Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Bordetella pertussis Toxin (PT)
NIBSC code: 90/518
Instructions for use
(Version 5.0, Dated 10/04/2008)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The British Reference Preparation of Pertussis Toxin is an extract of *Bordetella pertussis* culture supernatant. It is a reference preparation for use in the control testing of acellular pertussis vaccines.

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 has an assigned unitage of 2100 IU per ampoule based on its calibration in terms of preparation JNIH-5.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried residue of 0.5ml of 0.01M sodium phosphate pH 7.6, 0.5M NaCl which contained:

Pertussis toxin	20 micrograms
Trehalose	5 mg

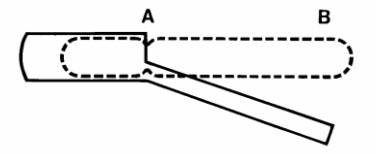
5. STORAGE

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.



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

Purified PT was generously donated by SmithKline Biologicals, Rixensart, Belgium, through the good offices of Dr C Capiau. The material was >98% pure by silver stained SDS-PAGE, and contained <0.1ng of endotoxin per mg of protein by LAL assay.

Ampoules coded 90/518 were prepared according to the procedures used for International Biological Standards (29th ECBS Report, 1978). A sodium buffered solution of PT, of known concentration, was diluted with a sterile solution of NaCl and trehalose to yield a solution of 0.001M sodium phosphate pH 7.6, 0.5M NaCl containing 1% trehalose and 0.004% PT. The solution was distributed in 0.5 ml aliquots into ampoules. The ampouled solution was lyophilised, and the ampoules sealed under nitrogen by heat fusion of the glass and stored at -20°C in the dark.

For practical purposes each ampoule contains the same quantity of PT. The entire contents of each ampoule should be completely dissolved in an accurately measured amount of solvent (distilled water, saline or buffer) and the solution kept cool (e.g +4°C) prior to use. No attempt should be made to weigh out proportions of the freeze dried powder. It is recommended that the solution, not for immediate use, is stored at -20°C or below. Repeated freezing and thawing should be avoided. The ampoules contain no bacteriostat and the preparation should not be assumed to be sterile.

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.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1) D.Xing, R G Das and P.Newland
Collaborative Study; evaluation of proposed international reference preparation of pertussis toxin, Code JNIH-5
WHO BS/03.1978

2) D.Xing et al. Vaccine 20 (2002) 3535 - 3542

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to: Dr C Capiau and SmithKline Biologicals for providing the material and Standards Processing Division for the filling.

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

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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: 0.5 - 1.0 g
Toxicity Statement: Toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No