



**WHO International Standard
1st WHO International Standard for Meningococcal Group X
Polysaccharide
NIBSC code: 14/156
Instructions for use
(Version 2.0, Dated 01/05/2019)**

1. INTENDED USE

The freeze-dried preparation of *Neisseria meningitidis* serogroup X capsular polysaccharide (MenX), provided by Finlay Institute, Cuba was prepared in ampoules (2014) at the Centre for Biological Reference Materials (CBRM, NIBSC) and coded 14/156. A collaborative study was carried out on this material by 11 laboratories in 2014/2015 to determine the MenX content in SI units based on the quantitative nuclear magnetic resonance assay, and to evaluate its suitability for use as a standard for quantification of MenX in final fills and bulks of MenX vaccines (including Phosphorus and HPAEC-PAD assays). The material is suitable for use in the quantitation of MenX content by other assays, although users should verify its suitability and determine the uncertainty of measurement in their specific assay. NIBSC, Potters Bar, UK is the custodian and distributor of this material.

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

The first WHO International standard for Meningococcal Group X polysaccharide 14/156, has a content of 0.776 ±0.089 mg/ampoule as determined by quantitative nuclear magnetic resonance. The residue weight of MenX PS is 302.2038.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried powder of 1ml of MenX PS in water. The moisture content is 1.86%

5. STORAGE

Ampoules should be stored at or below -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

Re-suspend the contents of the ampoule in 1ml of distilled water. To ensure complete solubilisation of the material allow to dissolve for at least 2 hours at room temperature or 12 hours at 4°C prior to use. The reconstituted material should be aliquoted and frozen at or below -20°C.

The standard can be used directly as a reference in the physico-chemical assays or for calibrating of secondary standards.

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.
Accelerated degradation studies revealed the freeze dried standard to be stable up to six months at 37°C.
Real-time and extended accelerated thermal degradation studies are ongoing.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

Caroline Vipond, Carolyn Swann, Thomas Dougall, Peter Rigsby, Fang Gao, Nicola Beresford, Barbara Bolgiano and the MenA/MenX IS Working Group. Evaluation of candidate International Standards for Meningococcal Serogroups A and X polysaccharide WHO/BS/2015.2255 Add
Vipond C, Swann CJ, Dougall TW, Rigsby P, Gao F, Beresford NJ, et al. Evaluation of candidate international standards for meningococcal serogroups A and X polysaccharide. *Biologicals*. 2017;47:33-45.

10. ACKNOWLEDGEMENTS

We would like to thank the Finlay Institute, Cuba for gifting the polysaccharide to make this standard

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 white powder	Corrosive:	No
Stable:	Oxidising:	No
Hygroscopic:	Irritant:	No
Flammable:	Handling:	See caution, Section 2
Other (specify):	No special handling precautions	



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: 5g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.