

BRIEFING

**Esomeprazole Magnesium.** This revision to the official USP monograph was posted on the USP Pending Monographs Web page as a draft USP Pending Monograph on April 30, 2010, and has been available for review and public comment for more than 90 days. The SM3 Expert Committee has reviewed all comments received and approved the monograph as an Authorized USP Pending Monograph. The Authorized USP Pending Monograph includes only sections that are different from the currently official USP monograph for Esomeprazole Magnesium, namely additional chemical information (molecular formula and molecular weight for the dihydrate form), *Identification* test A, the tests for *Water Determination* and for *Crystallinity*, the *Labeling* requirement, and the *Packaging and Storage* section.

The following is a summary of comments received and the Expert Committee's response:

**Comment 1.** The commenter requested widening of the range for *Water Determination* for amorphous material from 7.0%–9.0% to 7.0%–10.0% and submitted stability data to support the request.

**Response:** Comment incorporated.

**Comment 2.** The commenters requested revision of the test for *Color of solution* in the currently official USP monograph for Esomeprazole Magnesium to indicate that the *Sample solution* should be filtered. The commenters noted that this revision would make the test consistent with the test for *Appearance of solution* in the Esomeprazole Magnesium Trihydrate monograph in the *European Pharmacopoeia*.

**Response:** The SM3 Expert Committee will consider a future revision to the USP monograph for Esomeprazole Magnesium to address this issue.

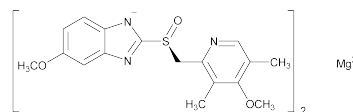
**Comment 3.** The commenter stated that its dihydrate material could not meet the requirements of the test for *Color of solution* and requested that either a statement indicating that this test is not applicable to the dihydrate form be included in the monograph or that the limit be increased from NMT 0.2 to NMT 0.5.

**Response:** Comment not incorporated, because several sponsors stated that their materials (both amorphous and dihydrate) meet the requirements of this test.

(SM3: E.Gonikberg.)  
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## Esomeprazole Magnesium

v.1 Authorized January 1, 2011



$C_{34}H_{36}MgN_6O_6S_2 \cdot 3H_2O$  767.17  
[217087-09-7].

$C_{34}H_{36}MgN_6O_6S_2 \cdot 2H_2O$  749.15  
[217087-10-0].

Anhydrous 713.12

1*H*-Benzimidazole, 5-methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl], magnesium salt (2:1);  
5-Methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridyl)-methyl]sulfinyl]benzimidazole, magnesium salt (2:1)

### IDENTIFICATION

- **A. INFRARED ABSORPTION (197K):** [NOTE—If a difference appears in the IR spectra of the analyte and the Standard, separately dissolve equal portions of the sample specimen and the USP Reference Standard in equal volumes of methanol, evaporate the solution to dryness in similar containers under identical conditions, and repeat the test on the residues.]

### SPECIFIC TESTS

- **WATER DETERMINATION, Method I (921):** 6.0%–8.0%. If labeled as a dihydrate: 4.5%–7.0%. If labeled as amorphous: 7.0%–10.0%.
- **CRYSTALLINITY (695):** If it is labeled as amorphous, most of the particles do not exhibit birefringence and extinction positions.

### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light. Store at room temperature. If it is labeled as amorphous, store at a temperature 2°–8° under nitrogen atmosphere.
- **LABELING:** Where it is a dihydrate form, the label so indicates. Where it is an amorphous form, the label so indicates.