

English/Japanese Edition

The Japanese GMP Regulations 2003

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The Ministry of Health, Labour and Welfare (MHLW) Ministerial Ordinances and MHLW Director-General Notification related to the Japanese GMP for Drugs are :

- Regulations for Buildings and Facilities for Pharmacies, etc. (MHW Ministerial Ordinance No.2 dated February 1, 1961 ; Amended : MHLW Ministerial Ordinance No. 92 dated May 20, 2003)
- Regulations for Manufacturing Control and Quality Control of Drugs (MHW Ministerial Ordinance No. 16 dated March 12, 1999 ; Amended ; MHLW Ministerial Ordinance No.95 dated May 20, 2003)
- Regulations for Importing/Retail Management and Quality Control of Drugs and Quasi-drugs (MHW Ministerial Ordinance No. 62 dated June 2, 1999 ; Amended : MHLW Ministerial Ordinance No. 97 dated May 20, 2003)
- MHLW Ministerial Ordinance on the Manufacturing Control and Quality Control When Manufacturing of a Single Product of the Drugs, Quasi-drugs, Cosmetics and Medical Devices Specified under Article 1-2-2, Paragraph 1, Items 1, 2 and 4 of the Enforcement Ordinance of the Pharmaceutical Affairs Law is Performed at Two or More Manufacturing Sites (MHW Ministerial Ordinance No. 26 dated March 30, 1994 ; Amended : MHLW Ministerial Ordinance No. 93 dated May 20, 2003)
- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (PFSB Director-General Notification No. 1200 dated November 2, 2001)

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