JP History and Legal Status

• Under the Article 41-1 of the “Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices”, the Minister of Health, Labour and Welfare establishes and publishes the Japanese Pharmacopoeia (JP).

• JP was first published in June, 1886 and implemented in July, 1887.

• JP has been revised periodically.

• The 17th edition came into effect on April 1, 2016 under the Ministerial Notification No.64.
## History of JP Edition

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Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices

Provisions of Articles 41-1 & 41-2

Article 41-1

To standardize and control the properties and quality of drugs, the Minister shall establish and publish the JP, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC).

Article 41-2

The Minister shall consult the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) on the investigation and the revision of the whole of JP at least every 10 years.
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Provisions of Articles 2 & 56

Article 2

The term “drug” in this Law refers to the following items:

(1) Items recognized in JP.

(2) and (3) are omitted.

Article 56

A JP drug for which the quality or properties are not in conformity with the standards established by JP shall not be sold or supplied, or manufactured, imported, stored, or exhibited for the purpose of sale or supply.