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 _____	

I. 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.

II. 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).

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– Major changes since the previous inspection

III. Miscellaneous

1. Samples Taken：
2. Distribution of Report：

IV. List of deficiencies

1. Critical deficiencies：

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

2. 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		

3. Other deficiencies：

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

V. Recommendations

VI. Summary and Conclusions

1. Describe the GMP execution of the inspected manufacturer, including the advantages and disadvantage.
2. 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

3. 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.
4. This inspection is performed via randomly verification. If there are other similar issues, please correct as well.

VII. 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

I. Critical Deficiencies

1.1. A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human.

1.2. A deficiency relates to misrepresentation, or falsification of product or data.

II. Major Deficiencies

2.1. A deficiency which has produced or may produce a product, which does not comply with its marketing authorization.

2.2. A deficiency which indicates a major deviation from the GMP Guide.

2.3. A deficiency which indicates a major deviation from the terms of the manufacturing authorization.

2.4. 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.

2.5. 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.

III. 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

I. Critical Deficiencies

1.1 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.

1.2 A combination of a number of major deficiencies that indicates a serious systems failure.

1.3 Procurement or supply medicinal products from or to a non-authorized-source.

1.4 Clod chain products are stored at ambient temperature.

1.5 Rejected or recall products found in sellable stock.

II. Major Deficiencies

2.1. A non-critical deficiency which indicates a major deviation from Good Distribution Practice.

2.2. 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.

2.3. A non-critical deficiency which indicates deviation from the term and provisions of the Western Pharmaceuticals Distribution License.

2.4. A combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency

III. Other Deficiencies

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