Medicines & Healthcare products Regulatory Agency



#### WHO International Standard 1st Standard for Interleukin-8 (Human, rDNA derived) NIBSC code: 89/520 Instructions for use (Version 7.0, Dated 23/04/2013)

#### 1. INTENDED USE

This International Standard is the primary biological standard for IL-8.

## 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 agreed on the basis of a WHO International Collaborative Study is 1,000 International Units of biological activity per ampoule.

## 4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains a freeze dried residue comprising, under an atmosphere of nitrogen:

IL-8, approximately 1 microgram 4.5 mg sodium chloride 3 mg trehalose

The IL-8 protein was expressed in E. coli.

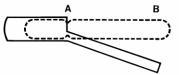
## 5. STORAGE

Due to the instability of IL-8 at low concentrations it is recommended that the solution be stored at  $+4^{\circ}$ C for no longer than one week. Unopened ampoules should be stored at  $-20^{\circ}$ 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.

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

#### 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 with 0.5ml of sterile distilled water. Rinse the ampoule with about 0.4ml of sterile phosphate buffered saline (PBS) and make up the total volume to 1.0ml with PBS. This solution will contain IL-8 at a concentration of 1,000 International Units/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. It is the policy of WHO not to assign an expiry date to their international reference materials. Accelerated degradation studies have indicated that this material is suitably stable, when stored at -20°C or below, for the assigned values to remain valid until the material is withdrawn or replaced. These studies have also shown that 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

Mire-Sluis, A.R, Gaines Das, R., Thorpe, R et al (1997) Implications for the assay and biological activity of interleukin-8: results of a WHO international collaborative study. Journal of Immunological Methods, 200, 1-16

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

Phys	ical and Chemic	al properties	
Physical	Corrosive:	No	
appearance:			
Lyophilised powder			
Stable: Yes	Oxidising:	No	
Hygroscopic:No	Irritant:	No	
Flammable:No	Handling:	See caution, Section 2	
Other (specify):			
	Toxicological p	properties	
Effects of inhalation: No adverse effects reported for this material			
Effects of ingestion: N	lo adverse effect	s reported for this material	
Effects of skin absorp	tion:No adverse	effects reported for this material	
	Suggested F	irst Aid	
Inhalation:Seek medical advice			
Ingestion: Seek medic	al advice		
Contact with eyes: Wash with copious amounts of water. Seek			
medical advice			
Contact with skin: V	Vash thoroughly	with water.	
Action o	n Spillage and I	lethod of Disposal	
material wetted with a appropriate disinfecta	in appropriate dis nt followed by wa	e taken up with absorbent sinfectant. Rinse area with an ater. age should be treated as	

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		

## 17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards

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

http://www.who.int/bloodproducts/publications/TRS932Annex2\_Inter\_biol efstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.

