



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Salicylic Acid BP
(Item No. 41023500)

Spec. No : SP-AK30-S2

Reference(s) : BP 2013 p. 1972-1973

Rev. No : 04

Other Requirements : -

Page : 1/2

BP 2013

Description : White or almost white, crystalline powder or white or colourless, acicular crystals.

Solubility : Slightly soluble in water, freely soluble in ethanol (96%), sparingly soluble in methylene chloride.

Identification : A. Melting point : 158 °C to 161 °C.
B. Infrared absorption spectrophotometry.
C. It gives reaction (a) of salicylates.

Appearance of solution : The solution (10% in ethanol 96%) is clear and colourless (Method II).

Related substances

— impurity A : not more than 0.1%;

— impurity B : not more than 0.05%;

— impurity C : not more than 0.02%;

— any other impurity : not more than 0.05%;

— total impurities : not more than 0.2%.

Chlorides : Maximum 100 ppm.

Sulfates : Maximum 200 ppm.

Heavy metals : Maximum 20 ppm.

Loss on drying : Maximum 0.5%.

Sulfated ash : Maximum 0.1%.

Assay : 99.0% to 100.5% of Salicylic Acid ($C_7H_6O_3$), calculated on the dried substance.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :	Approved by :	Eff. Date
S. Koppodechy, 29/05/17 Head of Raw Material Standard Section 2	Yunaporn, 29/05/17 Director of Raw Material Standard Division	VARAFIN, 29/05/17 Director of Regulatory Compliance and Documentation Division	B.C., 29/05/17 Director of Quality Assurance Department
			20/06/17

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Salicylic Acid BP (Item No. 41023500)	Spec. No : SP-AK30-S2
Reference(s) : BP 2013 p. 1972-1973	Rev. No : 04
Other Requirements : -	Page : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Salicylic Acid BP (Item No. 41023500).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other Tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S2.
Storage condition	Store at a condition stated on the label from the manufacturer. Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
03	Update ข้อกำหนดตาม BP 2011	29/04/11
04	Update ข้อกำหนดตาม BP 2013	20/06/17

เอกสารนี้ควบคุม
ใช้ในการจัดซื้อ

Prepared by : จ. ippoedech, 29/05/17 Head of Raw Material Standard Section 2	Reviewed by : yawuporn, 29/06/17 Director of Raw Material Standard Division	Approved by : B. Cu, 29/06/17 Director of Regulatory Compliance and Documentation Division	Eff. Date 20/06/17 Director of Quality Assurance Department
---	--	---	--