Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Botulinum type F antitoxin, equine
NIBSC code: 01/506
Instructions for use
(Version 7.0, Dated 24/01/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is a freeze-dried residue of horse antiserum to Clostridium botulinum type F toxin. It is intended for calibration of the bioassay for botulinum type F antitoxin. The material may also be suitable to confirm serotype identity of botulinum type F toxin.

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

This material is a candidate replacement for the 1st International Standard for botulinum type F antitoxin (BUSF). Full calibration has yet to be performed in collaborative studies. Preliminary tests at NIBSC have indicated 125 IU/ampoule by local flaccid paralysis assay relative to the 1st WHO International Standard (BUSF).

4. CONTENTS

Country of origin of biological material: United States.
This preparation contains the freeze-dried residue of 1.0 ml of horse plasma. The bulk material was donated in 1998 by the US Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD, USA. Horses were immunised with toxoid (pure neurotoxin from strain Langeland) then toxin (pure neurotoxin and complex from strain Langeland) and plasma collected after 95 weeks. (Langeland is a proteolytic type F strain.)

5. STORAGE

Unopened ampoules should be stored at -20ºC.
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
Clostridium botulinum antitoxins were established to define International Units for each type of antitoxin to be used in the control of therapeutic antitoxin preparations. Preparation and assay of the 1st International Standard for Clostridium botulinum types A, B, C, D and E antitoxin were described by Bowner [1]. In 1964 the Statens Serum Institut (Copenhagen, Denmark) put forward a candidate type F antitoxin and in 1966 this material was accepted as the 1st type F WHO International Standard, BUSF [2]. This material, as replacement for BUSF, is intended for calibration of the bioassay for botulinum type F antitoxin. The material may also be suitable to confirm type F serotype identity.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

Freeze-dried serum standards are expected to undergo negligible loss of activity during long term storage at the indicated storage temperature [3].

Once reconstituted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any changes in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

1. Bowner EJ. Preparation and assay of the International standards for Clostridium botulinum types A, B, C, D and E antitoxins. Bull World Health Organization 1963, 29, 701-709.

2. Jones RGA. Corbel MJ. & Sesardic D. A review of WHO International Standards for botulinum antitoxins. Biologicals 2006, 34, 223-226.

3. Jerne NK and Perry WLM. The Stability of Biological Standards, Bull. Wld. Hlth. Org. 1956, vol. 14 pp 167-182.

10. ACKNOWLEDGEMENTS

We would like to thank USAMRIID for kindly donating this material.

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

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

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

Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains equine plasma material	
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: Approx. 100mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No