



Commentary

PF 48(4)

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

Monographs:

Ziprasidone Hydrochloride

Monographs

Monograph/Sections: Ziprasidone Hydrochloride/Organic Impurities

Expert Committee: Small Molecules 4

No. of Commenters: 2

Comment Summary #1: The commenter recommended removing the reporting threshold in the test for *Organic Impurities* as it will vary based on product-specific factors.

Response: Comment not incorporated. USP is considering the issue of the removing reporting thresholds from certain monographs. A proposal for a new general chapter, (477) User-Determined Reporting Thresholds, was published in PF 48(5) for public comment. The responsible Expert Committee will review the comments and determine any next steps for the chapter.

Comment Summary #2: The commenter requested removing the first of two molecular weight correction factor ratios from the equation used to calculate the percentage of chloroindolinone, ziprasidone related compound F, and any unspecified impurity, in the test for *Organic Impurities*.

Response: Comment not incorporated. The use of two molecular weight correction factor ratios in the equation is needed to reflect how the relative response factors were validated. The resulting equation is consistent with the sponsor's test procedure.