

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium Bicarbonate BP

Spec. No. : SP-AK30-S8

(Item No. 41023660)

Reference(s): BP 2019 page II-880 to II-881

Rev. No. : 04

Other Requirements: GPO Specification

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BP 2019

Test Parameters	Requirement		
Description	White or almost white, crystalline powder.		
Solubility	Soluble in water, practically insoluble in ethanol (96%).		
Identification	A. A pale pink colour is produced. Heat; gas is evolved and the solution becomes red.		
	B. It gives the reaction of carbonates and bicarbonates.		
	C. It gives the reaction (a) of sodium.		
Appearance of solution	Solution S (5.0% w/v solution) is clear and colourless.		
Carbonates	The pH of freshly prepared Solution S is not greater than 8.6.		
Chlorides	Not more than 150 ppm.		
Sulfates	Not more than 150 ppm.		
Ammonium	Not more than 20 ppm.		
Arsenic	Not more than 2 ppm.		
Calcium	Not more than 100 ppm.		
Iron	Not more than 20 ppm.		
Assay	99.0% - 101.0% of NaHCO ₃ .		

GPO Specification

Test Parameter	Requirement				
Heavy metals	Not more than 10 ppm.	1 2	10 7		
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Approved by: Eff. Date Reviewed by: Prepared by: Tarmer Howelmy 27/01/20 28101120 23/01/20 15/02/20 J. Noppadech 23/01/20 Director of Quality Assurance Director of Raw Material Director of Drug Registration and Head of Raw Material Standard Section 2 Standard Division Pharmacovigilance Division. Department (A



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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Sodium Bicarbonate BP (Item No. 41023660).
Sampling plan	For Identification: 100%. For Other Tests: n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-S8.
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 ข้อกำหนคตาม BP 2014	15/09/14
04	Update ข้อกำหนดตาม BP 2019 และ GPO Specification	15/02/20

เอกสารใม่ควบคุม ใช้ในการจัดซื้อ

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