



**Non WHO Reference Material  
Calcitonin, Porcine  
NIBSC code: 89/540  
Instructions for use  
(Version 3.0, Dated 09/01/2008)**

**This material is not for in vitro diagnostic use.**

**1. INTENDED USE**

Formerly the 2<sup>nd</sup> IS, but please note that this preparation no longer has International Standard Status. The Standard was disestablished by the WHO Expert Committee on Biological Standardisation in 2001.

**2. CAUTION**

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

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**

Each ampoule contains 0.8 Units .

**4. CONTENTS**

Country of origin of biological material: United Kingdom.

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

Porcine calcitonin from porcine thyroid glands	approximately 10µg
Mannitol	approximately 5mg
and pure dry nitrogen at slightly less than atmospheric pressure	

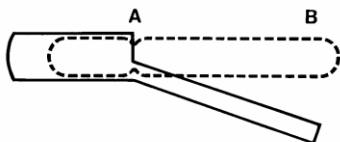
**5. STORAGE**

Unopened ampoules should be stored below -20°C in the dark.

**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**

For practical purposes each ampoule contains the same quantity of the substances listed above. Dissolve the total contents of the ampoule in a known volume of suitable solvent (buffer at pH 3.5) with carrier protein where extensive dilution is required. No attempt should be made to weigh out portions of the freeze-dried material.

For economy in use, it is recommended that the solution be sub-divided into several small containers, frozen rapidly e.g in dry ice and stored at -40°C or below. Careful evaluation will be needed to determine a feasible time of storage.

The material has not been sterilized and the ampoules contain no bacteriostat.

**8. PREPARATION OF AMPOULES**

Twenty five mg of porcine calcitonin (pCT), batch D53111, donated to WHO for ampouling were generously provided by Dr Norman Randall, Rhone Poulenc Rorer, UK.

In order to minimize loss of peptide by surface adsorption during ampouling, the bulk peptide was dissolved in 10ml of diluent for Millipore filtration (pore size 0.45µ). The filter was washed several times with diluent before the concentrated peptide solution was filtered and repeated subsequent washes of the filter after filtration of the peptide were added to the filtrate to ensure maximum recovery of peptide. The final concentration of peptide was nominally 20µg/ml. The diluent consisted of 0.001M acetic acid containing 10mg/ml mannitol. The mean fill weight per ampoule was 0.50669g (coefficient of variation 0.133%, n=40). The ampoule contents were freeze dried, secondarily desiccated and sealed under nitrogen according to procedures recommended by the World Health Organization Expert Committee on Biological Standardization (WHO ECBS 1990 see (1)).

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

**10. REFERENCE**

WHO Expert Committee on Biological Standardization (1990). Guidelines for the preparation, characterization and establishment of international and other standards and reference reagents for biological substances. Technical Report Series 800. Annex 4, 181-214.

**11. ACKNOWLEDGEMENTS**

Grateful acknowledgements are due to Dr Norman Randall, Rhone Poulenc Rorer, UK, for donating the material for ampouling; to the staff of the Standards Processing Division at NIBSC for the ampouling facilities, and to all the participants in the collaborative study.

**12. 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)

### 13. 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)

### 14. 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.

### 15. 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):	
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.	

### 16. 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.

### 17. 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:** 5mg

**Toxicity Statement:** Non-toxic

**Veterinary certificate or other statement** if applicable.

**Attached:** No