

**Briefing on New draft of General Information**  
**“Functionality-related Characteristics of Excipients Relevant to Preparations”**  
*〈G9-1-181〉*

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Pharmaceuticals and Medical Devices Agency  
Office of Review Management

Before publication of a proposed new draft to the Japanese Pharmacopoeia (JP) General Information “Functionality-related Characteristics of Excipients Relevant to Preparations” for public consultation, the following background information is provided for your review.

This new General Information explains the physical and chemical properties of excipients, as Functionality Related Characteristics (FRC), which are closely relevant to the improvement of the usefulness of active pharmaceutical ingredients and preparations in the manufacturing process, storage, and use of the preparations.

In addition to the specifications prescribed in each monograph with the main purpose of identifying substances and ensuring quality, test methods that are applied to evaluation of FRC are available for specific excipients. These test methods evaluate physical and chemical properties that are used as not quality requirements but indicators for addition of functions. For example, the water-retaining amount is one of the FRC of the excipients used for appropriately controlling the disintegration property of a pharmaceutical product.

<Policies for drafting this General Information>

- The test methods applied to the evaluation of FRC are not prescribed in each excipient monograph, and the FRC and the applicable test methods shall be provided as examples for each individual item in this General Information.
- Since the test methods included in this General Information are examples and are not mandatory for FRC evaluation, no acceptance criteria are prescribed for the test methods.
- For the time being, the FRC and the test methods applicable to its evaluation included in the General Information are limited to the subjects to PDG harmonization, except those already included in the monographs.

Furthermore, with the addition of this new General Information to the JP, the specifications and the test methods for consistency of Petrolatum and White Petrolatum which are subject to PDG harmonization and whose revised drafts are published for public consultations from September

30, 2019 to December 30, 2019 will be removed from each monograph. For details, please refer to the newly revised drafts in the Additional Revision of the Revision Drafts for the First Supplement to JP18 published in September, 2021.