Non WHO Reference Material

Chorionic Gonadotrophin, Human, for Radioiodination
NIBSC code: 75/533

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 75/533) containing highly purified human chorionic gonadotrophin (hCG) for radioiodination. The purification and characterization of this batch of hCG is described by Canfield and Ross (1976). It is part of the same batch of hCG which was used to prepare the third International Standard for Chorionic Gonadotrophin in ampoules coded 75/537 (Storr 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.

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. CONTENTS

Country of origin of biological material: United Kingdom.

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

- Human Chorionic Gonadotrophin: approximately 2µg
- Mannitol: approximately 100µg
- Acetic Acid: approximately 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 cuts and projectile glass fragments that enter eyes.

Avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

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. Reference Materials should be stored on receipt as indicated on the label. 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.

7. REFERENCES


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 characterization 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/tlm/

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

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.

2. When the liquid has reached the distal end of the lyophilized plug, stop the rise of liquid by removing the fingers from the large opening of the teat.

3. 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.

4. After 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.

5. When has been partially compressed, cover the large opening with a finger and allow the bulb to expand very slowly. Liquid will be drawn into the micro-ampoule.

6. When 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.

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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.

2. By closing the large opening of the teat.

3. When the liquid has reached the distal end of the lyophilized plug, stop the rise of liquid by removing the fingers from the large opening of the teat.

4. 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.

5. After 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.

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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.

2. By closing the large opening of the teat.

3. When the liquid has reached the distal end of the lyophilized plug, stop the rise of liquid by removing the fingers from the large opening of the teat.

4. 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.

5. After 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.

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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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
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</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
</tr>
<tr>
<td>Stable: Yes</td>
</tr>
<tr>
<td>Hygroscopic: Yes</td>
</tr>
<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Other (specify): Contains material of human origin</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
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</thead>
<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>

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.

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