PMRJ Reference Standards Information for Users

Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) has been registered by the Minister of Health, Labour and Welfare as an organization that produces and distributes Japanese Pharmacopoeia (JP) Reference Standards and other compendial reference standards of Japan.

How to Order PMRJ Reference Standards

Please visit PMRJ Reference Standards Online Store < https://www.pmrj-ec.jp/aec/user/?lang=en> and request for a quotation.

Usage

1. All the reference standards distributed by PMRJ are analytical reagents. They are not drugs or clinical diagnostic drugs, so they must not be used in humans or animals.
2. The reference standards distributed by PMRJ are guaranteed to be suitable for uses specified in the official compendia. The specified uses are given in the Intended Uses section of the leaflet for each reference standard. Please be aware that the quality of the reference standards is not guaranteed if they are used in tests other than those in which their use is specified.
3. If the official compendium directs that a reference standard be dried, dry a suitable amount of it according to the compendium at the time of use. Some reference standards that have been dried are hygroscopic, so perform weighing operations quickly.
4. If the Unit Quantity section of the leaflet directs that all of the reference standard contents be dissolved before use, do not weigh the reference standard before use.
5. Correction Information

5.1 Loss on Drying, and Water Content

If an official compendial test method specifies that an amount of reference standard calculated on the dried or anhydrous basis be weighed, separately determine the loss on drying or water content of the reference standard and calculate the amount of reference standard on the dried or anhydrous basis. However, if the Correction Information section of the leaflet contains a loss on drying or water content value, the weighed amount may be converted to the amount calculated on the dried or anhydrous basis by using the value given in the leaflet. For additional information, please see the FAQ on the PMRJ website.

5.2 Correction Factors

For some reference standards, the purity has been calculated by the mass balance method, etc., and is shown as a correction factor to apply when the reference standard is used in quantitative tests. If a correction factor is provided in the Correction Information section of the leaflet for a reference standard, be sure to correct the weighed amount of reference standard by multiplying it by the correction factor when the reference standard is used in the official compendial quantitative tests following the correction factor. When quantitative tests using the

reference standard contain directions to convert the reference standard value by calculating on the dried basis, calculating on the anhydrous basis, or calculating on the anhydrous and residual solvent–free basis, perform the correction after performing the applicable conversion.

If a correction factor is not provided in the leaflet, regard the reference standard as 100.0% and do not correct the weighed amount of reference standard. For additional information, please see the FAQ on the PMRJ website.

6. The Safety Data Sheet (SDS) for each reference standard can be accessed from the reference standard's webpage.
7. Test data that are not necessary to use the reference standards are not disclosed, and certificates of analysis for the reference standards are not issued.

Storage

Store each reference standard according to its exterior label and the Storage Conditions section of its leaflet. The reference standards distributed by PMRJ do not have expiration dates. Therefore, order only quantities that can be used immediately, and after receipt of a reference standard, immediately store it at the specified temperature and use it as soon as possible. The quality of a reference standard cannot be guaranteed if (1) significant time has passed since it was shipped, even if it has not been opened, or (2) it has been stored after opening.

The storage temperatures are defined as follows:

- Room Temperature: 1 – 30°C
- ≤25°C: 1 – 25°C
- Refrigerate (≤8°C): 1 – 8°C
- Freeze (≤−20°C): ≤−20°C
- Freeze (−20 – −30°C): ≤−20°C. Avoid storage below −30°C because the container may not withstand such low temperatures.
- Freeze (−80°C): −80°C ± 10°C

For further information

Please visit PMRJ Pharmaceutical Reference Standards Center website <https://www.pmrj-rs.jp/en> or contact Customer Service at jprslab-std@pmrj.jp.

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