Part 1  General information

Manufacturers Details

Company information

Name of manufacturer and address

PT. SANBE FARMA Sterile Preparations Plant
Building A

Telephone number   +62 22 686 7966
Fax number           +62 22 686 7969

North latitude: - 6,865159
East longitude : 107,494871

Corporate address of manufacturer

PT. SANBE FARMA
Jl. Taman Sari No. 10 Bandung 40116 Indonesia
Telephone number   +62 22420 7725
Fax number           +62 22423 8476

Inspected site

Address of inspected manufacturing site if different from that given above

As above

Unit  Unit III
Block  A

Manufacturing license number

Manufacturing license from National Agency for Drug and Food Control (NADFC), Republic of Indonesia:
License no.:      HK.07.IF/V/402/14
Date of issue:    26 September 2014
Valid until:      Permanent

Inspection details

Dates of inspection  13-14 February 2017 and 16-17 February 2017
Type of inspection  Routine

Introduction

Brief summary of  PT. SANBE FARMA Sterile Preparations Plant, manufactures and controls sterile

WHO public inspection report PT. SANBE FARMA sterile February 2017

This inspection report is the property of the WHO
Contact: prequalinspection@who.int
### the manufacturing activities

products in the following dosage forms: Small and large volume parenterals including infusions: liquid injections, dry powders for injection, eye drops, ear drops, eye ointments, and fat emulsions

The company produces no highly toxic or hazardous products in Unit III Building A. Oxytocin is the most potent of the materials handled.

The site includes a separate and dedicated building for the handling of high potency for the handling of cytotoxic drugs.

### General information about the company and site

PT SANBE FARMA, Unit III, located in Cimareme, Padalarang, Bandung - Indonesia, is the facility dedicated to production of non-beta-lactam injectable products within the PT Sanbe Farma group. The factory is situated Jl. Industri Cimareme No.8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat – 40553, Indonesia.

Building A.

The site complex adjoins property operated by a sister company, PT Caprifarmindo.

Laboratories.

The PT Sanbe Unit III Building A site was involved in the manufacture of Small Volume Parenterals (SVPs) and Large Volume Parenterals (LVPs – these are mainly in Poly Propylene plastic bags) products. The site houses separate areas for SVPs and LVPs. In the SVP area there were separate facilities for aseptically prepared formulations and aseptic filling into ampoules and vials as well as separate plastic eye drop lines. The company also has extensive facilities in Unit III for LVP terminally sterilized products, dry injection and fat emulation dedicatedly.

To the rear of Unit III there were two separate and dedicated buildings. One of these was dedicated to the manufacture of cytotoxic drugs and the other biological products. Each had its own management, facilities and services as well as laboratories.

In addition, there was an additional site dedicated to beta-lactam products located 10 kilometers from Unit III, for oral solid dosage forms (OSDs) and injectables. This site is located at Unit II, Jalan Mahar Martanegara. No 162 (Jl. Leuwigajah No. 162) RT.01, RW.12, Kelurahan Baros, Kecamatan Cimahi Tengah, Kota Cimahi - Indonesia. The inspection of the beta-lactam facility is reported separately.

### Brief report of inspection activities undertaken

### Scope and limitations

Areas inspected

See Part 2 below

Restrictions

Only Corima ampoule line was inspected

Out of scope

- LVP terminally sterilized (TS) products.
- SVP terminally sterilized (TS) products (there was a second ampoule line used

WHO public inspection report PT. SANBE FARMA sterile February 2017

This inspection report is the property of the WHO

Contact: prequalinspection@who.int
WHO product numbers covered by the inspection

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>AQL</td>
<td>Acceptance quality limit</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>
</tr>
<tr>
<td>BMR</td>
<td>batch manufacturing record</td>
</tr>
<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>
</tr>
<tr>
<td>CpK</td>
<td>process capability index</td>
</tr>
<tr>
<td>DQ</td>
<td>design qualification</td>
</tr>
<tr>
<td>EM</td>
<td>environmental monitoring</td>
</tr>
<tr>
<td>FAT</td>
<td>factory acceptance test</td>
</tr>
<tr>
<td>FBD</td>
<td>fluid bed dryer</td>
</tr>
<tr>
<td>FG</td>
<td>finished goods</td>
</tr>
<tr>
<td>FMEA</td>
<td>failure modes and effects analysis</td>
</tr>
<tr>
<td>FPP</td>
<td>finished pharmaceutical product</td>
</tr>
<tr>
<td>FTA</td>
<td>fault tree analysis</td>
</tr>
<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>
</tr>
<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>
</tr>
<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>
</tbody>
</table>

WHO public inspection report PT. SANBE FARMA sterile February 2017

This inspection report is the property of the WHO
Contact: prequalinspection@who.int
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIR</td>
<td>near-infrared spectroscopy</td>
</tr>
<tr>
<td>NMR</td>
<td>nuclear magnetic resonance spectroscopy</td>
</tr>
<tr>
<td>NRA</td>
<td>national regulatory agency</td>
</tr>
<tr>
<td>OQ</td>
<td>operational qualification</td>
</tr>
<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>
</tr>
<tr>
<td>PQ</td>
<td>performance qualification</td>
</tr>
<tr>
<td>PQR</td>
<td>product quality review</td>
</tr>
<tr>
<td>PQS</td>
<td>pharmaceutical quality system</td>
</tr>
<tr>
<td>PW</td>
<td>purified water</td>
</tr>
<tr>
<td>QA</td>
<td>quality assurance</td>
</tr>
<tr>
<td>QC</td>
<td>quality control</td>
</tr>
<tr>
<td>QCL</td>
<td>quality control laboratory</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality management system</td>
</tr>
<tr>
<td>QRM</td>
<td>quality risk management</td>
</tr>
<tr>
<td>RA</td>
<td>risk assessment</td>
</tr>
<tr>
<td>RCA</td>
<td>root cause analysis</td>
</tr>
<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>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<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>
</tr>
<tr>
<td>TLC</td>
<td>thin layer chromatography</td>
</tr>
<tr>
<td>TMC</td>
<td>total microbial count</td>
</tr>
<tr>
<td>TOC</td>
<td>Total organic carbon</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>
</tr>
</tbody>
</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 at batch release; regular reviews of the quality of pharmaceutical products were conducted.

   Quality Risk Management
   The SOP was reviewed. Risk assessment followed the standard approaches described in ICH Q9 met the general requirements of WHO GMP norms and standards:
   • Risk identification
   • Risk analysis
   • Risk evaluation
   • Risk control
   • Risk acceptance
   • Risk communication
   • Risk review

   Failure modes and effects analysis (FMEA) was used for risk assessment, and the company’s main approach to risk assessment was to follow a unified system based upon FMEA. The SOP gave little attention to other risk assessment tools which might be more appropriate under certain circumstances.

   In the FMEA approach scores from 1- 4 was used for individual elements of the Risk Priority Number (RPN) calculation.

   Risk registers were prepared month wise.

   RA XX “Risk assessment for YY injection” was discussed. This was generally satisfactory at the high level but did lack sufficient detail and granularity in others.

   Product Quality Review (PQR)
   The SOP “Product quality review” was reviewed. The PQR schedule for 2016 and 2017 was presented to the inspectors.

   A single common PQR was prepared for all Oxytocin (and other) market variant products made according to the same base manufacturing process.

   Statistical tools were used for data presentation and analysis. Process capability was calculated using Cpk.

WHO public inspection report PT. SANBE FARMA sterile February 2017

This inspection report is the property of the WHO
Contact: prequalinspection@who.int
PQR for Santocyn® injection (Oxytocin Solution for injection 10 IU/mL) was reviewed:

The PQR was broadly comprehensive and acceptable covering most of the requirements of WHO GMP.

Management review (MR)
The SOP “Management review” was reviewed. According to the SOP quality system review shall be performed quarterly. The SOP was applicable, but not limited to:
- Follow-up action’s from previous reviews
- Process performance and product conformity
- CAPAs
- Customer feedback and complaints
- Internal quality audits
- Changes and quality system planning
- Recommendations for improvements
- External assessments such as regulatory inspections and customer audits

Deviations
The SOP “Deviation report” and flow chart were reviewed. The SOP was applicable to unplanned deviations. Deviations and their target close out, were classified with the system based on risk assessment.

Ishikawa diagrams were used for root cause analysis.

Corrective actions and preventive action
The company has a unified CAPA SOP which was used to handle most CAPA arising from several reporting mechanisms. CAPAs related to the self-inspection were presented separately and were linked to the specific self-inspection.

The SOP “Corrective actions and preventive actions” was inspected together with the log and specific examples chosen by the inspectors. CAPAs were proposed by manager or supervisor of each department and the QA manager was responsible for reviewing and approving CAPAs prior to their implementation. CAPAs registers were produced month wise.

Change control (CC)
The SOP “Change management” and its flow chart were reviewed. The SOP was applicable for any GMP related changes.

CC registers were maintained by QA.

2. Good manufacturing practices for pharmaceutical products
Manufacturing processes were defined and reviewed. Qualifications and validations were seen to be 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. 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 of clean room personnel was performed as part of routine batch control.

Generally, the facilities were noted to be clean and well organized during the inspection.

4. Qualification and validation

Aseptic process validation
The SOP “Aseptic process validation” and “Aseptic process validation protocol /report (Media fill run) VAL-XX and VAL-YY were reviewed.

According to the SOP aseptic process validation should be performed initially for any new or substantially changed process by performing 3 consecutive batches and on-going aseptic process validation should be performed every 6 months normally utilising one batch. For sequential media fills the use of the largest ampoule size and smallest ampoule size were rotated every 6 months.

The most recent media fill was reviewed. The numbers of ampoules were filled with non-sterile Tryptic Soy Broth – TSB media. It was noted that the normal Oxytocin injection filling time was 12 hours. Media simulation was done in 6 phases, totally 18 hours.

According to the SOP section X prior to incubation the containers should be inverted or otherwise manipulated so as to ensure that all surfaces are thoroughly wetted by the growth media. During media fills ampoules were inverted every day and the records of this procedure presented to the inspectors.

The document “Justification to define mimic process of ampoule line products for aseptic process validation (Media fill run)” was discussed. This was generally satisfied and the inspectors were satisfied that the media simulation was sufficiently representative of routine production.

Autoclave validation
The new autoclave adjoining the aseptic ampoule line for garments and spare parts sterilization was installed in October 2015. IQ&OP protocol/reports were available. Autoclave re-qualification protocol VAL-XX and report VAL-YY were discussed. The Bowie Dick test was performed once per day for the garments load.

Depyrogenation oven qualification
Depyrogenation oven IQ&OQ was finished 18 January 2016. IQ&OQ protocol (VAL-XX & VAL-YY) and report were spot checked. Hot air oven qualification report VAL-ZZ was also spot checked.

Clean room qualification
The air to the ampoule filing room was supplied by the AHU XX. Performance qualification report VAL-XX after changes “at rest” was reviewed. The following tests were carried out:
- Air changes per hour/air velocity
- Air flow pattern
- Pressure differentials
- T and RH

WHO public inspection report PT. SANBE FARMA sterile February 2017

This inspection report is the property of the WHO
Contact: prequalinspection@who.int
Facility cleaning verification
Microbial counts
Particulate counts
Particulate removal tests

HVAC system was equipped with alarms, which were said to be routinely challenged.

Temperature mapping
The SOP “Temperature and humidity mapping of controlled storage area” was spot checked.

Temperature mapping protocol “Pre-mapping temperature and relative humidity protocol” VAL-XX and report “Pre-mapping temperature and relative humidity protocol” VAL-YY were reviewed.

Leak test validation
Oxytocin was filled into 2 mL glass ampoules. Validation of the leak test had been performed in autoclave by vacuum. Validation report VAL-XX “Autoclave X for leak test” was reviewed and discussed.

5. Complaints
The SOP “Product complaint handling” was discussed. Complaints were classified regarding product quality:

- Class I
- Class II
- Class III

and

- Adverse reactions

Complaints register for Unit III 2015 and 2016 was presented to the inspectors. Month-wise registers were used.

Several complaints investigation documents were reviewed.

Complaints were trended yearly.

6. Product recalls
The SOP “Product recall” was discussed. Recalls were classified as per BPOM/NADFC guidelines:

- Grade I - recall within 24 hours
- Grade II – recall within 5 days
- Grade III – recall within 7 days

The QA manager was responsible for dealing with recalls. The head of quality had overall responsibility for dealing with recalls.

Recall effectiveness was periodically evaluated by mock recall. If there was not real recall, mock recall should be performed every 2 years.
7. **Contract production, analysis and other activities**

Manufacturing operations and laboratory testing relating to oxytocin were not contracted out. Pest control activities and irradiation of eye drop bottles and components were contracted out.

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

The SOP “Audit” was discussed. Inspection was carried out by a nominated self-inspection team.

Inspection was carried out using check lists. Inspection report was written by the team and CAPAs addressed by the inspected department.

Observations were classified as:

- Critical
- Major
- Minor

Check list had the following headings:

- Quality management and personnel
- Standard operations procedures
- Self-inspection
- Premises and equipment
- Warehousing areas
- Dispensary
- Parenteral operations and eye drops
- Sterilization of parenteral and eye drops (Sterilization by filtration)
- Finishing of sterile products
- Quality assurance / quality control department

**Suppliers’ audits and approval:**

The SOP “Vendor approval of new supplier for raw material” was discussed. There was only one supplier of Oxytocin API.

9. **Personnel**

There appeared to be an adequate number of personnel qualified to perform and supervise the manufacturing and quality control. Controls were in place to prevent unauthorized people from entering production, storage and QC areas.
### Number of employees:

<table>
<thead>
<tr>
<th>Department</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVP</td>
<td>419</td>
</tr>
<tr>
<td>Production</td>
<td>163</td>
</tr>
<tr>
<td>Packaging</td>
<td>256</td>
</tr>
<tr>
<td>SVP</td>
<td>206</td>
</tr>
<tr>
<td>Production</td>
<td>99</td>
</tr>
<tr>
<td>Packaging</td>
<td>107</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>17</td>
</tr>
<tr>
<td>IPC</td>
<td>35</td>
</tr>
<tr>
<td>Quality Control</td>
<td>97</td>
</tr>
<tr>
<td>Validation</td>
<td>20</td>
</tr>
<tr>
<td>DCC</td>
<td>3</td>
</tr>
<tr>
<td>PPIC</td>
<td>76</td>
</tr>
<tr>
<td>Engineering</td>
<td>66</td>
</tr>
<tr>
<td>IT</td>
<td>22</td>
</tr>
<tr>
<td>Personnel and GA</td>
<td>41</td>
</tr>
<tr>
<td>Others</td>
<td>44</td>
</tr>
<tr>
<td>Cost Accounting</td>
<td>6</td>
</tr>
<tr>
<td>Security</td>
<td>20</td>
</tr>
<tr>
<td>Driver</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1046</strong></td>
</tr>
</tbody>
</table>

The SOP “Personnel qualification for manual visual inspection” was reviewed. Oxytocin ampoules visual inspection was performed manually. Operators were re-qualified once a year.

### 10. Training

Training was provided in accordance with a written training programme.

The SOP “Training” was reviewed. There were the following training modes in place:

- General orientation
- On the job training
- SOP training
- Outside training and seminars

Training effectiveness was evaluated by verbal questions, open questions and written answers.

The SOP “Personnel hygiene application and aseptic technique in sterile products manufacturing” was discussed. The SOP “Personnel qualification working in aseptic area” was also discussed.

Personal files for Mr. XX, a filling operator and Mr. YY, from maintenance engineering in Sterile Preparation Plant were spot checked.

The SOP “Preparation of specimen for qualification manual visual inspection” was spot checked.
11. Personal hygiene
All personnel, prior to and during employment, had to undergo an initial health examination. Thereafter 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 was avoided. Smoking, eating, drinking, chewing, and keeping plants, food, drink; smoking material and personal medicines was prohibited in production, laboratory and storage areas.

12. Premises

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

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
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.

15. Documentation
Documents were available and included SOPs, protocols and records. SOPs reviewed in the production areas were generally being followed and staff appeared appropriately knowledgeable as to their content.

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

Oxytocin injection was manufactured on a XX ampoule line. This was the only line used by the company for aseptic filing of aseptically manufactured ampoules. The company had two other lines for terminally sterilized ampoules; however these were not within the scope of inspection.

WHO public inspection report PT. SANBE FARMA sterile February 2017
This inspection report is the property of the WHO
Contact: prequalinspection@who.int
Since the previous inspection, the company had installed a Fedegari hot air oven between the grade C and grade B filling room. This was now in routine use for the sterilisation and depyrogenisation of ampoules for aseptic filing and represented significant improvement to the aseptic process over the situation that was seen previously.

The aseptic ampoule filling line was used to fill approximately 20 different products. Oxytocin was the most potent of those products. The solution transfer line hoses and silicone tubing between the filling needles, filing pumps and balancing tank on the machine were stated to be dedicated to a specific active ingredient and were re-used. Other parts of the filling machine were made from stainless steel and was multipurpose use e.g. filing pumps. Cleaning had been validated on a matrix basis.

Secondary packaging rooms were spacious and lines well segregated.

The SOP “Visual inspection manually for sterile product” was spot checked.

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 in a timely and ordered fashion. QC personnel had access to production areas for sampling and investigations as appropriate.

All test equipments (HPLCs, GCs, IRs and UVs) were standalone instruments.

HPLC No X was routinely used for Oxytocin analysis and was checked during the inspection.

The SOP “Audit trail in HPLC which use LC solution system” was spot checked. There were three access levels specified.

The SOP “Preparing and reviewing QC analytical report” was discussed.

The SOP “Sampling for analysis of starting material” was spot checked. According to the SOP starting materials samples were taken from every container and 100 % identity tests were performed.

The SOP “Packaging material sampling” was spot checked. AQL, inspection level II, was used for ampoule sampling. Defects were classified.

Stability testing
18 months stability data was available, but not reviewed by inspectors. One batch per year was placed for on-going stability studies.

Out of specification results (OOS)
The SOP (corporate) was applicable for all investigation of OOS results of raw materials and excipients, packaging materials, APIs and finished products obtained in QC laboratory as well as in stability studies.
This procedure was also applicable for microbiological OOS tests and sterility failure. It did not cover IPC activities in production.

There were different OOS registers for the chemical and microbiological labs. Registers were maintained on a month-wise basis.

**Environmental monitoring of clean area (EM)**
The SOP “Environmental monitoring in aseptic room using microbiological method” was discussed. Swab samples, air samples and settle plates were used for EM. Alert and action limits for the results of particulates and microbiological monitoring were defined and monthly trends of environmental monitoring were in place.

The “Environmental monitoring report of SVP filling room, December 2016” was reviewed and discussed.

**Monitoring of PW and WFI**
The SOP “Water quality routine monitoring” was spot checked. Alert limits were established 60 % from the specification. Sampling plan for drinking water, PW and WFI were in place. WFI critical sampling points at the return loop and storage tanks (SVP and LVP) were sampled and tested daily for endotoxins, conductivity and TOC.

Monthly and half yearly trends were performed and available for inspection. PW and WFI trends July – December 2016 were discussed.

**Reference materials**
The SOP “Reference standard and working standard” was spot checked.

Pharmacopoeia reference standard was used for Oxytocin impurity tests and a working standard for the assay test.

Working standards were prepared and dispensed by the R&D department in 12 amber glass vials. After opening each vial was required to be used within one month. Usage of reference materials were recorded in a log book.

Oxytocin reference materials were stored in the refrigerator at 2 – 8 ºC. T in the refrigerator was continuously recorded on charts. Charts were reviewed once per week. Temperature was controlled manually three times per day.

**Stability studies**
The SOP “Stability testing” was spot checked. Stability chambers Temperature and RH sensors were connected to the software and recorded continuously. Temperatures were checked manually three times per day. The chambers were equipped with a local sound alarm.
Retention samples
Finished product and APIs retention samples were stored in refrigerator at 2 – 8 °C. T in the refrigerator was continuously recorded. T in the refrigerator was continuously recorded on charts. Charts were reviewed once per week. T was controlled manually three times per day.

Storage period for finished product was expiry date + 1 year and for APIs was 2 years after finished product release.

Microbiology laboratory
Laboratory premises had separate rooms for positive controls, sterility tests, bioburden tests, media preparation and sterilization.

PART 3
Conclusion
Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, PT. SANBE FARMA Sterile Preparation Plant (Unit III, Building A, Corima ampoule line) located at Jl. Industri Cimareme No.8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat – 40553, Indonesia 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

   "Short name: WHO TRS No. 957, 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. 961, Annex 5
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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

   Short name: WHO TRS No. 957, Annex 1

   Short name: WHO TRS No. 957, Annex 2

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

WHO public inspection report PT. SANBE FARMA sterile February 2017
This inspection report is the property of the WHO
Contact: prequalinspection@who.int
   **Short name: WHO TRS No. 961, Annex 9**  
   [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. 943, Annex 3**  
   [http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1](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](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

   **Short name: WHO TRS No. 981, Annex 2**  

   **Short name: WHO TRS No. 981, Annex 3**  

   **Short name: WHO TRS No. 961, Annex 14**  
   [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. 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*

   *Short name: WHO TRS No. 996, Annex 5*

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