Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**Non WHO Reference Material**
**Rec. Single Chain Urinary-Type Plasminogen Activator (SCuPA), (Glyc)**
**NIBSC code: 95/668**
**Instructions for use**
**(Version 5.0, Dated 02/04/2008)**

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

## 1. INTENDED USE

This is comprised of a batch of ampoules coded 95/668. Each ampoule contains the residue after freeze drying of an accurately measured 1ml of SCuPA (Glyc.) solution which was made up of 50 micrograms of SCuPA in 0.01M phospate buffer pH7.4, containing 5mgs of pig collagen fraction per ml as stabiliser (Gaffney et al 1996)

## 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. UNITAGE

6,800 IU*/ampoule (by clot lysis assay, Heath & Gaffney, 1990)
7,500 IU*/ampoule (by chromogenic assay)

* This unit has been defined by the International Standard for high molecular weight (HMW) urinary-type plasminogen activator (u-PA) (Gaffney & Heath, 1990).

## 4. CONTENTS

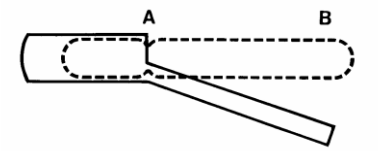
Country of origin of biological material: United Kingdom.
The bulk material was supplied by Abbott Laboratories (Chicago, USA) through the good offices of Dr A. Sashara as a frozen liquid. Following thawing this was diluted to 50 micrograms of ScuPA per ml using 0.01M phosphate buffer, pH7.4, containing 5mgs per ml of a pig collagen fraction (PCF) otherwise known as Prionex (from Pentapharm, Basel, Switzerland). This latter stabiliser allowed this reagent to be used as a standard in electropheretic gels since only the SCuPA was visualised by staining.

## 5. STORAGE

The reconstituted reagent should be used as soon as possible after reconstitution. Unopened ampoules should be stored at -20ºC.
**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

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The total contents of the ampoule should be reconstituted with 1.0ml distilled water and dissolved gently by swirling to avoid froth. No attempt should be made to weigh out any portion of the freeze dried material.

## 8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials. Following ampouling at +4ºC by the procedures outlined by Campbell (1974) the stability was established by indicating no loss in activity when stored at 4ºC for 1 year.

## 9. REFERENCES

Campbell, P.J (1974) J. Biol. Stand. 2: 259-267

Gaffney P.J, Edgell T.A, Dawson P.J, Ford A.W, Stocker, K. J (1996) Pharm. Pharmacol. 48, 896-898

Gaffney, P.J, Heath, A.B. (1990) Thromb. Haemost. 64, 398-401

## 10. ACKNOWLEDGEMENTS

## 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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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): | Contains material of human 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 an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water.<br>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**

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|---|
| ***Country of origin for customs purposes*:*** *United Kingdom*<br>** 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:*** *10 mg* |
| ***Toxicity Statement:*** *Toxicity not assessed* |
| ***Veterinary certificate or other statement*** *if applicable.*<br>***Attached:*** *No* |