Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Tetanus Toxoid (Non-Adsorbed)
NIBSC code: 02/232
Instructions for use
(Version 9.0, Dated 20/01/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE

Tetanus toxoid was provided to NIBSC by Aventis Pasteur MSD, France. The product was freeze-dried in a medium containing glycine in November 2002. It is been confirmed as suitable for use as a control antigen in immunodiffusion identity assays.

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 contains 900 Lf units of tetanus toxoid, non-adsorbed.

4. CONTENTS

Country of origin of biological material: France.
The material is purified tetanus toxoid, of purity >1000 Lf/mg pN, stabilized with glycine. The material was provided by Aventis Pasteur MSD in one glass bottle containing 800 ml of toxoid with an internal code number FA082448, with specifications of 5000 Lf/ml (4.42 mg protein Nitrogen (25 mg/ml protein by BCA assay). The product fully meets PhEur specifications for purity, safety and toxicity/toxicity reversal for use in manufacturing of adsorbed vaccines. Material (750 ml) was diluted 1/5 with 400 ml of 1M sodium chloride (0.1 M final concentration), 2000 ml of 10% glycine (5% final concentration) and 850 ml distilled water, and 1.0 ml was filled into ampoules for freeze-drying. The average weight of the ampoule content was determined as 0.0631 g of dry weight ± 0.38%. The residual moisture is less than 1% and samples measured were in the range 0.07% to 0.6%.

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

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The entire contents of each ampoule should be completely resuspended in an accurately measured amount of a suitable solution (e.g. saline). A suspension of the total content of an ampoule will contain 900 Lf in the total volume. The suspension should kept at 4°C and should not be frozen.

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.

When stored unopened at the recommended temperature (-20°C), the freeze-dried material is highly stable with a predicted degradation rate of 0.003% loss of activity per year [2].

Once reconstituted, 02/232 has been confirmed to be stable for up to 12 months in in vitro assays at NIBSC following storage at +4°C. However, users are encouraged to determine the stability of the material according to their own methods 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. Preneta-Blanc, R., Rigsby, P., Sloth Wilhelmsen, E., Tierney, R., Brierley, M. and Sesardic, D. 2007. Collaborative Study: Calibration of Replacement International Standard of Tetanus Toxoid for use in Flocculation Test. WHO Expert Committee on Biological Standardization. WHO/BS/07.2061.
2. Preneta-Blanc, R., Rigsby, P., Sloth-Wilhelmsen, E., Tierney, R., Brierley, M. and Sesardic, D. Calibration of replacement international standards of diphtheria and tetanus for use in flocculation test. Biologicals, 36 (2008), 315-326.

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

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

Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Chemically inactivated tetanus toxin. Tested and found to be free of active toxin and free from ability to reverse to toxin.	
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 ml
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No