Basic Principles for Preparation of JP18 (Abstract)

1. Including all the drugs essential for health care and medical treatment

2. Enhancing quality of the JP by proactive introduction of the latest sciences and technologies

3. Internationalizing further to keep up with the globalization of drug market

4. Making prompt partial revision as necessary and facilitating smooth implementation by the regulatory authority

5. Ensuring transparency in the revision process and promoting the use of JP
1. Including all the drugs essential for health care and medical treatment

Prioritized drugs to be included in JP18:

- Drugs used widely and needed highly in Japan
- Innovative drugs approved by the priority review process
- Non-substitutable drugs (e.g. orphan drugs)
- Drugs listed in the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopeia (USP) and used worldwide

2. Enhancing quality of the JP by proactive introduction of the latest sciences and technologies

2-1. Revision of General Notices:

The general notices should reflect advancement of latest sciences and technologies and should be applicable to all drugs.
2-2. **Revision of General Tests:**

To reflect latest sciences and technologies, the following elements are considered mainly when revising general tests.

- Proactively introduce widely-used test methods, which are not listed in JP, including those used for in-process controls
- Proactively introduce test methods that are adopted in EP and USP but not in JP
- Progress international harmonization
- Update and revise the existing General Tests in JP
- Move the test methods from General Information to General Tests
- Reduce environmental burden on conducting tests
2-3. Development of Official Monographs:
The following elements are considered when developing monographs.
• Proactively introduce the latest analytical methods for tests on identification, purity, assay, and others
• Update and revise the existing monographs of active substances corresponding to new monographs of preparations
• Clarify the policies on setting specifications for impurities depending on manufacturing process, respond to international harmonization and set test items (related substances, etc.) reasonably
• Reduce volume of samples, reagents, solutions and solvents used for tests
• Delete hazardous reagents
• Substitute with test methods that do not use animals (alternative tests)
• Include new monographs of drugs developed by advanced technologies
• Set appropriate and flexible specifications for preparations of different composition
• Apply requirement items such as "Manufacture" and “Potential Adulteration” as needed
2-4. **Update of Policy on Reference Standards:**

The reference standard setting policy is defined based on latest scientific methods and international trends as necessary.

2-5. **Development of policy on Biotechnological/Biological Products:**

Basic principles on quality assurance for biotechnological and biological products is developed in response to the recent increase in the number of drugs containing peptide or protein, which are manufactured using recombinant DNA technology and/or cell culture technology, as an active ingredient. Monographs of these biotechnological/biological products are proactively included in the JP.
2-6. Development of Standards for Control of Impurities in Response to International Trends:
A roadmap for implementing risk-based control of impurities, especially the ICH-Q3D guidelines for elemental impurities, is developed and will be put into practice.

2-7. Effective Application of General Information:
General Information provides important information to supplement JP. General Information shown in the followings is mainly developed.
• Supplementary explanation for important items in General Notices and others
• New test methods needed for drugs developed by advanced technologies
• Status of international harmonization chapters and monographs
• Valuable information for quality assurance of drugs
• Test methods for radioactive substances in crude drugs
• Test methods on drug packaging
3. Internationalizing further to keep up with the globalization of drug market

- Proactively contribute to the activities for development and harmonization of international pharmacopoeias with WHO and others
- Promote international harmonization of pharmaceutical excipients and general tests through Pharmacopoeial Discussion Group (PDG) and swiftly implement the harmonized items in JP
- Develop the approaches to promote internationalization of JP especially in Asia
- Support harmonization activities for crude drugs in Asia through the public forum for crude drugs
- Promptly publish the English version of JP and made it more user friendly
- Provide the educational training on JP for overseas regulatory agencies
4. Making prompt partial revision as necessary and facilitating smooth implementation by the regulatory authority

In addition to the periodical revisions including supplements, partial revisions are made when timely revisions are required for safety reasons and for international harmonization through PDG and/or ICH.

5. Ensuring transparency in the revision process and promoting the use of JP

- Invite comments on the JP drafts from the public through Internet and JP Forum
- Post and update JP information on website
- Make JP more comprehensible for the users
- Enrich and develop General Information, Appendix, Index, and others

Implementation schedule of JP18

- To be implemented in April, 2021