

**WHO International Standard
ARGININE VASOPRESSIN (AVP) 1st International Standard
NIBSC code: 77/501
Instructions for use
(Version 5.0, Dated 19/03/2008)**

1. INTENDED USE

Calibrant for arginine vasopressin bioassays.

Stocks of this WHO international standard for arginine vasopressin (AVP), ampoule code 77/501, will soon be exhausted and NIBSC has no plans to make a replacement standard because AVP is no longer classified as a biological by NIBSC since this substance can be adequately characterised by physico-chemical tests. The USP issues a standard that was calibrated against the IS and the EP issues a standard for the HPLC test described in that Pharmacopoeia.

2. CAUTION

This preparation is not for administration to humans.

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

Each ampoule contains approx. 20µg arginine vasopressin.
The assigned potency is 8.2 international units (IU) per ampoule

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze-drying of a solution that contained:

20µg Arginine Vasopressin
5mg human serum albumin
1ml N/200 citric acid

This material has not been sterilized and contains no bacteriostat.

5. STORAGE

Store at -20°C or below.

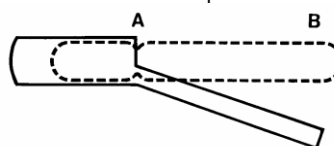
Arginine vasopressin is less likely to dimerize within the pH range 3.0-4.0
Unopened ampoules of the Standard should be stored below 0°C.

For economy of use, a solution of the standard (pH 3.0-4.0) containing a suitable preservative (eg 0.2% chlorbutol) may be stored at +4°C in tightly-closed containers for at least 3 months

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

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.

* See section 5 above

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.

Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

WHO Expert Committee on Biological Standardisation (1978), 30th Report.
WHO Technical Report Series No. 638, 1979.
Delderfield et al., J Biol Stds. 1978, 6, 331

10. ACKNOWLEDGEMENTS

The help of the following is gratefully acknowledged:
Professor G A Moore for synthesizing and supplying the arginine vasopressin with aid from MRC, Canada;
Dr E Stürmer and Professor G W Bisset for preliminary stability studies.
Dr P Corran (NIBSC) for chromatographic analyses and the participants in the International Collaborative Study.

11. FURTHER INFORMATION

Further information can be obtained as follows;

This material:

enquiries@nibsc.hpa.org.uk

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.who.int/biologicals/reference_preparations/en/

Ordering standards from NIBSC:

http://www.nibsc.ac.uk/products/ordering_information/frequently_asked_questions.aspx

NIBSC Terms & Conditions:

http://www.nibsc.ac.uk/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.hpa.org.uk

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

Physical and Chemical properties	
Physical appearance: Freeze-dried	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains dried 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 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

Information provided by the Institute is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but it is provided without liability to the Recipient in its application and use.

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If any of the Goods supplied by the Institute should prove not to meet their specification when stored and used correctly (and provided that the Recipient has returned the Goods to the Institute together with written notification of such alleged defect within seven days of the time when the Recipient discovers or ought to have discovered the defect), the Institute shall either replace the Goods or, at its sole option, refund

the handling charge provided that performance of either one of the above options shall constitute an entire discharge of the Institute's liability under this Condition.

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: 1g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No