Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Bordetella pertussis (Whole cell vaccine) 3 BRP
NIBSC code: 88/522
Instructions for use
(Version 6.0, Dated 09/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This *Bordetella pertussis* preparation, coded 88/522, has been established as the third British Reference Preparation for Pertussis (whole cell) Vaccine potency.

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

50 International Units per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried residue of 1.0 ml of an aqueous solution which contained :-

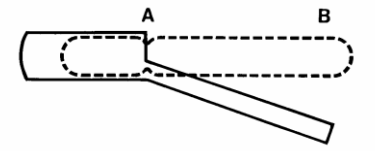
Dextran (90kD)	80mg
Glucose	50mg
B. pertussis	20 x 10^{10} organisms

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

The *B. pertussis* suspension was generously donated by Wellcome Biotech, Beckenham, UK through the good offices of Mr P. Knight.

The bacteria were grown and killed using standard methods and contained agglutinogens 1 ,2 and 3.
Ampoules coded 88/522 were prepared according to the procedures used for International Standards (29th ECBS Report 1978). The bacteria were suspended at 20 x 10^{10} cells/ml in a solution of 8% dextran (90kD) and 5% glucose. The suspension was distributed in 1.0ml aliquots into ampoules. The ampouled suspension was lyophilised and the ampoules sealed under nitrogen by heat fusion of the glass and stored at -20°C in the dark.

Collaborative Study
Nine laboratories in seven countries participated in a collaborative study to evaluate 88/522 as a reference preparation for pertussis vaccine potency. The study showed that :-
1.The intra and inter-laboratory variability with respect to the potency assay was in agreement with that shown in previous studies.
2.Similar estimates of potency were obtained for 88/522 in terms of both the 2nd British Reference Preparation and the 2nd International Standard.
3 That 88/522 was suitable for establishment and that it be assigned the potency of 50 IU / ampoule.

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.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Redhead K. Das RG
A collaborative assay on the proposed 3rd British Reference Preparation for pertussis vaccine and the relative potencies of the 2nd IS and the 2nd British Reference Preparation for pertussis vaccine.
Biologicals 1991, 19 : 107 - 111

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Mr P Knight and Wellcome Biotech for providing the material; the participants in the collaborative study; 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 code number, and the name and address of NIBSC are cited and cited correctly.

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

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: 1.0 - 2.0 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

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