Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
GLIAL CELL-DERIVED NEUROTROPHIC FACTOR (GDNF), human, rDNA-derived
NIBSC code: 09/266
Instructions for use
(Version 2.0, Dated 18/03/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The preparation coded 09/266 is intended for use as a biological reference standard for the biological activity of glial cell-derived neurotrophic factor.

2. CAUTION

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

The preparation contains material of human origin and either the final product or the source materials from which it is derived have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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

This preparation has been assigned a potency of 5000 units per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom.
The preparation contains recombinant human sequence glial cell-derived neurotrophic factor with an N-terminal methione residue, r-metHuGDNF.
Each ampoule contains the residue after freeze-drying of 0.5 ml of a solution that contained:

GDNF	20 microgram/ml
trehalose	2 mg/ml
human serum albumin	5 mg/ml
sodium chloride	150 mmol/l
sodium citrate , pH 5.0	10 mmol/l

5. STORAGE

The ampoules are shipped at ambient temperature. Unopened ampoules should be stored at -20 degrees C in the dark. For economy of use, it is recommended that the reconstituted solution be subdivided into several small containers and stored at, or below, -40 degrees C. 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 standard is intended for calibration of local standards. For all practical purposes, each ampoule contains the same quantity of GDNF. The entire contents of each ampoule should be completely dissolved in a known volume of suitable solvent. It is recommended that, when possible, buffer containing carrier protein should be used to minimize loss by surface adsorption.

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.
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9. REFERENCES

Queries concerning this material should be addressed to enquiries@nibsc.hpa.org.uk

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to colleagues in academia and industry for their assistance in the project to develop this reference standard for GDNF

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	Corrosive: No

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

Stable:	No	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
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 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: 15 milligram
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No