Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
1st International Standard for Meningococcal Capsular Group W Polysaccharide
NIBSC code: 16/152
Instructions for use
(Version 1.0, Dated 12/11/2019)

1. INTENDED USE

The product is intended to be used in assays for the quantitation of meningococcal capsular group W polysaccharide in (conjugated) polysaccharide vaccines or for the calibration of secondary standards. Resorcinol and HPAEC-PAD assays were the main methods performed as part of the collaborative study [1] to determine the fitness for purpose of the material in these assays. Other assays (HPLC, Anthrone assay and Nephelometry) were performed also, although users should verify its suitability and determine the uncertainly of measurement in their specific assay.

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 1st WHO International standard for Meningococcal Capsular Group W polysaccharide 16/152, has a content of 1.015 ± 0.071 mg polysaccharide/ampoule (expanded uncertainty with coverage factor k = 2.13, corresponding to a 95% level of confidence) as determined by the Resorcinol assay. Unitage was assigned following performance of a collaborative study [1] by twelve laboratories in 2017/2018 to determine the MenW polysaccharide content in SI units and to evaluate its suitability for use as a standard for quantitation of MenW in bulk MenW polysaccharide conjugate material.

4. CONTENTS

Country of origin of biological material: Italy.
Each ampoule contains the freeze dried powder of 1 ml of MenW polysaccharide in water, at a nominal concentration of 1 mg/ml. The moisture content is 0.37%, as determined by thermogravimetric analysis. The residue weight of MenW polysaccharide is 497.020 g/mol with a degree of O-acetylation of 58.5%, as determined through the collaobrative study [1].
The freeze-dried preparation of Neisseria meningitidis capsular group W (MenW, serogroup W, formerly known as Men W135 [2]) polysaccharide provided by GSK Vaccines S.r.l., Italy was prepared in ampoules in 2016 at the Centre for Biological Reference Materials (CBRM), NIBSC and coded 16/152. NIBSC, Potters Bar, UK is the custodian and distributor of this material.

5. STORAGE

Ampoules should be stored at or below -20ºC
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
Resuspend the contents of the ampoule in 1 ml of distilled water. To ensure complete solubilisation of the material, reconstitute the material 24 hours prior to use. Allow to dissolve for 4 hours at room temperature then transfer to 4ºC for the remaining time. The reconstituted material should be aliquoted and frozen at or below -20ºC. The standard can be used directly as a reference in the physico-chemical assays or for calibrating of secondary standards.
This MenW standard is 58.5% O-acetylated, and is appropriate for the measurement of the MenW content of material that has a similar O-acetylation level. If the standard is to be used for measuring the MenW content of a sample with a different degree of O-acetylation, a correction factor will have to be used.

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 lyophilised standard to be stable up to 36 months at 37ºC (as determined by HPAEC-PAD to measure the polysaccharide content of the material reconstituted with water). Storage of the lyophilised standard at 20ºC for up to 36 months or when reconsitituted (stored -20ºC) for up to 6 months did not affect the molecular size distribution as determined by HPLC-SEC.
Real-time and extended accelerated thermal degradation studies are on-going.

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

9. REFERENCES

1) Hannah Chan, Nicola Beresford, Timothy Rudd, Peter Rigsby, Caroline Vipond, Fang Gao, Barbara Bolgiano and the MenW/MenY IS Working Group. Evaluation of Candidate International Standards for Meningococcal Capsular Group W and Y Polysaccharides. WHO/BS/2019.2374.

2) Harrison OB, Claus H, Jiang Y, Bennett JS, Bratcher HB, Jolley KA, et al. Description and nomenclature of Neisseria meningitidis capsule locus. Emerg Infect Dis. 2013;19:566-73.

10. ACKNOWLEDGEMENTS

We would like to thank GSK Vaccines S.r.l. Italy for their gift of the polysaccharide used 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

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

World Health Organization

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:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	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: 0.00055 g
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_biolefstandardsrev2004.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.