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Desmopressin Tablets

General Notices

Details for the public consultation of this monograph are as follows:

EAG/Panel/Working Party	Biological and Biotechnological Products
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Notes:	Revised monograph Updated to more accurately reflect the salt form of the licensed preparations

Action and use

Vasopressin analogue; treatment of diabetes insipidus; nocturnal enuresis.

DEFINITION

Desmopressin Tablets contain Desmopressin Acetate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of desmopressin acetate, $C_{48}H_{68}N_{14}O_{14}S_2$

90.0 to 110.0% of the stated amount of the peptide.

IDENTIFICATION

In the test for Uniformity of content, the principal peak in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 75 revolutions per minute.
(b) Use 500 mL of *water* as the medium.

PROCEDURE

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) After 45 minutes, withdraw a 20 mL sample of the medium and filter.
(2) Prepare a solution of *desmopressin BPCRS* in *water* with a final concentration equal to that expected for solution (1).

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Uniformity of content may be used.

DETERMINATION OF CONTENT

Calculate the total content of desmopressin $C_{46}H_{64}N_{14}O_{12}S_2$, in the medium using the declared content of $C_{46}H_{64}N_{14}O_{12}S_2$ in *desmopressin BPCRS*.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions and the *normalisation procedure*:

(1) Shake a quantity of powdered tablets containing 0.5 mg with 1 mL of *water* to give a final concentration of 0.05% w/v of the peptide.
(2) Dissolve the contents of a vial of *desmopressin impurity standard BPCRS* in 0.5 mL of *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (12 cm x 4.0 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 220 nm.
(f) Inject 50 µL of each solution.

MOBILE PHASE

Mobile phase A *0.067M mixed* *phosphate buffer solution pH 7.0*.

Mobile phase B 10 volumes of *acetonitrile for chromatography* and 10 volumes of mobile phase A.

Time (Minutes)	Mobile phase A%	Mobile phase B%	Comment
0-4	76	24	isocratic
4-18	76→58	24→42	linear gradient
18-35	58→48	42→52	linear gradient
35-40	48→76	52→24	linear gradient
40-50	76	24	re-equilibration

The retention time of desmopressin is about 16 minutes.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *resolution* between the two principal peaks is at least 3.4.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not more than 2.0%;

the total area of any such peaks is not more than 4.0%.

Disregard any peak due to the solvent or with a relative amount less than 0.05%.

Uniformity of content

Tablets containing less than 2 mg and/or less than 2% w/w of Desmopressin Acetate comply with the requirements stated under Tablets using the following method of analysis. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions:

(1) Add sufficient *water* to one tablet to produce a solution containing 0.01% w/v of the peptide.
(2) 0.01% w/v of *desmopressin BPCRS* in *water*.
(3) Dissolve the contents of a vial *desmopressin impurity standard BPCRS*in 0.5 mL of *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (12 cm x 4.0 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 ml per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 220 nm.
(f) Inject 50 µl of each solution.

MOBILE PHASE

2 volumes of *acetonitrile for chromatography* and 8 volumes of *0.067M mixed phosphate buffer solution pH 7.0*.

The retention time of desmopressin is about 5 minutes.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the two principal peaks at least 2.8.

DETERMINATION OF CONTENT

Calculate the content of $C_{48}H_{68}N_{14}O_{14}S_2$ in each tablet from the chromatograms obtained and from the declared content of $C_{46}H_{64}N_{14}O_{12}S_2$ in *desmopressin BPCRS*.

ASSAY

Use the average of the individual results determined in the test for Uniformity of content.

STORAGE

Desmopressin Tablets should be protected from moisture.