

THE JAPANESE  
PHARMACOPOEIA

THIRTEENTH EDITION

***JP XIII***

**THE JAPANESE PHARMACOPOEIA**  
***THIRTEENTH EDITION***

*Under the supervision of the Research and Development Division,  
Pharmaceutical Affairs Bureau, Ministry of Health and Welfare*

*Official from April 1, 1996*

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Notice: This *English Version* of the Japanese Pharmacopoeia, Thirteenth Edition, is published to meet the needs of the non-Japanese speaking people. When and if any discrepancy arises between the Japanese original and its English translation, the former is authentic.

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## The Ministry of Health and Welfare Notification No. 73

In accordance with the provision of Article 41 of the Pharmaceutical Affairs Law (Law No. 145, 1960), we establish the Japanese Pharmacopoeia (hereinafter referred to as the “new Pharmacopoeia”) as follows\*, and will apply it from April 1, 1996. The Japanese Pharmacopoeia prescribed by the Ministry of Health and Welfare Notification No. 51 dated March 1991 according to the Law (hereinafter referred to as the “previous Pharmacopoeia”) shall be abrogated on March 31, 1996. In this case, the drugs included in the previous Pharmacopoeia which have been approved before or on April 1, 1996, in accordance with the provision of Article 14 of the Law (inclusive of application *mutatis mutandis* in Article 23; the same hereinafter) [inclusive of drugs (hereinafter referred to as “drugs not requiring approval”) designated as those not requiring approval to manufacture or import on March 31, 1996, in accordance with the Ministry of Health and Welfare Notification No. 104 issued in March 1994 (matters related to designation of drugs not requiring approval to manufacture or import in accordance with Paragraph 1 of Article 14 of the Pharmaceutical Affairs Law)], even though not admitted to the new Pharmacopoeia, shall be recognized to be included in the new Pharmacopoeia up to September 30, 1997, and the standards for the previous Pharmacopoeia [limited to those for such drugs] shall be recognized to conform to those for the new Pharmacopoeia. The titles and/or standards for drugs in the previous Pharmacopoeia, even though changed in the new Pharmacopoeia, shall be recognized as those in the new Pharmacopoeia up to September 30, 1997. The drugs admitted to the new Pharmacopoeia (except for those included in the previous Pharmacopoeia) which have been approved before or on April 1, 1996, (inclusive of those not requiring approval) in accordance with the provision of Article 14 of the Law shall be recognized not to be included in the new Pharmacopoeia up to September 30, 1997.

**Naoto Kan**  
Minister of Health and Welfare

March 13, 1996

\*The word “follows” here indicates the contents of Part I and Part II in the Japanese Pharmacopoeia, Thirteenth Edition (pp. 1—1064).

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