Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Neurotrophin-3, recombinant human methionyl, research reagent
NIBSC code: 98/718
Instructions for use
(Version 2.0, Dated 02/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The preparation coded 98/718 is intended as a reference standard for the biological activity of neurorotrophin-3 in in vitro bioassays.

2. CAUTION

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

The neurotrophin-3 is recombinant DNA-derived. The formulation contains material, human serum albumin, of human origin. The material of human origin has been tested and found negative for HBsAg, anti-HIV and anti-HCV. 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

Research reagent 98/718 has been assigned a potency of 5000 units of neurotrophin-3 per ampoule

4. CONTENTS

Country of origin of biological material: United States and United Kingdom.
Each ampoule contains the residue after freeze-drying of 1.0mL of a solution that contained

neurotrophin-3	5 microgram/mL
sodium citrate	10 mM, pH 5.6
trehalose	2 mg/mL
human serum albumin	5 mg/mL

5. STORAGE

The ampoules are shipped at ambient temperature. Unopened ampoules should be stored at -20 degrees C in the dark. Freezing and reuse of reconstituted material should be avoided unless this can be validated for the particular laboratory, storage and assay conditions. Repeated freezing and thawing should be avoided. The ampoules do not contain bacteriostat and solutions of the ampouled material should not be assumed to be sterile.
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 entire contents of each ampoule should be completely dissolved in a known volume of suitable solvent, for example phosphate buffer. It is recommended that, when possible, buffer containing carrier protein should be used to minimize loss by surface adsorption. The solvent should be compatible with the assay system used. Freezing and reuse of reconstituted material should be avoided unless this can be validated for the particular laboratory, storage and assay conditions. Repeated freezing and thawing should be avoided.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities and they should be stored on receipt as indicated on the label. Accelerated degradation studies have indicated that this material is suitably stable, when stored at -20ºC or below, for the assigned values to remain valid until the material is withdrawn or replaced. These studies have also shown that the material is suitably stable for shipment at ambient temperature without any effect on the assigned values. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Inquiries about this material should be addressed to enquiries@nibsc.hpa.org.uk

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Amgen, Inc., Thousand Oaks, CA. and Regeneron Pharmaceuticals, Inc., Tarrytown, NY, for the donation of materials and provision of advice to support development of the research reagent.

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 powder/pellet		Corrosive:	No
Stable:	No	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No

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

Flammable:	No	Handling:See caution, Section 2
Other (specify):		
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 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: 10mg
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No