



Article Content

Title : Western Pharmaceuticals Good Distribution Practice Regulations

CH

Announced Date : 2017-12-28

Category : Ministry of Health and Welfare (衛生福利部)

Attachment : Table 1 Quality Management Standards.PDF
Table 1 Quality Management Standards.doc
Table 2 Organization and Personnel Standards.PDF
Table 2 Organization and Personnel Standards.doc
Table 3 Premises and Equipment Standards.PDF
Table 3 Premises and Equipment Standards.doc
Table 4 Documentation Standards.PDF
Table 4 Documentation Standards.doc
Table 5 Operation Procedures Standards.PDF
Table 5 Operation Procedures Standards.doc
Table 6 Complaints, Returns and Recalls Standards.PDF
Table 6 Complaints, Returns and Recalls Standards.doc
Table 7 Outsourced Activities Standards.PDF
Table 7 Outsourced Activities Standards.doc
Table 8 Self-Inspections Standards.PDF
Table 8 Self-Inspections Standards.doc
Table 9 Transportation Standards.PDF
Table 9 Transportation Standards.doc
Table 10 Glossary.PDF
Table 10 Glossary.doc

Article 1 These regulations are promulgated pursuant to the Paragraph 4 of Article 53-1 of the Pharmaceutical Affairs Act.

Article 2 The quality management of business undertakings engaged in wholesaling, retailing, importing and exporting western pharmaceuticals (hereinafter referred to as the business undertakings), shall meet the regulations of quality management standards indicated in Table 1 (attached).
Table 1 Quality Management Standards.PDF
Table 1 Quality Management Standards.doc

Article 3 The organization and personnel of the business undertakings shall meet the regulations of organization and personnel standards indicated in Table 2 (attached).
Table 2 Organization and Personnel Standards.PDF
Table 2 Organization and Personnel Standards.doc

- Article 4 The premises and equipment of the business undertakings shall meet the regulations of premises and equipment standards indicated in Table 3 (attached).
Table 3 Premises and Equipment Standards.PDF
Table 3 Premises and Equipment Standards.doc
- Article 5 The documentation of the business undertakings shall meet the regulations of documentation standards indicated in Table 4 (attached).
Table 4 Documentation Standards.PDF
Table 4 Documentation Standards.doc
- Article 6 The operation procedures of the business undertakings shall meet the regulations of operation procedures standards indicated in Table 5 (attached).
Table 5 Operation Procedures Standards.PDF
Table 5 Operation Procedures Standards.doc
- Article 7 The customer complaints, returns, and recalls of the business undertakings shall meet the regulations of complaints, returns, and recalls standards indicated in Table 7 (attached).
Table 6 Complaints, Returns and Recalls Standards.PDF
Table 6 Complaints, Returns and Recalls Standards.doc
- Article 8 The outsourced activities of the business undertakings shall meet the regulations of outsourced activities standards indicated in Table 7 (attached).
Table 7 Outsourced Activities Standards.PDF
Table 7 Outsourced Activities Standards.doc
- Article 9 The self-inspections of the business undertakings shall meet the regulations of self-inspections standards indicated in Table 8 (attached).
Table 8 Self-Inspections Standards.PDF
Table 8 Self-Inspections Standards.doc
- Article 10 The transportation of the business undertakings shall meet the regulations of transportation standards indicated in Table 9 (attached).
Table 9 Transportation Standards.PDF
Table 9 Transportation Standards.doc
- Article 11 The definition of terms used in this regulation indicated in Table 10 (attached).
Table 10 Glossary.PDF
Table 10 Glossary.doc

Article 12 These regulations shall be effective as of the date of promulgation.

Web site : Laws & Regulations Database of The Republic of China (Taiwan)