Omeprazole Sodium (Cas No 95510-70-6)

TAJMTF-OLTMNV4728

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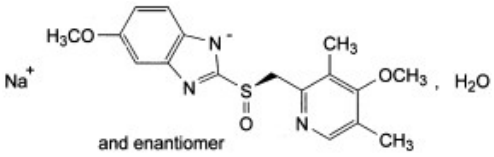
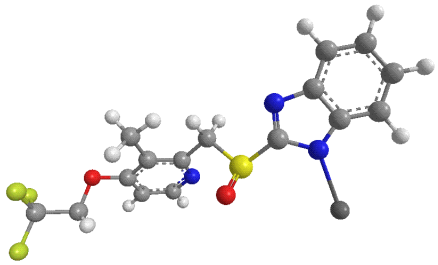
Omeprazole Sodium

(Ph Eur monograph 1032)





CAS NO. 95510-70-6

Molecular Formula: $C_{17}H_{18}N_3NaO_3S$,H_2O

Molecular Weight: **367.397890 [g/mol]**

Synonyms:
Losec Sodium, Andra, Nexium IV, Esomeprazole Sodium, OMEPRAZOLE SODIUM, Losec sodium (TN), Nexium IV (TN), H 168/68 sodium, Omeprazole sodium [USAN], Omeprazole sodium (USAN), Esomeprazole sodium (USAN), LS-33032, D01207, D04056, 1H-Benzimidazole, 5-methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl)-, sodium salt, 95510-70-6, 5-Methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridyl)methyl)sulfinyl)benzimidazole, sodium salt, 161796-78-7

DEFINITION
Sodium 5-methoxy-2-[(RS)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulphinyl]-1Hbenzimidazole monohydrate.

Content
98.0 per cent to 101.0 per cent (anhydrous substance).

CHARACTERS

Appearance
White or almost white, hygroscopic powder.

Solubility
Freely soluble in water and in ethanol (96 per cent), soluble in propylene glycol, very slightly soluble in methylene chloride.

IDENTIFICATION

ıA. Ultraviolet and visible absorption spectrophotometry (2.2.25).
Test solutionıDissolve 2.0 mg in 0.1 M sodium hydroxide and dilute to 100.0 ml with the same solvent.
Spectral rangeı230-350 nm.

Spectral rangeı230-350 nm.
Absorption maximaıAt 276 nm and 305 nm.
Absorption ratioıA305 / A276 = 1.6 to 1.8.
ıB. Examine the chromatograms obtained in the test for impurity C.
ResultsıThe principal spot in the chromatogram obtained with test solution (b) is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a). Place the plate in a tank saturated with vapour of acetic acid R. The spots rapidly turn brown.
ıC. Ignite 1 g and cool. Add 1 ml of water R to the residue and neutralise with hydrochloric acid R. Filter and dilute the filtrate to 4 ml with water R. 0.1 ml of the solution gives reaction (b) of sodium (2.3.1).

TESTS

Solution S
Dissolve 0.50 g in carbon dioxide-free water R and dilute to 25 ml with the same solvent.

Appearance of solution
Solution S is clear (2.2.1) and not more intensely coloured than reference solution B6 (2.2.2, Method II).

pH (2.2.3)
10.3 to 11.3 for solution S.

Impurity C
Thin-layer chromatography (2.2.27).
Test solution (a)ıDissolve 0.10 g of the substance to be examined in 2.0 ml of methanol R.
Test solution (b)ıDilute 1.0 ml of test solution (a) to 10 ml with methanol R.
Reference solution (a)ıDissolve 9 mg of omeprazole CRS in 2.0 ml of methanol R.
Reference solution (b)ıDilute 1.0 ml of test solution (b) to 100 ml with methanol R.
PlateıTLC silica gel F254 plate R.
Mobile phaseıMix 20 volumes of 2-propanol R, 40 volumes of methylene chloride R previously shaken with concentrated ammonia R (shake 100 ml of methylene chloride R with 30 ml of concentrated ammonia R in a separating funnel, allow the layers to separate and use the lower layer) and 40 volumes of methylene chloride R.
Applicationı10 µl.
DevelopmentıOver a path of 15 cm.
DryingıIn air.
DetectionıExamine in ultraviolet light at 254 nm.
LimitıTest solution (a):
ı
ı— impurity C: any spot with a higher RF value than that of the spot due to omeprazole is not (b) (0.1per cent). more intense than the spot in the chromatogram obtained with reference solution (b) (0.1 per cent).

Related substances
Liquid chromatography (2.2.29).
Test solutionıDissolve 3.0 mg of the substance to be examined in the mobile phase and dilute to 25.0 ml with the mobile phase.
Reference solution (a)ıDissolve 1.0 mg of omeprazole CRS and 1.0 mg of omeprazole

impurity D CRS in the mobile phase and dilute to 10.0 ml with the mobile phase.
Reference solution (b)ıDilute 1.0 ml of the test solution to 100.0 ml with the mobile phase.
Dilute 1.0 ml of this solution to 10.0 ml with the mobile phase.
Column: ı
ı— size: l = 0.15 m, Ø = 4 mm;
ı— stationary phase: octylsilyl silica gel for chromatography R (5 µm).
Mobile phaseıMix 27 volumes of acetonitrile R and 73 volumes of a 1.4 g/l solution of disodium hydrogen phosphate R, previously adjusted to pH 7.6 with phosphoric acid R.
Flow rateı1 ml/min.
DetectionıSpectrophotometer at 280 nm.
Injectionı40 µl.
Run timeı3 times the retention time of omeprazole.
Relative retentionıWith reference to omeprazole (retention time = about 9 min): impurity D = about 0.8.
System suitabilityıReference solution (a):
ı— resolution: minimum 3 between the peaks due to impurity D and omeprazole; if necessary adjust the pH of the mobile phase or the concentration of acetonitrile R; an increase in the pH will improve the resolution.
Limit:
ı— any impurity: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent).
Heavy metals (2.4.8)
Maximum 20 ppm.
1.0 g complies with test C. Prepare the reference solution using 2 ml of lead standard solution (10 ppm Pb) R.

Water (2.5.12)
4.5 per cent to 10.0 per cent, determined on 0.300 g.

ASSAY
Dissolve 0.300 g in 50 ml of water R. Titrate with 0.1 M hydrochloric acid , determining the end-point potentiometrically (2.2.20).
1 ml of 0.1 M hydrochloric acid corresponds to 36.74 mg of C17H18N3NaO3S.Heavy metals (2.4.8)
Maximum 20 ppm.
1.0 g complies with test C. Prepare the reference solution using 2 ml of lead standard solution (10 ppm Pb) R.

STORAGE
In an airtight container , protected from light.
IMPURITIES
Specified impuritiesıC.
Other detectable impuritiesı(The following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use): A, B, D, E.