Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Short Ragweed (Ambosia artemisiifolia [elatior]) Pollen Extract
NIBSC code: 84/581
Instructions for use
(Version 6.0, Dated 04/01/2019)

1. INTENDED USE

The first International Standard for Short Ragweed (*Ambosia artemisiifolia [elatior]*) Pollen Extract consists of ampoules, coded 84/581, containing the freeze-dried residue of 0.3ml aliquots of an extract of Short Ragweed pollen. This preparation was established as the first International Standard (*Ambosia artemisiifolia[elatior]*) Pollen Extract by the Expert Committee on Biological Standardisation of the World Health Organisation in 1984, and a potency of 100,000 International Units has been assigned to each ampoule. Stocks of the standard are divided between NIBSC and the Food and Drug Administration (FDA), Office of Biologics, 8800 Rockville Pike, Bethesda, MD., USA.

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2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

A potency of 100,000 International Units has been assigned to each ampoule

4. CONTENTS

Country of origin of biological material: United Kingdom.

The 1st International Standard was assessed together with 5 other freeze dried preparations of Short Ragweed pollen extract in an international collaborative study involving 12 laboratories in 5 countries(1). Examination of the activity of these preparations was by RAST inhibition, quantitative immunoelectrophoresis (CIE/CRIE), isoelectric focusing, quantitative skin testing, histamine release and other methods. The proposed standard was found to have biological activity and to be suitable to use as a standard. The major allergen of Short Ragweed pollen extract *Amb a* I (agE) was identified and quantified in the standard. Other antigens identified in the standard were *Amb a* II (AgK), Ag11, *Amb a* IV (Ra4), Ag27, *Amb a* VI (Ra6), *Amb a* V (Ra5) and Ag 30a. Each ampoule was assigned 100,000 International Units of potency.

The bulk material for the first International Standard for Short Ragweed (*Ambosia artemisiifolia [elatior]*) Pollen Extract consists of a freeze-dried extract prepared from a mixture of Short Ragweed pollen from 4 different years of collection. The pollen was more than 99% pure Short Ragweed pollen and there were less than 5% non-pollen particles by weight. The pollen was defatted in petroleum ether and extracted in deionised water at room temperature for 22 hours. The extract was centrifuged and filtered ending with a membrane of 0.22μm pore size.

5. STORAGE

Unopened ampoules should be stored at -20°C.

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The total contents of the ampoule should be reconstituted with 1ml of distilled water and dissolved by gently swirling to avoid froth. The reconstituted standard should be used as soon as possible after reconstitution and no attempt should be made to store it in the reconstituted state

8. STABILITY

Accelerated degradation studies have shown that the 1st International Standard is very stable in unopened ampoules stored at -20°C. No significant loss of activity was found in ampoules stored for 3 years at temperatures up to 23°C
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.
NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1. Helm, R.M., Gauerke, M.B., Baer, H., Lowenstein, H., Ford, A., Levy, D.A, Norman, P.S & Yunginger, J.W. Production and testing of an international reference standard of Short Ragweed Pollen Extract. J. Allergy Clin. Immunol. **73:** 790-800 (1984)

2. May, J.C., Sih, J.T.C, Miller, J.R, & Seligmann, E.B Jr. Optimisation of parameters in protein nitrogen unit precipitation procedure for allergenic extracts. J. Allergy Clin. Immunol. 63:87 (1979).

10. ACKNOWLEDGEMENTS

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11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties	
Physical appearance: **Freeze-dried powder**	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): *Contains material of biological origin*	
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion: Not established, avoid ingestion	
Effects of skin absorption:	Not established, avoid contact with skin
Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion: Seek medical advice	
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.
Action on Spillage and Method of Disposal	
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 0.01g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.