Pyridoxine Tablets

General Notices

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

<table>
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<th>EAG MC3</th>
<th>Medicinal Chemicals 3</th>
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<tr>
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<td>Notes:</td>
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Action and use

Vitamin B₆.

DEFINITION

Pyridoxine Tablets contain Pyridoxine Hydrochloride.

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

Content of pyridoxine hydrochloride, C₈H₁₁NO₃HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing 20 mg of Pyridoxine Hydrochloride with 50 mL of 0.025 M standard phosphate buffer for 15 minutes, dilute to 100 mL with the same solvent and filter. Dilute 5 mL of the filtrate to 100 mL with the same solvent. The light absorption of the resulting solution, Appendix II B, in the range 230 to 350 nm exhibits two maxima, at 254 nm and 324 nm.

B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is the same as that of the principal peak 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 50 revolutions per minute.
(b) Use 900 mL of 0.1M hydrochloric acid, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a sample of the medium and measure the absorbance of the filtered sample, suitably diluted with the dissolution medium if necessary, at the maximum at 368 nm, Appendix II B using dissolution medium in the reference cell.
(2) Measure the absorbance of a suitable solution of pyridoxine hydrochloride BPCRS in dissolution medium using dissolution medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of C₈H₁₁NO₃.HCl in the medium using the declared content of C₈H₁₁NO₃.HCl in pyridoxine hydrochloride BPCRS.

LIMITS

The amount of pyridoxine released is not less than 75% (Q) of the stated amount.

Related substances

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

(1) Shake a quantity of the powdered tablets containing 50 mg of Pyridoxine Hydrochloride with 15 mL of water, dilute to 20 mL with water and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with water, dilute 1 volumes of this solution to 5 volumes with water.
(3) 0.005% w/v of each pyridoxine impurity A EPCRS and 4-deoxypyridoxine hydrochloride (impurity B) in water.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with base-deactivated octadecylsilyl silica gel for chromatography (5 µm) (Hypersil BDS C18 is suitable).
(b) Use isocratic 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 210 nm.
(f) Inject 5 µL of each solution.
(g) Allow the chromatography to proceed for 3 times the retention time of pyridoxine.
MOBILE PHASE

0.272% w/v of potassium dihydrogen orthophosphate, adjusted to pH 3.0 with dilute orthophosphoric acid.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to pyridoxine (retention time about 5 minutes) are: impurity A, about 1.7; impurity B, about 1.9.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks due to impurity A and impurity B is at least 1.5.

in the chromatogram obtained by solution (3), the signal to noise ratio of the principal peak is at least 40.

LIMITS

Identify any peak corresponding to impurity B in the chromatogram obtained with solution (1), using the chromatogram obtained with solution (3), and multiply the area of this peak by a correction factor of 1.5.

In the chromatogram obtained with solution (1):

the area of any secondary peak is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%)

the sum of the areas of all secondary peaks is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (1%).

Disregard any peak with an area less than half the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for liquid chromatography, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 50 mg of Pyridoxine Hydrochloride with 15 mL of water, dilute to 20 mL with water and filter. Dilute 1 volume of the filtrate to 25 volumes with water
(2) 0.01% w/v solution of pyridoxine hydrochloride BPCRS in water.
(3) 0.005% w/v of each pyridoxine impurity A EPCRS and 4-deoxypyridoxine hydrochloride (impurity B) in water.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the resolution between the peaks due to impurity A and impurity B is at least 1.5.
in the chromatogram obtained by solution (3), the signal to noise ratio of the principal peak is at least 40.

DETERMINATION OF CONTENT

Calculate the content of $C_8H_{11}NO_3\cdot HCl$ in the tablets using the declared content of $C_8H_{11}NO_3\cdot HCl$ in pyridoxine hydrochloride BPCRS.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Pyridoxine Hydrochloride.

STORAGE

Pyridoxine Tablets should be protected from light and stored at a temperature not exceeding 30°.

When vitamin B₆ tablets are prescribed or demanded, Pyridoxine Tablets shall be dispensed or supplied.