NIBSC Confidence in Biological Medicines

Non WHO Reference Material RANTES (Human rDNA derived) NIBSC code: 92/520 Instructions for use (Version 6.0, Dated 03/05/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

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 100,000 arbitrary units per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze drying of 1 ml of a solution containing :

RANTES, approximately 10 microgram 9.0 mg sodium chloride 6.0 mg trehalose

The RANTES protein was expressed in E. coli.

5. STORAGE

For economy of use, it is recommended that the solution be sub divided into aliquots and stored at +4°C for up to 1 week. 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

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

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

Dissolve the total contents of the ampoule in 0.5ml of sterile distilled water. Rinse the ampoule with a further 0.4ml of sterile distilled water and make up the total volume to 1.0ml. This solution will contain RANTES at a concentration of 100,000 units per ml. It is advisable to include a carrier protein during initial reconstitution to prevent loss of material if this does not interfere in the intended assay method.

8. STABILITY

Reference materials are held at NIBSC within assured, temperaturecontrolled storage facilities and they should be stored on receipt as indicated on the label. An arbitrary unitage was assigned to this preparation at the time of production without confirmation of long term stability. Evidence from similar materials prepared by an equivalent

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process indicates that long term stability is likely to be maintained and the material is suitably stable for shipment at ambient temperature without any effect on the assigned values. 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

This standard was produced under WHO guidelines cited in the WHO Technical Reports Series, No. 800, 1990, Annex 4.

10. ACKNOWLEDGEMENTS

N/A

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

Physical and Chemical properties		
Physical	Corrosive:	No
appearance:		
Freeze-dried		
powder		
Stable: Yes	Oxidising:	No
Hygroscopic:No	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: S	eek medical advid	ce
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: 4.6g

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable. Attached: No

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