

## 2. Quality management system of the manufacturer

### 2.1. The quality management system of the manufacturer

#### 2.1.1. Brief description of the quality management system run by the company and reference to the standards used

The quality management system of **xxx Co., Ltd. xxx Plant** is established referring to **Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (GMP Ordinance)**, relevant regulations/normations, **Current Good Manufacturing Practice Regulations in the US (cGMP)** and **PIC/S GMP GUIDE**. **Quality Manual of xxx Co., Ltd. xxx Plant** serves as the highest level document in the document system of the site, and various written standards and procedures have been prepared under this manual.

These documents include quality policy, quality management organization, document control, personnel qualifications/hygiene control/education & training, manufacturing control, quality control, hygiene control of premises and equipment, qualification of premises and equipment, validation/maintenance, change control, deviation control, handling of quality information and quality defects, etc., recall procedure, self-inspection, management review.

The **Quality Manual** refers to the current version of **ISO 9000 Series**.

#### 2.1.2. Responsibilities related to maintaining of quality system including review management

The organization related to the quality management system of this manufacturing site is shown in **Appendix 5. GMP Organization Chart of xxx Co., Ltd. xxx Plant**. Senior management and other management are responsible for this.

**Head of Quality Assurance** supervises activities related to manufacturing control and quality control, to ensure appropriate and smooth conduct of such activities. **Head of Quality Assurance** is responsible for change control, deviation control, handling of quality information and quality defects, etc., product recall, and internal audit, and so on.

#### 2.1.3. Information of activities for which the site is accredited and certified

This manufacturing plant (**xxxxxxx**) is accredited. Hierarchy of the certificate is given in **Appendix 6. ISO 9001**.

Date of certification:

Scope of certification:

Name of certifying bodies:

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