THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Salicylic Acid BP (Item No. 41023500)	**Spec. No.** : SP-AK30-S2
Reference(s): BP 2019 page II-838 to II-839	**Rev. No.** : 05
Other Requirements: GPO Specification	**Page** : 1/3

BP 2019

Test Parameters	Requirement
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	First identification: A, B. Second identification: A, C.
	A. Melting point: 158 °C to 161 °C.
	B. Infrared absorption spectrophotometry.
	C. It gives reaction (a) of salicylates.
Appearance of solution	The solution (1 g in 10 mL of 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%.
	Unspecified impurities : Not more than 0.05%.
	Total impurities : Not more than 0.2%.
Chlorides	Not more than 100 ppm.
Sulfates	Not more than 200 ppm.
Loss on drying	Not more than 0.5%.
Sulfated ash	Not more than 0.1%.
Assay	99.0% to 100.5% of Salicylic Acid ($C_7H_6O_3$), calculated on the dried substance.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 29/01/20	Tanmee Lulsorn / 30/01/20	/ 30/01/20	Vichien Rungrungroj / 31/01/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

GPO COPY No. 2

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GPO Specification

Test Parameter	Requirement
Heavy metals	Not more than 20 ppm.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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Other Requirements: GPO Specification	**Page** : 3/3

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Salicylic Acid BP (Item No. 41023500).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
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
05	Update ข้อกำหนดตาม BP 2019 และ GPO Specification โดยปรับหัวข้อ Heavy metals มาอยู่ใน GPO Specification เนื่องจากไม่ระบุใน monograph	15/03/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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