

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title:</b> Sodium Hydroxide BP (Item No. 41023780)	<b>Spec. No. :</b> SP-AK30-S42
<b>Reference(s):</b> BP 2023 page II-936	<b>Rev. No. :</b> 03
<b>Other Requirements:</b> GPO Specification	<b>Page :</b> 1/2

### BP 2023

Test Parameters	Requirement
Description	White or almost white, crystalline masses, supplied as pellets, sticks or slabs, deliquescent, readily absorbing carbon dioxide.
Solubility	Very soluble in water, freely soluble in ethanol (96%).
Identification	A. pH: minimum 11.0.
	B. It gives reaction of sodium.
Appearance of solution	The solution is clear and colourless.
Carbonates	Maximum 2.0%, calculated as $\text{Na}_2\text{CO}_3$ as determined in the assay.
Chlorides	Maximum 200 ppm.
Sulfates	Maximum 200 ppm.
Iron	Maximum 10 ppm, determined on solution S.
Assay	97.0% to 100.5% of NaOH.

### GPO Specification

Test Parameter	Requirement
Heavy metals	Maximum 20 ppm.

Prepared by: Benjawan Ubonklee / 26/04/23 Head of Raw Material Standard Section 2	Reviewed by: Suvannee / 26/04/23 Director of Raw Material Standard Division	Approved by: (Noting) T. Lume Lumetorn / 26/04/23 Director of Quality Assurance Department	Eff. Date 15/05/23
	Umaporn / 27/04/23 Director of Quality System Development Division		

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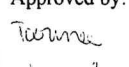
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### Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Sodium Hydroxide BP (Item No. 41023780).
Sampling plan	For Identification : 100%. For Other Tests : n plan ( $\sqrt{N} + 1$ ).
Testing procedure	Tests to be performed as per current version of WI-AK30-S42.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective Date
02	Update โดยอ้างอิงตาม BP 2011	29/06/11
03	Update โดยอ้างอิงตาม BP 2023 และ ปรับหัวข้อ Heavy metals เป็น GPO Specification	15/05/23

<b>Prepared by:</b> เจริญพร Ubonglee / 26/04/23 Head of Raw Material Standard Section 2	<b>Reviewed by:</b> <div style="display: flex; justify-content: space-between;"> <div>             / 26/04/23            Director of Raw Material            Standard Division         </div> <div>             / 27/04/23            Director of Quality System            Development Division         </div> </div>	<b>Approved by:</b> (Acting)  / 26/04/23 Director of Quality Assurance Department	<b>Eff. Date</b> 15/05/23
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