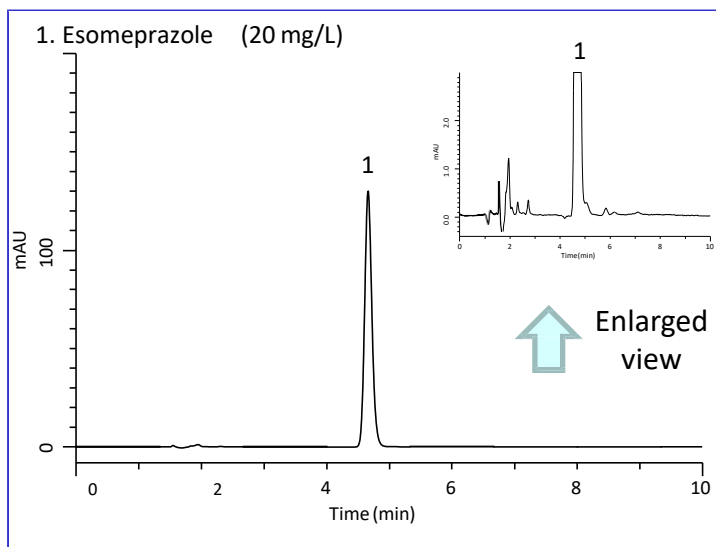


Assay Test for Esomeprazole Magnesium Delayed-Release Capsules under USP Method

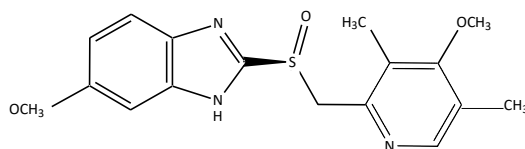
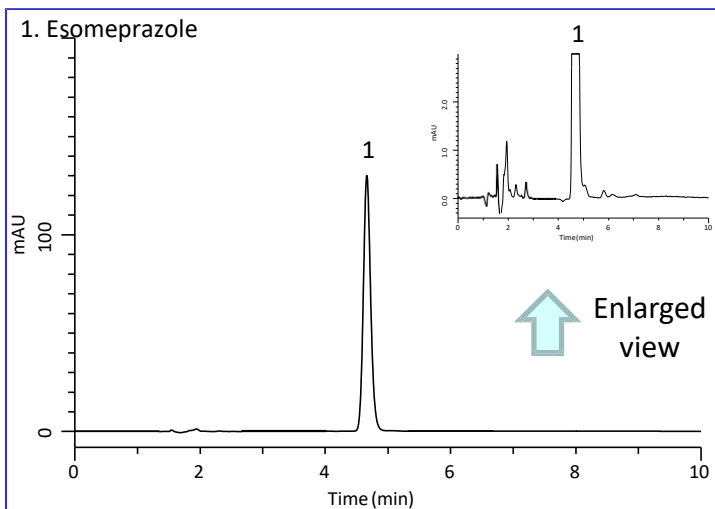
Esomeprazole Magnesium is a proton-pump inhibitor drug product. It is used for the treatment of gastric ulcers, duodenal ulcers and eradication of *Helicobacter pylori*.

In this note, Assay test results conducted under the United States Pharmacopeia (USP) by using InertSustain C18 are shown.

Standard solution



Capsule Sample



Structures are created using Chemistry 4-D Draw which is provided by ChemInnovation Software, Inc.

Conditions (USP)

Analytical column : InertSustain C18
(5 μ m, 150 x 4.6 mm I.D.)

Column Cat. No. : 5020-07345

Eluent : Buffer*

Flow rate : 1.0 mL/min

Column temp. : 25 $^{\circ}$ C

Detection : UV 302 nm

Injection Vol. : 20 μ L

* Buffer: a pH 7.3 phosphate buffer was prepared by mixing 10.5 mL of 1.0 M monobasic sodium phosphate buffer with 60 mL of 0.5M dibasic sodium phosphate buffer and then diluted with 1000 mL of water.

350mL of acetonitrile for HPLC is added to 500 mL of the solution above and then diluted with water to 1000 mL.

Example of Pretreatment Method for

Sample

Capsule Sample

Take out the contents from 20 capsules. Then mix the contents.

Transfer a portion of the Capsule content, equivalent to 20 mg of esomeprazole, to a 100 mL volumetric flask.

Extraction

Add 60 mL of diluent**.

Shake for 20 min and then sonicate for 2 min to completely dissolve the sample.

Add 20 mL of methanol and then sonicate for 2 min.

Cool the sample.

Dilution

Dilute to volume with 100 mL of diluent**. Filtrate with a 1 μ m filter

HPLC

GL Sciences disclaims any and all responsibility for any injury or damage which may be caused by this data directly or indirectly. We reserve the right to amend this information or data at any time and without any prior announcement.

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