Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

International Ref. Preparation
IRP Tetracosactide, For Bioassay
NIBSC code: 80/590
Instructions for use
(Version 4.0, Dated 05/12/2007)

1. INTENDED USE

This consists of a batch of ampoules (coded 80/590) containing tetracosactide (corticotrophin-1-24-tetracosapeptide). It was established as the International Reference Preparation (IRP) by the WHO Expert Committee on Biological Standardization in 1981[1]. For a detailed description of the IRP and its collaborative study by physicochemical and biological methods, see reference 2.

2. CAUTION

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

The material is not of human or bovine origin.
The preparation does not contain material of human origin.
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 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. UNITAGE

490 International Units of tetracosactide per ampoule.
(This was assigned on the basis that the International Unit approximates to 1µg of corticotrophin-1-24-tetracosapeptide.)

4. CONTENTS

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

Tetracosactide (as peptide)	- approx 490µg (671µg as bulk acetate)
Mannitol	- approx 20mg

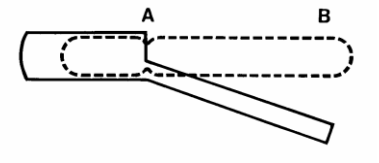
Nitrogen gas at slightly less than atmospheric

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

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 above materials. The entire contents of each ampoule should be completely dissolved in an accurately measured amount of solvent. No attempt should be made to weigh out portions of the freeze-dried powder.
For economy of use, it is recommended that the solution, without further dilution, is subdivided into several small containers and stored at -30°C or below. To maintain full activity of such stored aliquots, it is suggested that the solution of ampoule contents and its subdivision and freezing by liquid N_2 or a mixture of solid CO_2 and ethanol is done rapidly and that repeated freezing and thawing be avoided. A dilute solution prepared for use in an assay should be kept cool (eg. 4°C) and should contain not less than 0.1% w/v carrier protein (free of proteolytic enzymes). The material has not been sterilized and the ampoules contain non bacteriostat.
The preparation is not intended for administration to humans.

8. 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. For information specific to a particular standard contact, where known, the appropriate NIBSC scientist.
In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation,
Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

1. WHO Expert Committee on Biological Standardization (1982). 32nd Report. Wld. Hlth. Org. Techn. Rep. Ser. No. 673.
2. Storring. P.L., Witthaus, G., Gaines Das, R.E. and W. Stamm (1984) J. Endocrinol. 100, 51.

10. ACKNOWLEDGEMENTS

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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

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

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: Powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): none	
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: 21mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

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