



**WHO Reference Reagent**  
**Brain-derived neurotrophic factor (BDNF)**  
**NIBSC code: 96/534**  
**Instructions for use**  
**(Version 5.0, Dated 02/04/2013)**

## 1. INTENDED USE

The preparation coded 96/534 was established as the 1st WHO Reference Reagent (WHO RR) for brain-derived neurotrophic factor (BDNF) by the WHO Expert Committee on Biological Standardization in 1997, following evaluation of its biological activity and stability by NIBSC and by the manufacturer of the BDNF. The BDNF used in this preparation is the human form of the molecule with an N-terminal methionine residue, synthesized in E. coli by recombinant DNA technology.

## 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 assigned potency of the 1st WHO RR for BDNF is 16 000 units per ampoule.

## 4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze-drying of 1.0 ml of a solution that contained:

|  |                   |
|--|-------------------|
| BDNF   | 20.0 microgram/ml |
| NaH <sub>2</sub> PO <sub>4</sub> (anhydrous) | 4.0 mg/ml         |
| trehalose                                    | 30.0 mg/ml        |
| arginine                                     | 3.0 mg/ml         |
| Tween 20                                     | 0.1 mg/ml         |
| NaCl   | 4.5 mg/ml         |
| pH 7.0                                       |                   |

The BDNF concentration of the bulk material was determined by the manufacturer by measurement of the absorbance at 280nm.

## 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 manufacturers 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 WHO RR is intended for calibration of local standards. For all practical purposes, each ampoule contains the same quantity of BDNF. 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 -20°C 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

WHO TRS ECBS Report No. 889, 48<sup>th</sup> Report; WHO/BS document 97.1867

## 10. ACKNOWLEDGEMENTS

Grateful acknowledgement is due to the manufacturer of the BDNF for the donation of the material and for testing preparation 96/534.

## 11. FURTHER INFORMATION

Further information can be obtained as follows;

This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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                     |  |  |
| Stable:<br>No  | Oxidising:  | No                     |  |  |
| Hygroscopic:<br>Yes  | Irritant:   | No                     |  |  |
| Flammable:<br>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.<br>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](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

|   |
|---|
| <b>Country of origin for customs purposes*</b> : 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. |
| <b>Net weight:</b> 40mg   |
| <b>Toxicity Statement:</b> Toxicity not assessed  |
| <b>Veterinary certificate or other statement</b> if applicable.   |
| <b>Attached:</b> 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.bi](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter.bi)

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UK Official Medicines Control Laboratory

