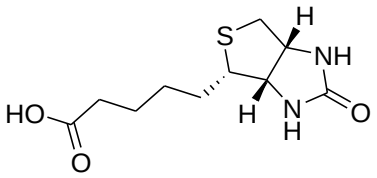
Biotin



$C_{10}H_{16}N_2O_3S$ Mol. Wt. 244.3

Biotin is 1*H*-Thieno[3,4-*d*]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3a*S*-(3aα,4β,6aα)]; (3a*S*,4*S*,6a*R*)-Hexahydro-2-oxo-1*H*-thieno[3,4-*d*]imidazole-4-valeric acid.

Biotin contains not less than 97.5 per cent and not more than 102.0 per cent of $C_{10}H_{16}N_2O_3S$.

Category. Vitamin

Description. A white crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *biotin IPRS* or with the reference spectrum of biotin.

B. Specific optical rotation (see Test).

C. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Specific optical rotation (2.4.22). +89° to +93°, determined in 2.0 per cent w/v solution in *0.1 M sodium hydroxide.*

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *acetonitrile* and 80 volumes of *water*.

Test solution. Dissolve 0.1 g of the substance under examination in the solvent mixture and dilute to 100.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture.

Reference solution. A 0.01 per cent w/v solution of *biotin IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octylsilane bonded to porous silica (3 µm),
- mobile phase: a mixture of 91.5 volumes of a buffer solution prepared by dissolving 1 g of *sodium perchlorate monohydrate* in 1000 ml of *water*, containing 1 ml of *orthophosphoric acid* and 8.5 volumes of *acetonitrile*,
- flow rate: 1.2 ml per minute,
- spectrophotometer set at 200 nm,
- injection volume 50 µl.

Inject the test solution. The area of any secondary peak is not more than 1.0 per cent and the sum of the areas of all the secondary peaks is not more than 2.0 per cent, calculated by area normalization.

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{10}H_{16}N_2O_3S$.

Storage. Store protected from moisture.

Solubility: Very slightly soluble in *water* and in *ethanol*; insoluble in other common *organic solvents.*