Non WHO Reference Material 1st British INTERFERON GAMMA (HUMAN, LEUKOCYTE-DERIVED)

NIBSC code: 82/587 Instructions for use (Version 7.0, Dated 19/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

As a biological reference standard for interfon gamma (glycosylated).

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

3000 International Units (IU) per ampoule. (This value was derived by proportional relationship to the 1st International Standard for Interferon Gamma, Human Gg23-901-530, 4000IU)

4. CONTENTS

Country of origin of biological material: United Kingdom. Each ampoule contains the freeze dried residue of 1ml of a solution that contained:

Interferon gamma human, leukocyte-derived Phosphate buffered saline (PBS), pH7.2, 6mg Human serum albumin (HSA)

The Interferon gamma was partially-purified from supernatant of lectinstimulated human leukocytes.

5. STORAGE

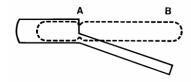
For economy of use, it is recommended that the final solution be subdivided into several small aliquots ands stored at -40°C or below. Avoid repeated thawing/freezing. Unopened ampoules should be stored at -20°C.

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.





Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

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. Rinse the ampoule with 0.4ml of sterile distilled water and make up the total volume to 1.0ml with distilled water. The final solution will contain IFN gamma at a concentration of 3000 IU/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 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 -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

This standard was produced under WHO guidelines cited in WHO Technical Reports Series 626, 1978, Annex 4.

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

Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory

NIBSC Confidence in Biological Medicines

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

(EC) No 1272/2008: Not applicable or not classified		
Physical and Chemical properties		
Physical appearance: White	Corrosive:	No
powder		
Stable:	Oxidising:	No
Yes		
Hygroscopic: Yes	Irritant:	No
Flammable: No	Handling:	See caution, Section 2
Other (specify): Contains material of human 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: V	ash thoroughly	with water.
Action on Spillage and Method of Disposal		
Spillage of ampoule contents should be taken up with absorbent		

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: 19

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No

National Institute for Biological Standards and Control,

Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory