Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

International Ref. Preparation
International Standard for IPV 12/104
NIBSC code: 12/104
Instructions for use
(Version 2.0, Dated 03/12/2018)

1. INTENDED USE

Preparation was established by WHO Expert Committee on Biological Standarisation in 2013 as the 3rd International Standard for Poliomyelitits vaccine (inactivated) (WHO, 2013). It was shown to be suitable for determination of antigenic content of inactivated poliovirus vaccine by in vitro assays.
The prepartion is a liquid trivalent blend of formaldehyde-inactivated monovalent pools of poliovirus type 1 (Mahoney), poliovirus type 2 (MEF) and poliovirus type 3 (Saukett). The material has been prepared by a manufactuer and has been tested for sterility, absence of adventitious agents and no content of serum albumin (2ng/ml). This standard is for use with IPV made with wildtype polio virus strains, for IPV made with Sabin strains the standard 17/160 is required.

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

277 D antigen units per ml for type 1 antigen
65 D antigen units per ml for type 2 antigen
248 D antigen units per ml for type 3 antigen

4. CONTENTS

Country of origin of biological material: United Kingdom.

5. STORAGE

The material should be stored at -70°C

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

The 3rd IS for IPV should be used to calibrate laboratory reference reagents to be used in the in vitro assays for the determination of the antigenic content of inactivated poliovirus vaccines.
The material is supplied in its final format and must not be further diluted other than as required for individual assay proceddures. Each ampoule is intended to be used only once

Please note that the 3rd IS is provided for calibration purposed and therefore the supply of the reagent will be limited to 3 ampoules per organization a year.Please note that the 3rd IS is provided for calibration purposed and therefore the supply of the reagent will be limited to 3 ampoules per organization a year.

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.
Stability studies have been carried out and details can be found in the Collaborative Study Report. See section 9 for details
NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 21 to 25 October 2013
Report on the WHO collaborative study to establish the 3rd International Standard (replacement) for inactivated polio vaccine
Javier Martin Thomas Dougall, Laura Stephens, Gillian Cooper and Alan Heath

10. ACKNOWLEDGEMENTS

The study participants and the IPV manufacturers who kindly donated the candidate materials

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: A pale pink liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Does not contain 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	

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

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: 0.6g
Toxicity Statement: Non-toxic
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.