2010: Rundu Mintong purchased Zhuhai Sanxin;
2011: Rundu Mintong changed its name to Zhuhai Rundu Pharmaceutical Co., Ltd
2013~2015: Zhuhai Rundu Pharmaceutical Co., Ltd had obtained a CEP certificate of Candesartan Cilexetil & Olmesartan Medoxomil.

History
The site was previously inspected by WHO:

The site was inspected by the following authorities:

<table>
<thead>
<tr>
<th>Date</th>
<th>Name of competent authority</th>
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</thead>
<tbody>
<tr>
<td>16th to 19th November 2013</td>
<td>China FDA</td>
</tr>
<tr>
<td>17th to 19th January 2014</td>
<td>China FDA</td>
</tr>
<tr>
<td>7th to 9th July, 2015</td>
<td>China FDA</td>
</tr>
<tr>
<td>19th to 22th October 2015</td>
<td>WHO</td>
</tr>
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<td>28th January 2016</td>
<td>China FDA</td>
</tr>
<tr>
<td>8th to 10th March 2016</td>
<td>China FDA</td>
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<tr>
<td>23rd to 25th September 2016</td>
<td>China FDA</td>
</tr>
<tr>
<td>26th to 28th September 2017</td>
<td>Japan PMDA</td>
</tr>
<tr>
<td>23rd to 26th August 2017</td>
<td>China FDA</td>
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<tr>
<td>24th to 26th November 2017</td>
<td>China FDA</td>
</tr>
<tr>
<td>29th to 31st, May 2018</td>
<td>China FDA</td>
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</tbody>
</table>

Brief report of inspection activities undertaken

Scope and limitations
Areas inspected
See Part two below

Restrictions
N/A

WHO product numbers covered by the inspection
API used in medicines for malaria treatment

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADE</td>
<td>acceptable daily exposure</td>
</tr>
<tr>
<td>AHU</td>
<td>air handling unit</td>
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<tr>
<td>ALCOA</td>
<td>attributable, legible, contemporaneous, original and accurate</td>
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<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>APQR</td>
<td>annual product quality review</td>
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<td>AQL</td>
<td>acceptance quality limit</td>
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<tr>
<td>BET</td>
<td>bacterial endotoxin test</td>
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<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>
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<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>CAPA</td>
<td>corrective actions and preventive actions</td>
</tr>
<tr>
<td>CC</td>
<td>change control</td>
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<tr>
<td>CFU</td>
<td>colony-forming unit</td>
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<td>CoA</td>
<td>certificate of analysis</td>
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<td>Cpk</td>
<td>process capability index</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>EU</td>
<td>endotoxin unit</td>
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<td>FAT</td>
<td>factory acceptance test</td>
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<td>FG</td>
<td>finished goods</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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<td>FTA</td>
<td>fault tree analysis</td>
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<td>FTIR</td>
<td>Fourier transform infrared spectrometer</td>
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<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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<tr>
<td>HVAC</td>
<td>heating, ventilation and air conditioning</td>
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<td>ID</td>
<td>identity</td>
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<td>IR</td>
<td>infrared spectrophotometer</td>
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<td>IPC</td>
<td>In process control</td>
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<td>IQ</td>
<td>installation qualification</td>
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<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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<td>LOD</td>
<td>loss on drying</td>
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<td>M</td>
<td>Meter</td>
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<td>MB</td>
<td>Microbiology</td>
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<td>MBL</td>
<td>microbiology laboratory</td>
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<td>MF</td>
<td>master formulae</td>
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<td>MR</td>
<td>management review</td>
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<td>NIR</td>
<td>near-infrared spectroscopy</td>
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<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>Ph. Eur</td>
<td>European Pharmacopoeia</td>
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<td>PHA</td>
<td>preliminary hazard analysis</td>
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<td>PM</td>
<td>preventive maintenance</td>
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<td>Ppk</td>
<td>process performance index</td>
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<tr>
<td>PQ</td>
<td>performance qualification</td>
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<td>PQR</td>
<td>product quality review</td>
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Part 2  Brief summary of the findings and comments

1. Pharmaceutical quality system (PQS)

Brief summary of the findings and comments

Production and control operations were specified in written form and GMP requirements were essentially being met. Managerial responsibilities were specified in written job-descriptions. Product and processes were monitored, and the results were taken into account during batch release; regular monitoring and reviews of the quality of pharmaceutical products were being conducted according to documented schedules and procedures.

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Page 4 of 15
Management review (MR)
The SOP “Pharmaceutical quality system management review” was briefly discussed. The SOP was effective from 1 September 2018. Till the date of inspection MR had not been performed. According to the SOP MR should be conducted every year before April – this date was related to the board of directors and shareholders meeting. Standard agenda was specified.

Quality Risk Management (QRM)
SOP on QRM was briefly discussed. Tools to be used in risk assessment were described in this SOP. A register of RA was maintained. The register for 2018 was briefly discussed. A RA was made for a temporary change. The change was well documented.

Product Quality Review (PQR)
The SOP “Annual product review APR” was briefly discussed. According to the SOP APR should be finalized by 31st March next year.
APR of product under inspection for 2017 was briefly discussed.

Deviations
The SOP “Deviation management” and registers for 2017 and 2018 were briefly discussed. Planned deviations were classified as temporary changes. Deviations were classified as:
• Significant – investigation should be started within one day
• Major – investigation should be started within one day
• Minor

Deviations were recorded in the batch manufacturing records. Two tools were used for root cause analysis:
• Ishikawa diagram
• Cause and effect diagram

According to the SOP deviations were trended once in a year. Several deviation investigation reports were briefly discussed.

Corrective actions and preventive action (CAPA)
The SOP “Corrective actions and preventive actions” and registers for 2017 and 2018 were briefly discussed. The SOP was applicable to deviations, complaints, recalls, internal and external audits, water system, environmental monitoring, OOS, OOT, APQ, change controls.

Change control (CC)
The SOP “Change control management procedure” and registers for 2016, 2017 and 2018 were briefly discussed. Changes were classified as:
• Planned
• Temporary
• Major
• Minor
• General
Several CCs were briefly discussed.
Data integrity
The SOP “Data reliability management procedure”, SOP “Raw data back-up procedure (applicable for Agilent OpenLab and Chromeleon 7)”, SOP “Chromatographic data audit trial management procedure”, SOP “Agilent OpenLab data back-up, disaster management and data restoration procedure” and SOP “Chromeleon 7 data back-up, disaster management and data restoration procedure” were briefly discussed. Back-up registers for 2018 were presented to the inspectors. These were used for standalone equipment only.

The SOPs “Agilent OpenLab data store access levels”, “Agilent OpenLab data store annex – details of access levels”, SOP “Chromeleon 7 distribution of privileges” and “Chromeleon 7 privileges” were briefly discussed. There were 5 access levels.

Self-inspection
The SOP “Audits management procedure” was briefly discussed. The SOP explained internal audits and external audits procedure. Audits were carried out by internal audit team. Training for internal auditors was provided once per year. Internal audit plan for 2018 was shown to the inspectors. Comprehensive internal audits were carried out twice per year.

Supplier’s qualification
SOP “Suppliers qualification” was briefly discussed. It listed categories of materials, with starting materials and structural reagents under Category A. Manufacturers and suppliers of these materials would require an on-site audit. In case of significant deviations of these and other products also an on-site audit had to be performed. The supplier audit schedule for 2017 and 2018 was presented to the inspectors.

Complaints
The SOP “Customer complains handing procedure” and registers for 2017 were briefly discussed. Handling/investigation of the complaints was QA responsibility. Complaints were classified as:
- Adverse drug reaction
- Quality related

Several complaints investigation records were briefly discussed.

Product recalls
The SOP “Product recall procedure” and last mock recall were briefly discussed. Recalls were classified as:
- Level I, customers should be informed within 24 hours
- Level II, customers should be informed within 48 hours
- Level III, customers should be informed within 72 hours

The Company stated that there were no recalls in the Company history. According to the SOP recall procedure effectiveness was verified by a mock recall for domestic and foreign markets.
Product returns
The SOP “Returned products management procedure” and register for 2017 and 2018 were briefly discussed.

Out of specification results (OOS)
The SOP “OOS result investigation procedure” and register for 2017 and 2018 were briefly discussed. The SOP was applicable for chemical and microbiological OOS investigations. The SOP was based on MHRA guideline and applied Phase I and Phase II investigations. According to the company procedure analyst error (identified before analysis), system suitability failure, instrument failure, column failure was considered as deviations and recorded accordingly.

Several OOS investigation reports were briefly discussed.

Batch release
Batches were released by the QP after stepwise releases by the Workshop, QC and QA. All batches were released with a certificate stating that they were tested according to the “Enterprise Standard” which was explained as the total of PQ (WHO) and Chinese Pharmacopeia grade. The total of tests in STPs PQ material and for CP material was always done.

Personnel
According to the presentation, the site employed approximately 945 full time employees.

Training
The SOP “Training and competence qualification procedure” and annual training plan for 2018 were briefly discussed. There were several types of training explained:
- Company level:
- Department level:
Training effectiveness was evaluated by multiple choice questions, false/true and open questions.

Analysts qualification was limited to the SOP training, theoretical training, for example software, operation of instruments. It was discussed that comparison testing would be the way for analyst’s qualification.

2. Documentation system
Documentation system was generally established. Documents related to the manufacture of intermediates and APIs were prepared, reviewed, approved and distributed according to written procedures. The SOPs were also displayed at appropriate points. The issuance, revision, superseding and withdrawal of documents were controlled with maintenance of revision histories.
Batch numbers were issued according to a procedure and consisted of a product code, year and month of production, a number to indicate type of batch the work shop number and a sequential number.
3. Production system

Production operations followed defined procedures. Manufacturing instructions were given in Production Instructions and recorded in Batch Production Records and Batch Packaging Records. SOPs and described the requirements for these documents. Qualifications and validations were performed according to prepared protocols. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Checks on yields and reconciliation of quantities were carried out. Access to production premises was restricted to authorized personnel.

During this inspection, there was no production operations carried out, except in the clean rooms. Explanation was that production operations were on hold from 3rd October till the end of November because of installation of new production equipment.

Separate rooms, equipped with air extraction system were provided for dispensing of raw materials. Rooms were provided for cleaning of equipment and storage of centrifuge bags and tools.

Blending

The SOP “Blending procedure for intermediates and APIs” and blended batches register for 2017 were briefly discussed.

Reprocessing and reworking

The SOP “APIs and intermediates reprocessing and reworking procedure” and reprocessed batches registers for 2017 and 2018 were briefly discussed. According to the company explanation APIs were not subjected to reworking. Reprocessed batched were subjected to stability studies.

Recovery of materials and solvents

The SOP “Recovery of solvents and mother liquor”, “Specification and standard test procedure for recovered ethanol” and “95% ethanol standard test procedure” were briefly discussed. Recovered ethanol specifications had more test items than fresh ethanol specifications.

Hold time studies

Hold time studies were performed in 2017 and were briefly discussed.

4. Facilities and equipment system

During inspection inspectors visited API manufacturing Workshop 6 and Workshop 5, Class D rooms clean rooms used for drying, milling, sieving, primary and secondary packaging. Production rooms were in good order, generally clean and well maintained. Temperature and humidity were controlled by the HVAC system. Pressure cascades were adequate. Production equipment and permanently installed processing lines were appropriately identified. Product dedicated parts, such as hoses and filters, were appropriately labeled with the product number. Calibration due date and equipment cleaning date and due date were indicated on the equipment labels.
During inspection inspectors also visited solvents tank farm, solvents in drums warehouse, starting materials and packaging materials warehouses, and Zone III warehouse for API storage. The warehouses had sufficient space for the orderly placement of goods. A set of rooms for the sampling of raw materials was added to the warehouses in September 2017. Receiving bays offered protection against weather. A current list of approved vendors and suppliers was shown. The receiving procedures for the tank farm were discussed.

As an example of equipment qualification, the IQ, OQ and PQ reports were seen for the vibratory sifter. Although in production there was no requirement for material that passed through the sieve, during qualification ≥98% was required.

Laboratories
Laboratory areas were separated from production areas.

Microbiological laboratory had separate rooms for microbial limit test, positive controls/master strains and sterility test. Microbiological laboratory had separate air handling system. Microbiological laboratory was not visited during the inspection.

Chemical/physical laboratory for raw materials and APIs testing premises were spacious and had adequate space for placement of instruments and equipment and materials.

Purified water system (PW)
PW was generated by reverse osmosis and was in continuous circulation at ambient temperature. Conductivity and temperature were controlled on-line. Flow meter was installed in the return loop and velocity was monitored continuously. UV lamp working hours and intensity were also monitored on-line. PW system was sanitized once per week using steam for 30 – 45 minutes. Water system was seen to be in good order and well maintained. The initial qualification documentation was briefly discussed.

Heating, ventilation and air conditioning system (HVAC)
Three air handling units (AHU) were serving filtered air to the Class D clean rooms. Two AHUs used 100% fresh air and one partly re-circulated air. Filter cascade was following: G4 →F8→H13. H13 HEPA filters were installed in the rooms. Pressure differentials between primary and secondary filters were controlled and recorded every 2 hours. According to the company procedure HEPA filters were replaced every two years. In case air flow was out of set limits an alarm was generated to the control panel. HVAC system was seen to be in good order and well maintained.

Nitrogen used in production was generated on site. The nitrogen generator was briefly visited and looked to be in good order. It was qualified in 2015 and again in 2017 after two user points were added. The documentation was adequate.

Temperature mapping
Temperature and relative humidity mapping study for Zone II “Piperaquine Phosphate Warehouse Room No 4” was briefly discussed. According to the company procedure re-qualification was performed once in three years in September. T&RH was recorded every 5 minutes for 7 days.
Calibration
The SOP “Metrological instruments management procedure” and calibration schedules (2018) for production equipment and laboratory equipment & instruments were briefly discussed. According to the SOP class “A” instruments should be calibrated every 6 months and class “B” instruments once per year. Pressure gauges placed on equipment with safety concerns were classified as class “A” instruments. All other pressure gauges, balances, T & RH meters etc. and analytical instruments and equipment were classified as class “B”.

Maintenance
SOP “Equipment maintenance management procedure” was briefly discussed. A list of equipment under maintenance was kept. The Annual schedule for 2018 was seen, this was adequate. A procedure was in place for corrective or repair maintenance.

Cleaning validation
In the production process, a vibratory sifter was used. Equipment XX, which was also used for sieving other APIs. Cleaning validation reports were briefly discussed.

Computerized system validation
SOP “Computerized systems management procedure” described the validation principles and processes. A list of types of computerized systems was annexed to the SOP. Hardware, software and PLCs were all included. As an example, the qualification of the production management system DCS was briefly discussed.

5. Laboratory control system
The QC function consisted of QC Analytical and QC Microbiology departments.

For starting materials and APIs, the following tests were performed in the microbiological laboratory:
- Microbial limit test
- Specific organisms
- Total bacteria
- Moulds & yeasts
- Water
- Compressed air
- Nitrogen
- Environmental monitoring

Re-calculations were done for assay and total impurities for API under scope of inspection batch Nos:
- AA
- BB
- CC
- DD
- EE
- FF
All re-calculations confirmed original results.
During inspection, API under scope of inspection batch No XX analytical raw data was cross checked with equipment log books, standards usage, HPLC & GC columns usage and weighing slips. No discrepancies were observed.

**Analytical balances**
According to the company procedure analytical balances were verified daily using 3 standard weights and calibrated yearly according to the USP Chapters 41 and 1251. The SOP “Analytical balance calibration and establishment of minimum weight procedure” was briefly discussed. Standard weights and calibration certificates were presented to the inspectors.

**HPLC & GC calibration**
HPLC and GC calibration was carried out yearly by laboratory staff.

The SOP “Management of analytical raw data” was briefly discussed. According to the SOP analysts were not allowed to perform manual integration. Manual integration could be performed only for impurities and related substances and should be authorized by QC manager. Manual integration request was recorded in the “Approval sheet for integration of chromatographic parameters”.

**Sampling**
The SOP “Raw materials sampling procedure” and SOP “Packaging materials sampling procedure” were briefly discussed.

**Reference standards**
The SOP “Standards and reference standards management procedure” and SOP “XX primary standard specifications and testing procedure” were briefly discussed. Working standard was qualified against primary standard because pharmacopoeia reference standard was not available. Primary reference standard selection criteria were specified. Working reference standards were dispensed in amber color vials for single use and store in locked cabinet at the room temperature.

**Retention samples**
Retention samples were stored in T and RH controlled room. Samples were appropriately identified and stored in the same packaging system in which the API was stored. Piperaquine Phosphate re-test date was specified as 2 years, reserve samples were retained for six years after the retest date.

**Stability studies**
Accelerated stability studies had been finalized as well as 18M long term stability studies. During inspection long term (30°C, 65 ± 5 %) stability studies were still running. T & RH in the chamber were recorded online every 30 minutes and checked twice per day. Chambers were equipped with Wi-Fi alarm systems (SMS) and connected to a UPS.

**Environmental monitoring of clean area (EM)**
Monitoring data for the clean rooms Class D were seen for 2017 and 2018 to date. The rooms were well under control.
Microbiological monitoring of PW
A trend report for 2016 was seen for the chemical and microbiological quality of the PW. The results indicated that the system was well under control.

Technical agreements
No technical agreements were in place for the outsourcing of manufacturing or testing activities. There was a technical agreement with the sole client for XX product. Based on this contract the company had notified the client of the change from WS1 to WS5&6. The letter was sent aa.bb.cccc. and receipt was acknowledged by the client.

6. Packaging and labelling system
The packaging of API was a fully manual operation.

PART
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, Zhuhai Rundu Pharmaceutical Co Ltd located at No 6 North Airport Road, Sanzao Town, Zhuhai, Jinwan District, Guangdong, 519 041, China (People's Republic of) (Zone II: Building #26, API Workshops 6 and 5, Zone III: warehouse) was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients 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 GMP guidelines used for assessing compliance

   Short name: WHO TRS No. 957, Annex 2

   Short name: WHO TRS No. 986, Annex 2

   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. 1010, Annex 8
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

   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 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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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. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_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. 981, Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/
   Short name: WHO TRS No. 961, Annex 14
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 992, Annex 4

   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

   Short name: WHO TRS No. 996, Annex 10