



The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER: RPP-SP-QC-RM-029

DOCUMENT TITLE: SPECIFICATION OF SODIUM LAURYL SULFATE ITEM NO. 44122550

DOCUMENT NOTES:

Document Information

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Author: NATTAPORN_R

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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	30 Sep 2015
02	<ul style="list-style-type: none"> - Revise specification as per USP40/NF35 - Added Identification specification C and D. <ul style="list-style-type: none"> • C. Foam forming: A copious foam is formed. • D. Chemical test: An intense blue color develops in the methylene chloride layer. - Added Assay (content of sodium alkyl sulfates) specification; Not less than 85% of sodium alkyl sulphates, calculated as $C_{12}H_{25}NaO_4S$. - Change specification of alkalinity from Not more than 0.6 ml for neutralization to Not more than 0.5 ml for neutralization. 	05 Mar 2018
03	<p>Periodic review and revise specification as per USP42/NF37</p> <p>Add Identification by Infrared absorption test parameter as per Change-20-064.</p> <p>Revise reference of Heavy metals (Method II) test parameter from USP40/NF35 to GPO In-house specification</p>	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description	Small, white or light yellow crystals; having a slight, characteristic odor.
02	Solubility	Freely soluble in water, forming an opalescent solution.
03	Identification	
	A. Infrared Absorption	The infrared absorption spectrum of the sample must be concordant with the spectrum of Sodium lauryl sulfate standard.
	B. Test for Sodium	A white, crystalline precipitate is formed.
	C. Test for Sulfate	Test solution shows positive test for sulphate with Barium Chloride TS and Lead acetate TS.
	D. Foam forming	A copious foam is formed.
	E. Chemical test	An intense blue color develops in the methylene chloride layer.
04	Assay (Content of sodium alkyl sulphates)	Not less than 85% of sodium alkyl sulphates, calculated as $C_{12}H_{25}NaO_4S$.
05	Heavy metals, Method II*	Not more than 20 ppm
06	Sodium chloride and Sodium sulfate	The combined content of sodium chloride and sodium sulfate is not more than 8.0%.
07	Alkalinity	Not more than 0.5 ml for neutralization.
08	Total alcohols	The residue represents the total alcohols and is not less than 59.0% of the weight of Sodium lauryl sulfate taken.
09	Unsulfated alcohols	The weight of the residue is not more than 4.0% of the weight of Sodium lauryl sulfate taken.

* According to GPO In-house Specification

B. Packaging and Storage

Preserve in well-closed containers.

C. Reference

According to USP42/NF37, Sodium Lauryl Sulfate monograph, page 5958-5959.

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D. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Sodium lauryl sulfate (Item No. 44122550).
Sampling plan	Identification: Every container. Other tests : $\sqrt{N} + 1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Sodium lauryl sulfate (Item No. 44122550).
Retest period	1 year.

Signature Manifest

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Step 1. Preparer

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Step 2. Reviewer

Name/Signature	Title	Date	Meaning/Reason
SUTAN OTAMO (SUTAN_O)	DIRECTOR OF QC DIVISION	09 Apr 2020, 04:33:06 PM	Approved
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NOPPAWAN ANGKULSANSANEE (NOPPAWAN_A)	DIRECTOR OF COMP Q SYS DIV.	15 Apr 2020, 12:37:49 PM	Approved

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Step 4. Notify

Name/Signature	Title	Date	Meaning/Reason
DONNAPA PUEKWATTANA (DONNAPA_P)	QA-IT&Doc	15 Apr 2020, 01:52:39 PM	Email Sent
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