Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Sabin Inactivated Polio Vaccine (sIPV) 17/160
NIBSC code: 17/160
Instructions for use
(Version 2.0, Dated 11/12/2018)

1. INTENDED USE

WHO International Standard (IS) for Sabin Inactivated Polio Vaccine (sIPV) was established by the WHO Expert Committee on Biological Standardisation (ECBS) in October 2018. It was shown to be suitable for the determination of antigenic content of sIPV by in vitro assays.
The preparation is a liquid trivalent blend of formaldehyde-inactivated monovalent pools of Sabin poliovirus type 1, 2 and 3. The material has been prepared by a manufacturer and has been tested for sterility and absence of adventitious agents.
Due to the antigenic differences between IPV made with wild-type or Sabin strains the sIPV IS has been assigned a new antigen unit, Sabin D-Antigen Unit (SDU). This is independent of the D-Antigen units used for conventional IPV products, for which the IS 12/104 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

100 SDU/ml for poliovirus type 1
100 SDU/ml for poliovirus type 2
100 SDU/ml for poliovirus type 3

(SDU/ml: Sabin D-Antigen Unit per millilitre)

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial contains 0.5 ml of bulk Sabin Inactivated Polio Vaccine

5. STORAGE

The material should be stored at -70°C.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

The 1st IS for sIPV should be used to calibrate laboratory reference reagents to be used in the in vitro assays for the determination of the antigenic content of Sabin Inactivated Poliovirus Vaccines.
The material is supplied in its final format and must not be further diluted other than as required for individual assay procedures. Each vial is intended to be used only once.

Please note that the 1st IS is provided for calibration purposes and therefore the supply of the reagent will be limited to 3 ampoules per organisation 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.
NIBSC follows WHO policy with respect to its reference materials.

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9. REFERENCES

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 29 October to 2 November 2018
Report on the WHO collaborative study to establish the 1st International Standard for Sabin Inactivated Polio Vaccine (sIPV)
Laura Crawt, Eleanor Atkinson, Alison Tedcastle, Elaine Pegg, Philip Minor, Gillian Cooper, Peter Rigsby and Javier Martin

10. ACKNOWLEDGEMENTS

The study participants and sIPV 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 yellow liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	Unknown
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		

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: 0.5ml
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.