Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material

Bordetella pertussis 18323 coating antigen

NIBSC code: 23/150

Instructions for use

(Version 1.0, Dated 19/06/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

This material consists of killed Bordetella pertussis cells strain 18323. It was produced by microbial fermentation, followed by heat inactivation for 30 minutes at 56°C and lyophilization.

The material is intended to be used as the coating antigen in the pertussis serological potency test (PSPT) which measures anti-B. pertussis antibodies induced in mice vaccinated with whole cell pertussis vaccine. The test is intended as a measure of vaccine potency and a replacement for the in vivo active mouse protection test (Kendrick test) which is the historical potency test for these vaccines (1, 2).

2. CAUTION

The material is of bovine origin. The material is certified to be obtained from animals taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE & which has not been fed rations containing ruminant derived protein during that period. This preparation is not for administration to humans or animals.

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

When reconstituted with 1 ml phosphate buffered saline (PBS) pH 7.2 each vial contains Bordetella pertussis 18323 cells at a concentration of 25 IOU/mL (International Opacity Units).

4. CONTENTS

Country of origin of biological material: Belgium.

This material consists of freeze-dried killed Bordetella pertussis cells strain 18323. The preparation contains animal-derived additives, i.e. casamino acids (10 g/L) of bovine origin.

Quality control tests of the product showed no growth on general growth media and Bordetella-specific media.

The product is non-infectious and non-pathogenic.

5. STORAGE

The freeze-dried material should be stored between +2°C and +8°C. The contents of the ampoule should be reconstituted with 1 ml phosphate buffered saline pH 7.2. Reconstituted material should be stored at 4°C.

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

6. DIRECTIONS FOR OPENING

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

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

The material should be reconstituted with 1 ml PBS pH 7.2. Reconstituted material should be stored at +4°C.

Detailed suggested SOPs for the PSTP are given on the Developing Countries Vaccine Manufacturers Network (DCVMN) at https://dcvmn.org/pspt-consortium/.

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.

Once reconsititued the material should be stored at +4°C.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

1. van der Ark, et. al. Development of pertussis serological potency test. Serological assessment of antibody response induced by whole cell vaccine as an alternative to mouse protection in an intracerebral challenge model. Biologicals. 1994 Sep;22(3):233-42

2. van der Ark, et. al. The Pertussis Serological Potency Test. Collaborative study to evaluatereplacement of the Mouse Protection Test. Biologicals. 2000 Jun;28(2):105-18.

10. ACKNOWLEDGEMENTS

United Kingdom Health Security Agency (UKHSA) is acknowledged for providing the bacterial culture used to prepare this material. BioLyo, Belgium is acknowledged for preparing the freeze-dried material and donating it to NIBSC. And DCVMN for overseeing the project.

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

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*: Belgium * 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: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

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