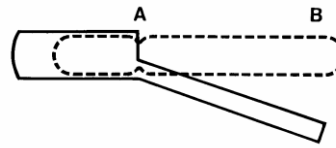




**WHO International Standard
Botulinum type B antitoxin, 2nd International Standard
NIBSC code: BUSB
Instructions for use
(Version 7.0, Dated 15/09/2014)**



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.

1. INTENDED USE

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

This material was established in 1985 as the 2nd WHO International Standard for Clostridium botulinum type B antitoxin [1].

This material was held and distributed by the Stratens Serum Institut until the 1st July 1997, at which point the National Institute for Biological Standards and Control (NIBSC) took over as custodian and distributor of this material.

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

Each ampoule (labelled BUSB 5004) contains 31 International Units.

4. CONTENTS

Country of origin of biological material: Donated anonymously from unknown source.

Equine antiserum produced by immunising horses with toxoid and toxin derived from the culture fluid of the Okra (or Okura) strain of Clostridium botulinum type B was then purified by pepsin digestion and fractionation by ammonium sulphate precipitation. The final product comprised of an F(ab')₂ fragment preparation. The donated antitoxin, which was received in the freeze-dried form at the Stratens Serum Institut (Copenhagen, Denmark), was dissolved in distilled water, filtered, filled and freeze-dried in ampoules labelled BUSB 5004.

Each ampoule contains an estimated 3.6mg of equine F(ab')₂.

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

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.

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 [2]. This material, as replacement for the 1st International Standard (BTUSB, 60/21), is intended for calibration of the bioassay for botulinum type B antitoxin. The material is also suitable to confirm type B 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.

It is the policy of WHO not to assign an expiry date to their International Reference Materials.

Units assigned to this material were valid at the time of calibration and there is no data available on long term stability. However, 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. Jones RGA, Corbel MJ. & Sesardic D. A review of WHO International Standards for botulinum antitoxins. *Biologicals* 2006, 34, 223-226.
2. 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.
3. Jerne NK and Perry WLM. The Stability of Biological Standards, *Bull. Wld. Hlth. Org.* 1956, vol. 14 pp 167-182.

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

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: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Pepsin digested, purified equine antibody	
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*: Denmark * 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: 3.6mg
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_biol_standardsrev2004.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.