COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Fluoride USP (Item No. 41011390)	**Spec. No.** : SP-AK30-S34
Reference(s) : USP 39 p. 5871-5872	**Rev. No.** : 03
Other Requirements : -	**Page** : 1/2

USP 39

Test Items	Specification
Description	White, odorless powder.
Solubility	Soluble in water; insoluble in alcohol.
Identification A. Fluoride Test B. Sodium Test	 The surface of the glass is etched. Prepare a solution to contain 1 g of sample in 25 ml of water. Add 2 ml of 15% potassium carbonate, and heat to boiling. No precipitate is formed. Add 4 ml of potassium pyroantimonate TS and heat to boiling. Allow to cool in ice water and if necessary rub the inside of the test tube with a glass rod. A dense precipitate is formed.
Acidity or alkalinity	- If no color appears, a pink color persisting for 15 seconds is produced by not more than 2.0 ml of 0.10 N sodium hydroxide. - If the solution is colored pink by the addition of phenolphthalein TS, it is rendered colorless by not more than 0.50 ml of 0.10 N sulfuric acid.
Loss on drying	Not more than 1.0%.
Fluosilicate	Not more than 1.5 ml of 0.10 N sodium hydroxide is required.
Chloride	Not more than 0.012%.
Heavy metals	Not more than 30 ppm.
Assay	98.0-102.0% of NaF, calculated on the dried basis.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 06/12/16 Head of Raw Material Standard Section 1	J. Noppadech (Acting) / 06/12/16 Director of Raw Material Standard Division	Vichain Ruangwongsoj 06/12/16 Director of Regulatory Compliance and Documentation Division	A. Yotkuat / 14/12/16 Director of Quality Assurance Department	20/01/17

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Sodium Fluoride USP (Item No. 41011390).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S34.
Storage condition	Preserve in well-closed containers.
Retest period	1 year after first testing date.

History

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก BP 2007	20/11/09
02	เปลี่ยน Spec จาก BP2007 เป็น USP 37 เพื่อให้สอดคล้องกับ Finished product ซึ่งอ้างอิง USP 30 โดยเนื้อหาของ Monograph Sodium Fluoride ตาม USP 30 และ USP 37 เหมือนกัน	29/05/15
03	อ้างอิง CR No. AN80-59187 Up spec เป็น USP 39 เพื่อให้สอดคล้องกับ spec ของ Sodium Fluoride tablet 0.55 mg	20/01/17

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