



PF 45(6),

**No Comments were received for the following when they were proposed in Pharmacopeial Forum:**

Goserelin Acetate

**Comments were received for the following when they were proposed in Pharmacopeial Forum:**

**Monographs:**

Zolmitriptan

**Monograph/Sections:** Zolmitriptan / Multiple sections  
**Expert Committee:** Chemical Medicines Monographs 4  
**No. of Commenters:** 2

**Comment #1:** The commenter requested revising the Relative response factor (RRF) for 'zolmitriptan related compound G' from 0.52 to 1.18 and the RRF for 'zolmitriptan related compound F' from 0.41 to 0.59 within the test for *Limit of Zolmitriptan R-Isomer and Other Impurities*.

**EC Response:** Comment not incorporated. The comment is outside of the scope of the revision. The Expert Committee will consider future revisions to the monograph upon receipt of additional supporting information.

**Comment #2:** The commenter requested removing the 'reporting threshold' from the tests for *Organic Impurities* and for *Limit of Zolmitriptan R-Isomer and Other Impurities* as the appropriate value will vary based on product-specific factors that should be addressed as an application assessment issue.

**EC Response:** Comment not incorporated. The comment is outside of the scope of the revision. A general position regarding the inclusion or absence of reporting thresholds in monographs is still under discussion. The Expert Committee will consider future revisions to the monograph upon the outcome of these discussions.

**Comment #3:** The commenter requested removing the 'reporting threshold' from the test for *Limit of Zolmitriptan R-Isomer and Other Impurities* because the reporting threshold of 0.10% exceeds the ICH reporting threshold and is inconsistent with the acceptance limits for 'zolmitriptan related compound G' and for 'any individual unspecified impurity' at 0.1% each.

**EC Response:** Comment not incorporated. The comment is outside of the scope of the revision. A general position regarding the inclusion or absence of reporting thresholds in monographs is still under discussion. The Expert Committee will consider future revisions to the monograph upon the outcome of these discussions.