



COPY No.



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Bicarbonate BP (Item No. 41023660)	Spec. No : SP-AK30-S8
Reference(s) : BP 2014 p. II-824	Rev. No : 03
Other Requirements : -	Page : 1/3

BP 2014

Description	: White or almost white, crystalline powder, free from gritty particles; odourless.
Solubility	: Soluble in water, practically insoluble in ethanol (96 %).
Identification	: A. To 5 mL of test solution add 0.1 mL of phenolphthalein solution R. 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. [Test solution : 5.0%w/v in carbon dioxide-free water.]
Appearance of solution	: Test solution is clear (2.2.1) and colourless (2.2.2, Method II). [Test solution : 5.0%w/v in carbon dioxide-free water.]
Carbonates	: The pH of freshly prepared test solution is not greater than 8.6. [Test solution : 5.0%w/v in carbon dioxide-free water.]
Chlorides	: Maximum 150 ppm.
Sulfates	: Maximum 150 ppm.
Ammonium	: Maximum 20 ppm.
Arsenic <Method A>	: Maximum 2 ppm.
Calcium	: Maximum 100 ppm.
Iron	: Maximum 20 ppm.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Ruppachady, 10/09/14 Head of Raw Material Standard Section 2	Reviewed by : C. Suwanasopha, 10/09/14 Director of Raw Material Standard Division	Approved by : G. P., 12/09/14 Director of Regulatory Compliance and Documentation Division	Approved by : Prapachada, 12/09/14 Director of Quality Assurance Department	Eff. Date 15/09/14
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Page : 2/3

Heavy metals : Maximum 10 ppm.

Assay : 99.0% to 101.0% of NaHCO_3 .เอกสารไม่ควบคุม
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Prepared by : <u>J. Noppadach 10/09/14</u> Head of Raw Material Standard Section 2	Reviewed by : <u>C. Suwanmontani, 10/09/14</u> Director of Raw Material Standard Division	Approved by : <u>(Attin) Prapradu S., 12/09/14</u> Director of Quality Assurance Department	Eff. Date 15/09/14
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Sodium Bicarbonate BP (Item No. 41023660).
Sampling plan	$1 + \sqrt{N}$ 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 or store in well-closed containers and protect from light.
Retest period	1 year after first testing date.

เอกสารไม่ควบคุม
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Prepared by : J. Noppadech, 10/09/14 Head of Raw Material Standard Section 2	Reviewed by : <div style="display: flex; justify-content: space-between;"> <div> C. Suwanasopha, 10/09/14 Director of Raw Material Standard Division </div> <div> G. R., 12/09/14 Director of Regulatory Compliance and Documentation Division </div> </div>	Approved by : <div style="display: flex; justify-content: space-between;"> <div> (Atty.) P. Noppadech, 12/09/14 Director of Quality Assurance Department </div> </div>	Eff. Date 15/09/14
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