Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Methylated Human Serum Albumin (mHSA)
NIBSC code: 23/106
Instructions for use
(Version 1.0, Dated 26/07/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

For use as a coating reagent in Meningococcal polysaccharide ELISA assay, the mHSA solution is added in the coating buffer to a final concentration of 5 µg/ml [1, 2].

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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

N/A

4. CONTENTS

Country of origin of biological material: United States of America.
Each ampoule contains the freeze-dried residue from 1 ml of a 1 mg/ml solution of methylated HSA in distilled water. The material was prepared as follows [1]: 5 g of purified human albumin was purchased from Sigma (code number A8763). The material was suspended in 500 ml methanol (VWR 20847) and 4.2 ml 12 N HCl (VWR 20255) was added. The mixture was allowed to stand in the dark for 3 days with occasional mixing. The precipitate was collected by centrifugation in six tubes at 7000 rpm for 10 mins. Each of the pellets were washed 4 times with 20 ml methanol (centrifuged each time as above) and 4 times with 20 ml anhydrous ether (allowed to stand for 10 mins per wash and centrifuged each time as above). After evaporation of residual ether, the final mHSA pellet was dried under a stream of nitrogen and finally dried over potassium hydroxide pellets in a vacuum desiccator for 10 mins. The protein concentration was estimated using the BCA method and the solution was then diluted to 1 mg/ml in distilled water. The material was filled at 1 ml per ampoule and freeze-dried. The final protein concentration of the material in a reconstituted ampoule was 1.2 mg/ml as measured by UV absorbance (using a theoretical absorption coefficient [3]. This concentration would be consistent when compared with the previous batch of mHSA.

5. STORAGE

Store freeze dried ampoules and reconstituted aliquots 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 contents of the ampoule should be rehydrated with 1 ml of sterile water. This preparation should be validated against previous batches of mHSA for individual requirements.

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.

Assigned content of ampoule valid at time of manufacture. Performance of this preparation in a polysaccharide identity ELISA was similar to the previous preparation of mHSA, 12/176. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

1. Gheesling, L. L. et al. (1994). Multicenter comparison of Neisseria meningitidis serogroup C anti-capsular polysaccharide antibody levels measured by a standardized enzyme-linked immunosorbent assay. J Clin Microbiol. 32(6):1475-82.
2. Carlone, G. M. et al. (1992). Multicenter comparison of levels of antibody to the Neisseria meningitidis group A capsular polysaccharide measured by using an enzyme-linked immunosorbent assay. J Clin Microbiol. 30(1):154-9.
3. Tarelli, E. et al. (1998). Recombinant human albumin as a stabilizer for biological materials and for the preparation of international reference reagents. Biologicals. 26(4):331-46.

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.

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

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 human 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: 0.001 g.
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No