

Nefazodone Hydrochloride

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monograph Development—Psychiatrics and Psychoactives

In accordance with section 9.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the USP 2005–2010 Monograph Development-Psychiatrics and Psychoactives Expert Committee (MD-PP) intends to revise the Nefazodone hydrochloride monograph based on comments received indicating that the current Identification test B for chloride counter ion cannot be successfully performed. It is proposed to change the solvent for the Nefazodone hydrochloride from water to methanol due to the slightly soluble nature of drug substance in water.

It is anticipated that the proposed revisions will be published in Pharmacopeial Forum 35(3) [May–June 2009] as a proposed Interim Revision Announcement pursuant to section 9.02(b) of the Rules and Procedures. In the absence of any adverse comments, the revision will be published as final in Pharmacopeial Forum 35(5) [Sept–Oct 2009] with an official date of October 1, 2009.