

BRIEFING

Esomeprazole Magnesium. A USP Pending Monograph revision is proposed to add a dihydrate form of Esomeprazole Magnesium to the monograph. Currently, there is an official *USP–NF* monograph for this drug substance which differs from this form with respect to the *Water* content.

It is proposed to revise the test for *Water* to provide a separate requirement for the dihydrate form. The revision proposal therefore includes only the additional chemical information (molecular formula, molecular weight, and CAS number) for the dihydrate form, the test for *Water*, and a *Labeling* requirement. It is also proposed to delete the term “trihydrate” from the chemical names in the chemical information section. This proposal will be adopted into the *USP–NF* via a flexible monograph approach once the full FDA approval is received for a drug product using a dihydrate form of the active ingredient.

(MD-GRE: E. Gonikberg.) RTS—C77656

SPECIFIC TESTS

Change to read:

- **WATER DETERMINATION, Method I (921):** 6.0%–8.0%. ▶ If labeled as a dihydrate: 4.5%–7.0%. ◀ (1-Mar-2010)

ADDITIONAL REQUIREMENTS

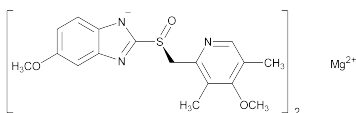
Add the following:

- ▶ **LABELING:** Where it is a dihydrate form, the label so indicates. ◀ (1-Mar-2010)

Esomeprazole Magnesium

Draft 1

Change to read:



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

▶ $C_{34}H_{36}MgN_6O_6S_2 \cdot 2H_2O$ Dihydrate: 749.15
[217087-10-0]. ◀ (1-Mar-2010)

$C_{34}H_{36}MgN_6O_6S_2$ Anhydrous: 713.12
1*H*-Benzimidazole, 5-methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl], magnesium salt (2:1); ~~trihydrate~~
▶ ◀ (1-Mar-2010)

5-Methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]benzimidazole, magnesium salt (2:1) ~~trihydrate~~ ◀ (1-Mar-2010)