

JP History and Legal Status

- Under the Article 41-1 of the “Act 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 18th edition came into effect on June 7, 2021. The supplement I to 18th edition came into effect on December 12, 2022. **The supplement II to 18th edition came into effect on June 28, 2024.**

History of JP Edition

Edition	Date of Issue	Number of monographs
JP1	1886.6.25	468



JP17	2016.3.7	1962
Supplement I to JP17	2017.12.1	1977
Supplement II to JP17	2019.6.28	2008
JP18	2021.6.7	2033
Supplement I to JP18	2022.12.12	2042
Supplement II to JP18	2024.6.28	2048

Act 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 Council.

Article 41-2

The Minister shall consult the Pharmaceutical Affairs Council on the investigation and the revision of the whole of JP at least every 10 years.

Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

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.