

Sodium Fluoride and Acidulated Phosphate Topical Solution

Type of Posting: Notice of Intent to Revise

Posting Date: 07–Mar–2007

The USP 2005–2010 Monograph Development—Gastrointestinal, Renal and Endocrine Expert Committee has proposed a revision to the Sodium Fluoride and Acidulated Phosphate Topical Solution monograph. Comments were received that the current assay method employing ion-selective electrode has a history of poor precision for some over-the-counter formulations. To address these problems, a new assay method based on ion chromatography is proposed.

It is proposed to use a flexible monograph approach and to add this new method as Test 2, and also to add a Labeling requirement for the manufacturers using Test 2. With this approach, parties currently using the existing ion-selective electrode assay method would not be affected by this revision.

It is proposed to use a flexible monograph approach and to add this new method as Test 2, and also to add a Labeling requirement for the manufacturers using Test 2. With this approach, parties currently using the existing ion-selective electrode assay method would not be affected by this revision.

In addition, comments were received that the type of a calomel reference electrode, required in the test for pH, is no longer available. It is proposed to specify that a suitable electrode system could be used in pH procedure. This proposal also affects the Sodium Fluoride and Phosphoric Acid Gel monograph.

It is proposed to publish the revision proposal in Pharmacopeial Forum 33(3) [May–June 2007]. In the absence of any adverse comments, it is proposed to implement the revision via the Interim Revision Announcement pertaining to the *USP 30–NF 25*, with an official date of October 1, 2007.

Should you have any questions, please contact Elena Gonikberg, Ph.D., Senior Scientist and Liaison to the Monograph Development—Gastrointestinal, Renal, and Endocrine Expert Committee (301-816-8251 or eg@usp.org).