Briefing on General Test and General Information related to Balances

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Pharmaceuticals and Medical Devices Agency
Office of Review Management

With the publication of the following four drafts of General Test and General Information related to Balances for public consultation, the information below is provided for your review.

- Draft of revised General Test "*<9.62> Measuring Instruments, Appliances*"
- Draft of new General Information "*<G1-6-182> Concept of Weighing in the Japanese Pharmacopoeia*"
- Draft of new General Information "*<G1-7-182> Calibration, Inspection, and Weight of a weighing instrument (balance)*"
- Draft of new General Information "*<G1-8-182> Installation Environment, Basic Handling Method, and Precautions for Weighing of a Balance*"

These drafts are prepared based on "*Making qualitative improvement by introducing the latest science and technology, 2-1 Revision of the General Tests, Clarification of the concepts of minimum weight value and balance to be used*" in Basic Principles for Preparation of the Japanese Pharmacopoeia 19th edition (Ministry of Health, Labour and Welfare, Administrative Notice, October 25, 2021).

The draft of revised General Test "*<9.62> Measuring Instruments, Appliances*" and the drafts of new General Information were developed by referring to the content and requirements provided in United States Pharmacopeia and European Pharmacopoeia.

The drafts mentioned above are to be included in Supplement II to the Japanese Pharmacopoeia 18th edition. Since some parts of Guideline for Preparation of the Japanese Pharmacopoeia 19th edition will be affected after the drafts inclusion, the guideline will be revised in the future.

The outline of the features and revision points of the four drafts are shown below.

- Draft of revised General Test "*<9.62> Measuring Instruments, Appliances*"
  - Regarding the definition of the balances, based on the specification of the marketed balances, it is clarified that the balance should be readable to each digit (e.g., some balances can only display the reading limit digits as "0, 2, 4, 6, ⋯etc." rather than 0 to 9.).

- Following new requirements of the balances are stipulated in the draft.
  - The calibration to ensure traceability to the International System of Units (SI)
  - The conformity to the requirements of the performance (Repeatability and Accuracy (trueness)).

  Note that it is necessary to understand that "the calibration to ensure traceability to the SI" is different from "the (weighing) results traceable to the SI".
- The confirmation of the requirements of the performance (Repeatability and Accuracy (trueness)) of the balances should be carried out in the "inspection" as to be an obligation of the balance user. In addition, unlike United States Pharmacopeia and European Pharmacopoeia, this revision draft of General Test does not mention about "the weighing over the minimum weight" taking into consideration the impact on the users of Japanese Pharmacopoeia.
- "Periodically" is used to determine the frequency of the confirmation of the requirements of the performance (Repeatability and Accuracy (trueness)), which is based on the quality risk management and considering the impossibility for setting a specific frequency.
- Requirements for weights are newly added to the draft.

- Draft of new General Information "*<G1-6-182> Concept of Weighing in the Japanese Pharmacopoeia*"
  - The basic concept of the traceability to the SI is described in the draft including the content that "the calibration to ensure traceability to the SI" is different from "(weighing) traceable to the SI".
  - When "the (weighing) results traceable to the SI" is required, all requirements (a - f) should be met. After the factors for obtain "the (weighing) results traceable to the SI" are introduced in this section, the statement that the factors for "the calibration to ensure traceability to the SI" is required in the JP, however it is not always required for "the (weighing) traceable to the SI" in the JP and its reason are described in the draft.
  - Furthermore, after providing examples for choosing the balances and the number of significant digits based on the certain cases, the draft also describes the importance to use the appropriate balances and the number of significant digits based on the concept "fit for the purpose". It is provided as an approach to help determine the scope of application of each requirement since it is difficult to establish the comprehensive classification of the scope of this draft. It is considered that there is an error of not less than 130% at the digit of the reading limit, even if the weighing was performed over the minimum weight. Therefore, in case of the determination of the conformity by the result of rounded value derived from the data close to the specification limit, it is necessary to confirm whether

the adequate balance that takes into account the error is chosen or not.

- Among the content in the draft of revised General Test "*<9.62>*, the requirements of the performance (Repeatability and Accuracy (trueness)) and the factors that may affect them are described concretely.

・ Draft of new General Information "*<G1-7-182> Calibration, Inspection, and Weight of a weighing instrument (balance)*"

- Calibration and Inspection of a weighing instrument (balance), and the handling of Weight are described in the draft, respectively.
- The terms of "Calibration" and "Inspection" are used in the drafts with the following meanings.

Calibration	In principle, the task should be carried out by qualified personnel based on the knowledge and experience to check the condition of the balance using a mass standard weight, leading to the evaluation (or justification) related the performance of the balances. Calibration results need to be accompanied by an uncertainty indicating reliability, when the purpose of the task is "the calibration to ensure traceability to the SI", the results should be obtained as a documented calibration certificate.
Inspection	Generally, it is carried out by the users of the balances. For SI-traceable calibrated balances, performance should be checked at least for repeatability and accuracy (trueness) using the acceptance criteria, and the inspection should be performed at appropriate frequencies and intervals considering the risk.

- Specific checking methods for the characteristics of the balances are described in the draft.

・ Draft of new General Information "*<G1-8-182> Installation Environment, Basic Handling Method, and Precautions for Weighing of a Balance*"

- The Basic Handling Method, and Precautions for Weighing of a Balance are described in the draft.
- The concept of external factors that may affect the weighing results, such as cautions on the characteristics of the sample are described in the draft.

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