NIBSC Confidence in Biological Medicines

Non WHO Reference Material PORCINE LYSINE VASOPRESSIN NIBSC code: 62/014 Instructions for use (Version 5.0, Dated 30/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

Calibrant for porcine lysine vasopressin

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. 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 potency is 2.0 international units (IU) of vasopressor activity per mg.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze drying of 1.0ml of a solution that contained: 25 mg of a powder prepared from acetone-extracted posterior lobe of porcine pituitary gland.

This material has not been sterilized and contains no bacteriostat.

5. STORAGE

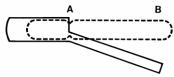
Store at -20°C or below.

For economy of use it is recommended that the reconstituted solution be subdivided into several small containers, which are frozen rapidly to below -40°C and then stored below -40°C in the dark. Repeated freezing and thawing should be avoided.

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.



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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

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

For all practical purposes each ampoule contains the same amount of the same materials. Dissolve the total contents in a known amount of suitable buffer solution with carrier protein (free of peptidase), where extensive dilution is required, to minimise loss by surface adsorption.

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. 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. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Not Applicable

10. ACKNOWLEDGEMENTS

The material was generously donated by The Crookes Laboratories Ltd., Basingstoke, Hants.

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

100 1272/2000. Not applicable of flot classified				
Physical and Chemical properties				
Physical appearance:		Corrosive:	No	
Freeze-dried				
Stable:	Yes	Oxidising:	No	





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Hygroscopic: Yes	Irritant: No			
Flammable: No	Handling:See caution, Section 2			
Other (specify): Contain	ns dried material of mammalian 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 a virucidal agent. Rinse area with a virucidal agent 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: 25mg

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No

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