



**WHO Reference Reagent
Inhibin B, Human
NIBSC code: 96/784
Instructions for use
(Version 2.0, Dated 17/01/2008)**

1. INTENDED USE

This consists of a batch of ampoules containing immunoaffinity-purified natural human inhibin. The preparation contains a mixture of inhibin A, inhibin B and inhibin α -subunit which, after dilution in a solution containing Tris (25mM), sodium chloride (0.85% w/v), human serum albumin (0.5% w/v) and Triton X100 (0.1% v/v) was freeze-dried and secondarily desiccated and evaluated in an international collaborative study as a candidate WHO reference reagent for inhibin B.

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

The assigned unitage is 12 U per ampoule. On the basis of immunoassay results the nominal mass content is 12 ng per ampoule. These units should not be assumed to be interconvertible. Because of possible toxic effects from the formulation, this preparation may not be suitable for some bioassay systems.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1ml of a solution which contained:

Tris	3.03mg/ml
Human Serum albumin	5mg/ml
Sodium chloride	8.5mg/ml
Triton X100	1mg/ml
Human inhibin	-

NB. When received at NIBSC, the preparation contained 6 M guanidine. If reconstituted in 1 ml, the solution will contain 0.03 M guanidine (approximately 2.85 mg/ml).

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

For practical purposes each ampoule contains the same quantity of inhibin B. The entire content of each ampoule should be completely dissolved in an accurately measured amount of buffer solution. No

attempt should be made to weigh out portions of the freeze dried powder. The use of water to reconstitute ampoule contents is not recommended. The material has not been sterilized and the ampoules contain no bacteriostat.

8. COLLABORATIVE STUDY AND ASSIGNMENT OF UNITAGE

A preparation of immunoaffinity-purified inhibin B was examined and compared with local standards in current use in bioassays and immunoassays in six laboratories in five countries.

The study provided evidence that the preparation would be suitable to serve as a Reference Reagent for inhibin B since it was shown:

- qualitatively - to have appropriate inhibin biological activity
- to have inhibin B immunoreactivity
- quantitatively - to give a mean estimate of 12.9 ng per ampoule (95% confidence limits 12.0 - 13.8) by immunoassay
- to be sufficiently stable to serve as a reference reagent

Accordingly, the preparation in ampoules coded 96/784 was established as the First WHO Reference Reagent for Inhibin B, and assigned a unitage of 12 Units per ampoule by WHO (October, 2000). However because of possible toxic effects from the formulation, this preparation may not be suitable for some bioassay systems. On the basis of the immunoassay results, preparation 96/784 was assigned a nominal mass content of 12 ng per ampoule. The bioactivity units and the immunoactivity units should not be assumed to be interconvertible.

9. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. For information specific to a particular biological standard, contact standards@nibsc.ac.uk.

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

NIBSC follows the policy of WHO with respect to its reference materials. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Professor Nigel Groome, Oxford Brookes University, Oxford, UK for providing the material and Dr P Dawson and the staff of Standards Division for ampouling the preparation.

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
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of human origin. Can react with oxidising materials. Avoid contact with acids and alkalis
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: 20mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. Attached: 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.

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

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_efstandardsrev2004.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.