**Food and Drug Administration, The Ministry of Health and Welfare**

**GMP Inspection Report**

|  |  |  |
| --- | --- | --- |
| Name of Inspected Site |  | |
| Address |  | |
| Inspection Dates |  | |
| Accompanying Personnel and Authority | Public Health Bureau of (城市): (name) | |
| Inspectors | Name of inspectors and/or technical specialists | |
| Reference no. | Inspection reference number: | |
| GMP Standards | Pharmaceutical Affair Law, Regulation of Inspection on Pharmaceutical Manufacturer, Guide to GMP for Medicinal Products (Part I- PIC/S GMP: PE009-13 & Part III PIC/S GDP: PE011-1) | |
| Activities Carried out by Company | Manufacture of Active Pharmaceutical Ingredient  Manufacture of Finished Medicinal Product  Manufacture of Intermediate or Bulk  Packaging  Importing  Laboratory Testing  Batch Control and Batch Release  Others | **□**  **□**  **□**  **□**  **□**  **□**  **□**  **□** |
| GDP activities carried out | **□** Procure **□** Storage **□** Supply **□** Import  **□** Export **□** Transportation **□** Other \_\_\_\_\_\_\_\_ | |
| Product Category of GDP activities | **□** Medicinal Products  **□** Specific Medicinal Products (**□** Controlled drug product **□** Penicillin **□** Cephalosporin **□** Estrogens  **□** Cytotoxic **□** Radiopharmaceuticals)  **□** Medicinal Gas  **□** Cold Chain Products (**□** Non-Biological Medicinal Products **□** Biological Medicinal Products\_\_\_\_\_\_\_\_\_)  **□** Other \_\_\_\_\_\_\_\_\_\_ | |

1. **Brief report of inspection activities undertaken**

* Briefly describe the scope of the inspection including

1. Short description of the inspection (Products related inspection and/or general GMP inspection)
2. The reason for the inspection should be specified (GMP assessment, routine inspection or for-cause inspection)

* The inspected areas included the ……. This inspection was included on-site tour and documentation review.

1. **Introduction**

Short description of the company and the activities

* (Name of Inspected Site) is a legal registered factory (工廠登記No. ) and a registered pharmaceutical company (藥商登記issue by 城市No. ) with a Manufacturing Authorization (製造許可No. ) …..
* The previous GMP inspection … (describe date, purpose and inspector names).
* Major changes since the previous inspection

1. **Miscellaneous**
2. Samples Taken：
3. Distribution of Report：
4. **List of deficiencies**
5. **Critical deficiencies：**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Category** | **Content of Deficiencies** | **Reference**  **(PIC/S GMP Guide)** |
|  |  |  |  |
|  |  |  |  |

1. **Major deficiencies：**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Category** | **Content of Deficiencies** | **Reference**  **(PIC/S GMP Guide)** |
|  | Pharmaceutical Quality System |  |  |
|  | Personnel |  |  |
|  | Premises and Equipment |  |  |
|  | Documentation |  |  |
|  | Production |  |  |
|  | Quality Control |  |  |
|  | Outsourced Activities |  |  |
|  | Complaints and Product Recall |  |  |
|  | Self Inspection |  |  |
|  | Transportation |  |  |

1. **Other deficiencies：**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Category** | **Content of Deficiencies** | **Reference**  **(PIC/S GMP Guide)** |
|  |  |  |  |
|  |  |  |  |

1. **Recommendations**
2. **Summary and Conclusions**
3. Describe the GMP execution of the inspected manufacturer, including the advantages and disadvantage.
4. The overall inspection results of inspected manufacturer is

* Comply with the PIC/S GMP Guide (Describe the approved dosage form or products)
* Decision made based on the corrective action report
* Re-inspection arranged after receiving the corrective action report submitted by manufacturer
* GMP Noncompliance with the PIC/S GMP Guide

1. The pharmaceutical GMP practice should ensure the integrity, consistency and accuracy of recording, handling, archiving and using the datum and records to truly represent the actual operation of the activities and the failed data must not be hid. Identified by GMP inspections internationally, bad practice and falsify cases caused a great impact on product quality and patient safety, therefor the importance of data integrity becomes commonly recognized. The pharmaceutical company should follow documented procedure to create, handle, review, report, archive, recover and audit the data and record integrity and these measures are included in TFDA GMP inspection scope.
2. This inspection is performed via randomly verification. If there are other similar issues, please correct as well.
3. **Personnel met during inspection**

Listing the name and the title of key personnel met during inspection

|  |  |
| --- | --- |
| **Title** | **Name** |
|  |  |
|  |  |

Signed and dated by **the Lead inspector**

Food and Drug Administration, The Ministry of Health and Welfare, Inspector [name]

*Signature*

**Definition of GMP Deficiencies**

1. **Critical Deficiencies**
2. A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human.
3. A deficiency relates to misrepresentation, or falsification of product or data.
4. **Major Deficiencies**
5. A deficiency which has produced or may produce a product, which does not comply with its marketing authorization.
6. A deficiency which indicates a major deviation from the GMP Guide.
7. A deficiency which indicates a major deviation from the terms of the manufacturing authorization.
8. A deficiency which indicates a failure to carry out satisfactory procedures for release of batches or a failure of the authorized person to fulfill his/her required duties.
9. A combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.
10. **Other Deficiencies**

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice.   
(A deficiency may be “other” either because it is judged as minor or because there is insufficient information to classify it as major or critical)

**Definition of GDP Deficiencies**

1. **Critical Deficiencies**
   1. A critical deficiency, departure from GDP Guide, leads to a significant risk to the patient or public health. The risk includes accessibility of falsified medicinal product of patient.
   2. A combination of a number of major deficiencies that indicates a serious systems failure.
   3. Procurement or supply medicinal products from or to a non-authorized-source.
   4. Clod chain products are stored at ambient temperature.
   5. Rejected or recall products found in sellable stock.
2. **Major Deficiencies**
3. A non-critical deficiency which indicates a major deviation from Good Distribution Practice.
4. A non-critical deficiency which has caused or may cause a medicinal product not to comply with its marketing authorization in particular its storage and transportation conditions.
5. A non-critical deficiency which indicates deviation from the term and provisions of the Western Pharmaceuticals Distribution License.
6. A combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency
7. **Other Deficiencies**

A deficiency which is not classified as either critical or major, but which indicates a departure from GDP Guide.