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INFORMATION LEAFLET Ph. Eur. Reference Standard

Sodium aminosalicylate dihydrate for equipment qualification CRS batch 1

1. Identification

Catalogue code: Y0001816 Unit Quantity: ca 5000 mg

2. Scientific Information

2.1 Intended use

Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.
Established for use with the monograph(s): 2.2.32., 2.5.12.,2.5.32.

2.2 Analytical information related to intended use, when applicable

2.2.32. – Loss on drying

Certified loss on drying value[1)]: 169.6 mg/g
Uncertainty[2)]: 0.4 mg/g

Test procedure: Determine the loss on drying in triplicate using 1000 mg of substance per determination. Drying conditions: 105 °C until constant mass (Ph. Eur. 2.2.32.)

Container dimensions (recommended): diameter about 50 mm; height about 30 mm.

2.5.12. – Semi-micro determination of water

Certified water content[1)]: 171.6 mg/g
Uncertainty[2)]: 1.0 mg/g

Test procedure: Carry out the test in triplicate using 100 mg of substance per determination.

Hydranal composite 5 was found suitable. If other solvents/titrants are used, carry the suitability test described in Ph. Eur. 2.5.12.

2.5.32. – Micro determination of water (liquid sample introduction)

Certified water content[1)]: 170.5 mg/g
Uncertainty[2)]: 1.1 mg/g

Test procedure: Prepare a 20 mg/mL solution of sodium aminosalicylate dihydrate in dry methanol in triplicate. Carry out the determination injecting 1 mL of each solution per determination.

In addition a determination of the blank shall be carried out in triplicate employing the same conditions as for the determination of the water content of the test sample (same type of container than the one employed for the preparation of the sample solution, single use syringes). The mean value of water found in the blank shall be taken into account for the determination of the water content of the samples.

Hydranal composite AG was found suitable.

1) Unweighted mean value of means of accepted sets of results, each set having being obtained in a different laboratory with the method described above.
2) Estimated expanded uncertainty U with a coverage factor k = 2, corresponding to a level of confidence of about 95 % as defined in ISO/IEC Guide 98-3:2008 - Uncertainty of measurement -- Part 3: Guide to the expression of uncertainty in measurement (GUM: 1995). Uncertainty contributions arising from characterisation as well as homogeneity assessments were taken into account.

Further Analytical data

Loss of weight by Thermogravimetry (Ph. Eur. 2.2.34.) determined on 10 - 20 mg of substance applying the below temperature programme:

169.4 mg/g
n=3
Standard deviation: 0.5 mg/g

Temperature-Programme:

Heating rate: 10 °C/min to 105 °C; then hold for 60 min.

2.3 Validity

Ph. Eur. RS are periodically tested to ensure their continuous fitness for purpose. For each valid Ph. Eur. RS, a Batch Validity Statement at the time of use can be downloaded and printed from the EDQM website (Reference Standards Database).

2.4 Instructions for use

The container should not be opened until required for use. Allow the closed container to equilibrate at ambient temperature before opening to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. Ph. Eur. RS are for immediate use. Once the container has been opened, its entire content must be used immediately. Any further storage and re-use are not warranted.

Suggested acceptance criteria:
Taking into account inter-laboratory standard deviation as well as the mean intra-laboratory standard deviation obtained the inter-laboratory study for the value assignment, the result of a measurement performed (following the above experimental conditions) is considered acceptable if the mean of 3 replicate determinations falls within the following limits:

Loss on drying (2.2.32.):	167.2 mg/g to 172.0 mg/g
Semi-micro determination of water (2.5.12.):	165.4 mg/g to 177.8 mg/g
Micro determination of water (2.5.32) – liquid sample introduction:	167.3 mg/g to 173.7 mg/g

It is understood that a laboratory may apply a different approach to set acceptance criteria.

3. Storage conditions

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

4. Safety

For scientific research, development and analysis only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. More information is available at the EDQM website (Reference Standards Database): Safety Data Sheet for hazardous chemicals and Safety Data Statement for other materials.

5. Shipping conditions

Each Ph. Eur. RS is shipped under conditions that preserve its suitability for use and comply with the relevant regulations. For more details see EDQM website (Reference Standards Database).

6. Warranties, Liabilities and responsibility

– *Safety*
In the event of any safety concerns, please read carefully the safety data sheets or safety data statements available for each product. It is for Purchasers to determine independently the risks associated with the items and to take appropriate safety measures, including the provision of appropriate information, equipment and training of those persons coming into contact with the item.

– *Warranties*
Except for the use of Reference Standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and by professionals with the necessary technical skills and at their own discretion and risk, the EDQM 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 except that as described above.

The EDQM does not guarantee that the items will meet the Purchaser's specific expectations. The EDQM only guarantees that the items (i) were fit for use according to EDQM's intended use of the product ;(ii) were fit for use at the moment that they were handed over to the carrier being responsible for the delivery of the items to the Purchaser with such accessories including packaging, delivery instructions or other instructions for the item's

delivery and reception as the Purchaser may expect to receive; and (iii) possess qualities and performance capabilities which are normal in goods of the same type and which the Purchaser may expect given the nature of the goods and the information provided on the EDQM's website and (iv) the carrier and the Purchaser received clear and accurate instructions for the item's delivery and reception. No other guarantees, whether explicitly or implied, are given by the EDQM. The EDQM does not guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

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7. Arbitration & Applicable Law

The aim of the EDQM is to settle any disputes amicably in the framework of its Terms and Conditions. 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 EDQM and the Purchaser as regards the application of these General Terms 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.

This transaction shall be governed by the Council of Europe's relevant regulatory framework, complemented, where necessary, by French national substantive law.

8. Citation

Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

9. Adoption

The suitability for intended use has been officially adopted by the European Pharmacopoeia Commission.

10. Signature

This document is approved by:

Ms Caroline Offerlé
Head of the Quality and Risk Management Section