Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Chorionic Gonadotrophin Alpha Subunit, Human For Radioiodination
NIBSC code: 76/508
Instructions for use
(Version 5.0, Dated 28/03/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This consists of a batch of micro-ampoules (coded 76/508) containing highly purified Alpha Subunit of human chorionic gonadotrophin (hCG-α) for radioiodination. The purification and characterization of this hCG-α is described by Canfield and Ross (1976). It is part of the same batch of hCG-α which was used to prepare the International Reference Preparation of Chorionic Gonadotrphin in Alpha Subunit, Human, for Immunoassay ampoules coded 75/569 (Storring et al, 1980).

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.

However, as with all preparations of human origin, this material cannot be assumed to be free from infectious agents. Suitable precautions should be taken in the use and disposal of the ampoule and its contents. Such safety procedures probably will 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. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the freeze-dried residue of 0.5 ml of a solution which contained:

Each siliconized micro-ampoule contains the residue, after freezer-drying, of 5µl of a solution which contained:

α Subunit of human chorionic gonadotrophin	approx	2µg
mannitol	approx	100µg
acetic acid	approx	3µg

Nitrogen gas at slightly less than atmospheric pressure.

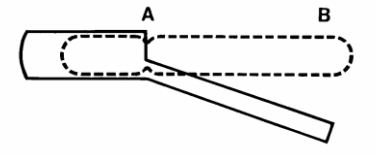
4. STORAGE

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.

5. 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.

Use of the contents of micro-ampoules – method of using micro-ampoules with the aid of the vaccine bulb provided.

1. Open the micro-ampoule in the horizontal position by gently marking 2-3mm from each end with glass file (supplied) and breaking off both ends. If the lyophilized plug has fragmented, tap the fragments away from the ends of the micro-ampoule before opening.
2. Manipulate one of the open ends of the micro-ampoule into the small hole in the vaccine bulb provided, without creating pressure (i.e. without covering the large opening).
3. When the vaccine bulb is in place, and keeping the micro-ampoule as close as possible to the horizontal, place the free end into a measured or non-measured volume of solvent. If a small measured volume is to be used, it may be found convenient to expel it from a pipette as a discrete drop on a non- wettable surface (e.g. Parafilm).

The entire drop (or an unmeasured aliquot from a larger measured volume) can then be drawn up into the micro-ampoule by the following procedure:

4. Gently squeeze the teat, still without covering the large opening.
5. When teat has been partially compressed, cover the large opening with a finger and allow the bulb to expend very slowly. Liquid will be drawn into the micro-ampoule.
6. When the liquid has reached the distal end of the lyophilized plug, stop the rise of liquid by removing the finger from the large opening of the teat.
7. When the plug has dissolved (which takes only seconds), the solution may be discharged into a suitable collecting vessel by closing the large opening and squeezing the teat.
8. If a large measured volume of solvent has been used, the micro-ampoule can be washed out into it by repeating the above procedure a number of times.

6. STABILITY

NIBSC follows the policy of WHO with respect to its reference materials.

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. Unopened ampoules should be stored on receipt as indicated on the label. 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.

7. REFERENCES

Canfield R E & Ross G T (1976). Bull. Wld Hlth Org., 54, 463-470.

Storring P L, Gaines Das R E & Bangham D R (1980). J.Endocrinol., 84, 295-310.

8. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to the Center for Population Research, USA and Reproduction Research Branch of the National Institute of Child Health and Human Development, USA for providing the hormone preparation; Drs R E Canfield and G T Ross and their colleagues for its purification and characterisation and Dr P J Campbell for ampouling.

9. 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

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

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10. 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

11. 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.

12. 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: Freezed 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
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.	

13. 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.

14. 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: 0.1mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

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