



**WHO International Standard  
INTERFERON BETA (HUMAN, rDNA, Glycosylated)  
NIBSC code: 00/572  
Instructions for use  
(Version 7.0, Dated 11/04/2013)**

### 1. INTENDED USE

This is the 3<sup>rd</sup> WHO International Standard for glycosylated human interferon beta (IFN- $\beta$ ) and is intended for use as the primary biological reference standard in bioassays for glycosylated human IFN- $\beta$ .

The unitage of 00/572 is continuous with that of the 2nd International Standard, Gb23-902-531, and therefore 00/572 is suitable to serve as a bioassay calibrant for measuring the potency of glycosylated IFN- $\beta$  derived either from human fibroblasts or from CHO cells. However, it has been shown to be unsuitable for measuring the potency of recombinant non-glycosylated IFN- $\beta$  Ser17 mutein derived from *E. coli* or for other non-glycosylated IFN- $\beta$  preparations and therefore should not be used for this purpose. In the latter case, the 1st International Standard of recombinant non-glycosylated IFN- $\beta$  Ser17 mutein, Gxb02-901-535, should be used.

Regarding the calibration of immunoassays, it is pointed out that the suitability of 00/572 for this purpose has not been tested.

### 2. CAUTION

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

The preparation contains 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

40,000 International Units (IU).

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
The recombinant human interferon beta (IFN- $\beta$ ) contained in this ampoule was produced from Chinese Hamster Ovary (CHO) cells harbouring IFN- $\beta$  cDNA and highly purified by chromatographical procedures.

Approximately 200 nanograms of recombinant (Chinese Hamster Ovary cell-derived) human IFN- $\beta$   
1.875% human serum albumin  
0.3% bovine casein.

The ampoule does not contain bacteriostat.

### 5. STORAGE

Unopened ampoules should be stored at -20°C.

**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- $\beta$  at a concentration of 40000 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- $\beta$  to container surfaces. For economy of use, it is recommended that the solution be sub-divided into several small aliquots and stored at -40°C or below.

### 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. It is the policy of WHO not to assign an expiry date to their international reference materials. 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. 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](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

Physical and Chemical properties	
<b>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008:</b> <b>Not applicable or not</b>	Corrosive: No
Physical appearance: White powder	
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains human and bovine source material
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](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> 1 g
<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\\_biol\\_standardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biol_standardsrev2004.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.