Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Twelve Grass Pollen Extract
NIBSC code: 77/616
Instructions for use
(Version 7.0, Dated 24/07/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This is comprised of a batch of ampoules coded 77/616. Each ampoule contains the residue after freeze drying from approximately 1.0ml of extract from a mixture of 12 grass pollens.

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

No unitage has been assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom
The reagent was supplied by a commercial manufacturer as a 3000ml batch of grass pollen extract derived from a mixture of pollens from the following grasses:
Bent grass (Agrostis capillaris/tenuis), Foxtail (Alopecurus pratensis), Sweet vernal (Anthoxanthum odoratum), False oat (Arrhenatherum elatius), Brome (Bromus spp.), Dogstail (Cynosurus cristatus), Cocksfoot (Dactylis glomerata), Fescue (Meadow) (Festuca pratensis), Yorkshire Fog (Holcus lanatus), Rye Grass (Lolium perenne/multiflorum), Timothy grass (Phleum pratense), Meadow grass (Poa pratensis/trivialis). The extract was made in phenol saline.

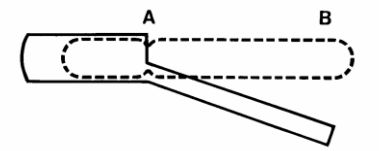
At NIBSC the extract was distributed in 1.0ml volumes into approximately 2000 ampoules, coded 77/616. The contents of the ampoules were then freeze dried and secondarily desiccated under the conditions normally used for international biological standards[(1)]. The mean dry weight was 5.99mg (range, 5.79 - 6.36mg; n=6) and the mean moisture level detached by the coulometric Karl Fischer titration method was 0.68% (range 0.56 - 0.82%; n=3). The mean O_2 content was 0.60% (range, 0.0 - 0.80%; n=3)..

5. STORAGE

The reconstituted reagent should be used as soon as possible after reconstitution. 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

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

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 1.0ml distilled water and dissolved by gentle swirling to avoid froth. The reconstituted reagent should be used as soon as possible after reconstitution
The reagent can also be used in in vitro assays such as the radioallergosorbent test (RAST), RAST inhibition, quantitative immunoelectrophoresis (CIE & CRIE), SDS-PAGE and immunoblotting.

8. STABILITY

Accelerated degradation studies[(1)] have shown freeze dried allergen extracts stored in unopened ampoules at -20°C to be extremely stable over a number of years.
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

9. REFERENCES

(1) Campbell, PJ., International Biological Standards and Reference Preparations. II. Procedures used for the production of biological standards and reference preparations. J. Biol. Stand **2**:259-267 (1974

10. ACKNOWLEDGEMENTS

N/A

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

Biological Activity.
The reagent can also be used in *in vitro* assays such as the radioallergosorbent test (RAST), RAST inhibition, quantitative immunoelectrophoresis (CIE & CRIE), SDS-PAGE and immunoblotting.

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Distribution into ampoules

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

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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

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