Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Working Standard
INTERFERON BETA SER17 MUTEIN (Human, rDNA derived)
NIBSC code: 00/574
Instructions for use
(Version 3.0, Dated 23/08/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is intended as a biological reference standard for interferon-beta Ser 17 mutein. [Interferon-beta Ser 17 mutein is a stable recombinant human interferon-beta molecule expressed in E. coli following site-specific mutagenesis of the interferon-beta gene to replace the cysteine residue at position 17 with a serine residue. Since it is produced in E. coli it is not glycosylated. This preparation, 00/574, was included in a WHO international collaborative study to evaluate existing and new interferon-beta standards. Based on the study's results, this preparation has been assigned a potency of 64,000 international units (IU) per ampoule when calibrated against the International Standard of Interferon-beta Ser 17 mutein, Gxb02-901-535, 6,000 IU. (Journal of Immunological Methods, 306 (2005) 1-15)].

2. CAUTION

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

Human and bovine source material
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. The bovine casein used as an excipient was sourced from a country where bovine spongiform encephalopathy (BSE) has not been found. 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

64,000 international units (IU) per ampoule

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1 ml of phosphate buffered saline that contained:

Interferon-beta Ser 17 mutein	1,125 ng
Human serum albumin	10 mg
Bovine casein	3 mg

The Interferon-beta Ser 17 mutein was expressed in E. coli.

5. STORAGE

Unopened ampoules should be stored at -20ºC.
For economy of use, it is recommended that
the solution be sub-divided into several small aliquots and stored at -40ºC.
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
Dissolve the total contents of the ampoule in 0.5ml of sterile distilled water and transfer to a sterile container. Rinse the ampoule with 0.4ml of sterile distilled water and add to the first solution. Make up the total volume to 1.0ml with sterile distilled water. The final solution will contain IFN-β at a concentration of 64000 International Units (IU) per ml. Use carrier protein where dilution is required. It is recommended that initial dilutions, i.e. 1:10, 1:100, are either made in cell culture medium containing - 5%v/v –10%v/v calf serum or in phosphate-buffered saline, pH 7.0-7.4, containing 0.3%v/v bovine casein to prevent adsorption of IFN-β to container surfaces.

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. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Meager A Gaines Das R. (2005). Biological standardisation of human interferon beta: establishment of a replacement World Health Organization international biological standard for human glycosylated interferon beta. J. Immunological Methods 306:1-15.

This reference standard was produced under WHO guidelines cited in the WHO technical Reports Series 925, 2005.

10. ACKNOWLEDGEMENTS

N/A

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.

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

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: n/a	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of human and bovine 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
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: 1g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No

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