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PROGESTERONE ICRS batch 1

0. Traceability

The present standard has been established by Apoteket SA, Sweden on behalf of the WHO.
The link between label information, the EDQM identification, and leaflet is as follows:

ICRS Name and Batch	Label colour (1)	Vial label
PROGESTERONE ICRS batch 1	Yellow label (1)	International Chemical Reference Substance PROGESTERONE RS Control No. 167033 WHO Centre for Chem. Ref. Subst. Stockholm, Sweden
	White EDQM label	PROGESTERONE RS Code : ICRS0400 Batch :1.x

(1) Vials with a yellow label correspond to PROGESTERONE ICRS batch 1.0. Vials with a white EDQM label correspond to PROGESTERONE ICRS batch 1.x (x≥1).

1. Intended use

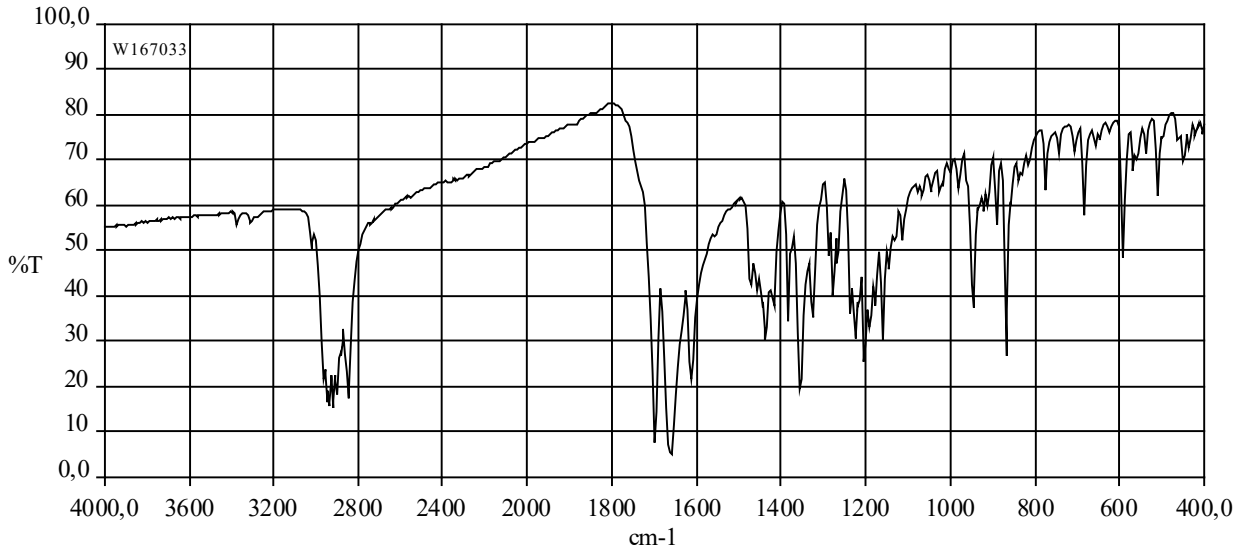
The above mentioned International Chemical Reference Substance is intended to be used for tests described in The International Pharmacopoeia.

2. Safety

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, when applicable, can be accessed via the EDQM website (Reference Standards Database) or is available upon request from the EDQM (www.edqm.eu HelpDesk).

3. Analytical data

Infrared absorption spectrophotometry (IR): A spectrum, 2.6 mg of progesterone in 300 mg of potassium bromide, is given in figure W167033.



High performance liquid chromatography (HPLC): The purity was estimated by peak area normalization to 99.9% at 240 nm.

Thin-layer chromatographic identity test (TLC): The chromatogram obtained with 5 µg (the amount prescribed in the monograph) showed no secondary spots.

Thermogravimetric analysis (TG): When heated to 105°C a loss of 0.1% (w/w) was observed.

Assigned content: When used in the spectrophotometric assay according to the monograph the content of progesterone ($C_{21}H_{30}O_2$) is taken to be 100.0% calculated with reference to the dried substance (corresponding to 99.9% on the "as is" basis).

4. Instructions for use

Before use, allow the closed container to equilibrate at ambient temperature to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. Special instructions apply to freeze-dried materials. ICRS are for immediate use. Once the container has been breached, its entire content must be used immediately. Any further storage and re-use are not warranted.

5. Storage conditions

Store the original container at 5°C ± 3°C, protected from light. Re-instate promptly upon receipt.

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.

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.

8. Product liability

The Council of Europe makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose. The product must be handled by professional persons having technical skill and at their own discretion and risk. It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the conditions of use and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted by law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

9. Disputes

In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe (EDQM) and the customer as regards the application of this contract shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

10. Signature

This document is approved by:

Head of the Quality and Risk Management Section

Name: Caroline OFFERLE

Date: 13/09/2023