Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Cholera Vaccine (Inaba)
NIBSC code: 73/554
Instructions for use
(Version 11.0, Dated 24/01/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is the freeze dried residue of a suspension of *Vibrio cholerae* cells serotype Inaba. It is intended for standardization of the potency assay of cholera 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

No unitage was assigned. Assigned content of vial valid at time of manufacture – no information on long term stability.

4. CONTENTS

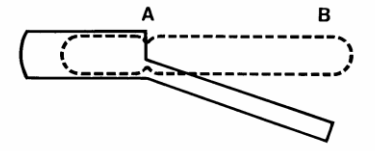
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried residue of approximately 0.5 ml of a suspension of *V. cholerae* Inaba NIH 35A3 (80 x 10^9 organisms per ml). Add 0.5 ml of sterile ditilled water, followed by 4.5 ml of physiological saline to give 5 ml of a suspension containing approximately 8 x 10^9 organisms per ml and kept at 4^{o}C prior to use. It is recommended that the solution is used immediately. The preparation should not be assumed to be sterile

5. STORAGE

Unopened ampoules should be stored at -20^{o}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

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

The 1st British Reference Preparation has been calibrated in terms of the WHO 2nd International Reference Preparation of Cholera Vaccine (Ogawa) in an international collaborative study.
The analysis of the results of the study indicate that, when reconstituted as recommended, the potency of the 1st British Reference Preparation of Cholera Vaccine (Ogawa) is equivalent to 2.39 times that of the 2nd International Reference Preparation of Cholera Vaccine (Ogawa).

8. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials.
They remain valid with the assigned potency and status until withdrawn or amended. 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.

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

9. REFERENCES

Ford, A. and Seagroatt, V. J. Biol. Standardisation 1977; 5: 69-78.

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.

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

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: 0.1 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No

14. MATERIAL SAFETY SHEET

Physical and Chemical properties	
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: **Not applicable or not cla** Physical appearance: Off white coloured cake	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains killed bacteria
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:	Not established, avoid inhalation
Ingestion:	Not established, avoid inhalation
Contact with eyes:	Not established, avoid inhalation
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.

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