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PHENOLPHTHALEIN M.P. ICRS batch 2

1. Intended use

The WHO Melting Point Reference Substance for phenolphthalein is supplied primarily for calibration of different instruments and methods used for determination of melting temperatures against the method of *The International Pharmacopoeia.*

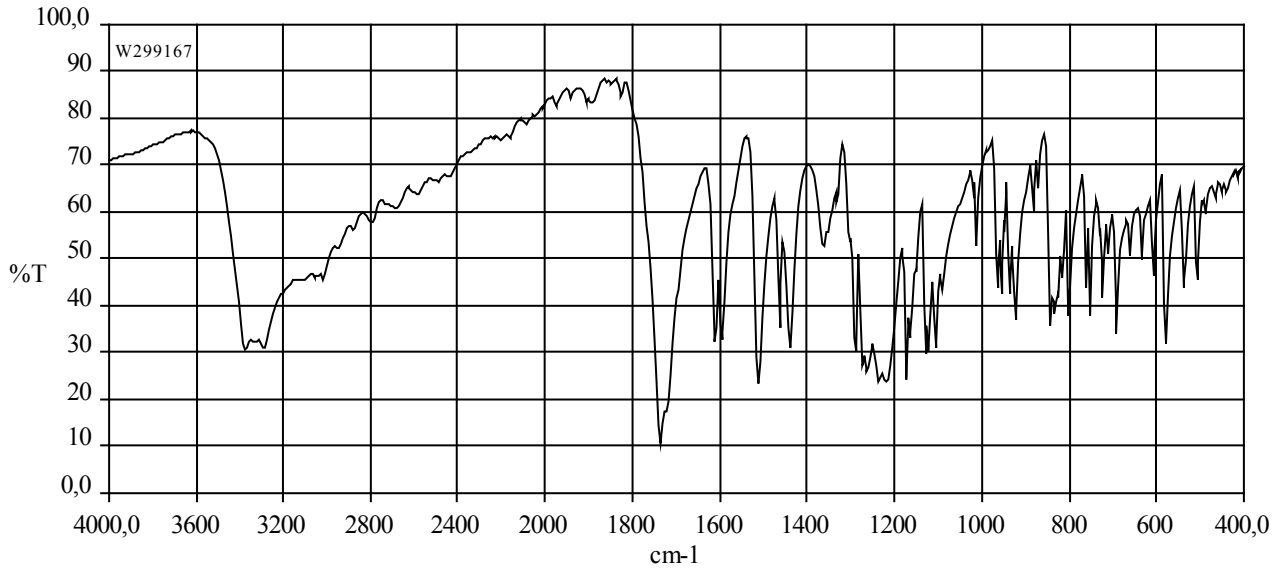
2. Caution

Danger.

For laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. This material is not for administration to humans or animals. The corresponding safety data sheet can be accessed via the EDQM website (Reference Standards Database) or is available upon request from the EDQM (Helpdesk-FAQ section).

3. Analytical data

Infrared absorption spectrophotometry (IR): A spectrum, 1.5 mg of phenolphthalein in 300 mg of potassium bromide, is given in figure W299167.



Assigned melting point: 263.1°C (n=5, RSD=0.2%). The assigned melting point has been established from results obtained in a collaborative trial. The determination was performed by the capillary melting point method at a heating rate of 1°C/min according to *The International Pharmacopoeia.*

Differential scanning calorimetry (DSC): The purity was estimated to 100.0 mol%.

4. Storage

Phenolphthalein M.P. ICRS should be kept in a tightly closed container, protected from light.

5. Directions for use

The following facts should be considered when the WHO Melting Point Reference Substances are used:

1. Before use the substances should be finely powdered and carefully dried, for instance in a vacuum desiccator over silica gel, for 24 hours.
2. The melting temperature stated for each of the WHO Melting Point Reference Substances refers to the **Melting temperature** as defined in *The International Pharmacopoeia*, **i.e. the corrected temperature at which the substance is completely melted as shown by the disappearance of the solid phase.**
3. As the melting temperature for a substance always depends to some extent upon particulars in the method used for the determination, it is recommended that, when the WHO Melting Point Reference Substances are used for calibrating purposes, the directions given in *The International Pharmacopoeia* - especially concerning the rate of heating - are closely followed. This means that the substance should be brought into contact with the heating medium at a temperature 5°C below the expected lower limit of the melting range, i.e. generally **about 6°C below the Melting temperature stated here for each substance,** and that the temperature should then be raised about 1°C per minute.

6. Reference

This certificate is extracted from the report, which is the basis for the adoption of this International Chemical Reference Substance by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-seventh Report, WHO Technical Report Series, 908.

7. Citation

The user has an obligation to ensure that any reference made to the present Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the correct name, and code of the Standard and the correct name and address of EDQM as given in the present leaflet.

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10. Signature

This document is electronically signed by:

Dr Pierre Leveau
Head of the Quality, Safety and Environment Division