Basic Principles for Preparation of JP19 (Abstract)

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Provisional Translation by
Japanese Pharmacopoeia Secretariat

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Basic Principles for Preparation of JP19 (Abstract)

1. Enriching monographs by prioritizing inclusion of drugs which are important in healthcare
2. Making qualitative improvement by introducing the latest science and technology
3. Promoting further internationalization in response to globalization of drug market
4. Making prompt partial revision as necessary and facilitating smooth administrative operation
5. Ensuring of transparency regarding the revision, and disseminating the JP throughout Japan and the rest of the world

1. Enriching monographs by prioritizing inclusion of drugs which are important in healthcare

Prioritized drugs to be included in the JP are:

- Superior in efficacy and safety
- Innovative drugs with no other approved drugs or with the prospect of major improvements in efficacy, including significant improvements in safety, compared to other drugs or treatment methods
- Highly needed for medical treatments
- Non-substitutable drugs such as orphan drugs
- Used by many patients and used widely in medical practice

1. Enriching monographs by prioritizing inclusion of drugs which are important in healthcare

Prioritized drugs to be included in the JP are (cont.):

- Widely used inside and outside of Japan

- Listed in official standards such as the Japanese Pharmaceutical Codex, the Japanese Standards for Non-Pharmacopoeial Crude Drugs, and the Japanese Pharmaceutical Excipients, and used widely in Japan for years

- Listed in the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopeia (USP) and used worldwide

- Promoting further internationalization of the JP

- Requiring early-listing in the JP ahead of other pharmacopoeias

2. Making qualitative improvement by introducing the latest science and technology

2-1. Revision of the General Notices:

The General Notices define the common rules throughout the JP; thus, shall reflect the development of latest sciences and technologies and shall apply to all drugs, which shall be considered when adding necessary items.

2-2. Revision of the General Tests:

The test methods shall be revised to reflect the latest sciences and technologies in consideration of mainly the following matters:

- Proactive introduction of the test methods that are widely-used but not yet included in the JP such as those used in-process controls
- Proactive introduction of the test methods that are included in the European Pharmacopoeia and the United States Pharmacopeia but not yet in the JP
- Promotion of international harmonization
- Modernization of existing general tests
- Sift of test methods from the General Information to the General Tests
- Further promotion of clean analysis
- Clarification of the concepts of minimum weight value and balance to be used

2-3. Improvements to the Official Monographs:

The monographs shall be improved in consideration of mainly the following matters:

- Proactive introduction of the latest analytical procedures into identification tests, purity tests, assay methods and others
- Modernization of existing monographs for active substances with addition of a new monograph for preparations
- Clarification of the policies on specification of impurities that are dependent on manufacturing processes, response to international harmonization, and reasonable setting of test items such as related substances
- Reduction in volume of samples, reagents, solutions and solvents for testing
- Further promotion of clean analysis
- Substitution with test methods that do not use animals (alternative tests)

2-3. Improvements to the Official Monographs:

The monographs shall be improved in consideration of mainly the following matters (cont.):

- Inclusion of new monographs for advanced technological drugs
- Inclusion of appropriate, flexible specifications in monographs to correspond to preparations of different formulation
- Utilization of the sections such "Manufacture" and “Potential adulteration" as needed
- Clear specification of critical quality attributes, that are controlled in the process, by referring to the section “Manufacture”
- Modernization on a priority basis if the test methods and/or monographs have not been modernized for years and are behind international standards and if specification values are significantly different from international standards

2-4. Improvements to the Reference Standards:

The policy on setting of reference standards shall be timely developed based on the latest quality control approach and international trends.

2-5. Improvements to biotechnological/biological products:

In response to recent increase in approved biopharmaceuticals and biosimilars, that are manufactured using advanced technologies, and increase in highly significant products in medical treatments, the monographs for these biotechnological and biological products shall be listed and the General Tests and the General Information shall be improved to reflect the latest scientific knowledge and technologies.

2-6. Improvements in the control of impurities in response to international trends:

In response to international trends, the control of impurities in consideration of risks and especially the control of elemental impurities in consideration of International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)-Q3D “Guideline for Elemental Impurities” shall be carried out based on the roadmap to be included in the JP. Moreover, ICH-M7 “Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk” shall be also taken into consideration.

2-7. Effective use of the General Information:

The General Information provides significant information to supplement the JP and mainly includes:

- Supplementary explanation of key issues in the General Notices and others
- New test methods necessary for quality assessment of advanced technological drugs
- Status of implementation of internationally harmonized methods and specifications
- Information necessary for quality assurance of drugs
- Enrichment of test methods related to the packaging of pharmaceutical products
- Explanation of how to use the JP for various purposes

3. Promoting further internationalization in response to globalization of drug market

- Promotion of international harmonization of monographs
- Proactive contribution to international activities related to pharmacopoeias including WHO
- Promotion of international harmonization of general tests and excipient monographs through the Pharmacopoeial Discussion Group (PDG), swift implementation of harmonized test methods and specifications in the JP and promotion of international utilization of the achievements

3. Promoting further internationalization in response to globalization of drug market (cont.)

- Implementation of the approaches to promote internationalization of the JP
  - Ensuring of transparency of information on impurities by further promotion of provision of information on related substances such as names and structural formula of related substances/impurities in monographs for utilization of the JP as an international standard in many countries including the Asian region
  - Posting of information about columns on the PMDA website in accordance with provision of information on related substances
- Proactive support for harmonization activities in the field of crude drugs in the Asian region through public forums for crude drugs.
- Improvements in the user-friendliness and prompt publication of the JP English version for overseas users.
- Educational training about the JP for foreign regulatory agencies

4. Making prompt partial revision as necessary and facilitating smooth administrative operation

Not only regular revisions such as editions and supplements but also partial revisions shall be made when new information related to safety of drugs are obtained and when test methods and/or monographs are internationally harmonized through PDG or ICH.

5. Ensuring of transparency regarding the revision, and disseminating the JP throughout Japan and the rest of the world

- Public consultations and background information in the process of development of JP drafts
  - Invitation of comments on the JP drafts from the public shall be continued through Internet.
- Publication of the JP through Internet
  - Provision of information about revisions such as editions and supplements including partial revisions shall be continued through Internet.
- Development of the JP in a user-friendly manner
- Enrichment and expansion of the General Information, the Appendix, and the Index
- Utilization of the JP in pharmaceutical education

Implementation schedule of JP19th edition

- To be implemented in April, 2026