

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Icing Sugar USP/NF (Item No. 41021880)	<b>Spec. No. :</b> SP-AK30-I001
<b>Reference(s) :</b> USP 41/NF 36 page 5632 – 5633 [under Confectioner's Sugar]	<b>Rev. No. :</b> 05
<b>Other Requirements :</b> GPO Specification	<b>Page :</b> 1/3

**USP 41/NF 36**

Description	: Fine, white, odorless powder, free from gritty particles. (Confectioner's Sugar is Sucrose ground together with corn starch to a fine powder.)
Solubility	: Soluble in cold water, freely soluble in boiling water.
Identification	: A. A reddish-violet to deep blue color is produced. B. It meets the requirements of the test for Optical Rotation, Specific Rotation in Specific Tests.
Residue on ignition	: Not more than 0.08%.
Chloride and sulfate, Chloride	: Not more than 0.014%.
Chloride and sulfate, Sulfate	: Not more than 0.006%.
Calcium	: The solution remains clear for not less than 1 minute.
Microbial enumeration tests and tests for specified microorganisms	: The total aerobic microbial count does not exceed $10^3$ cfu/g, and the total combined molds and yeasts count does not exceed $10^2$ cfu/g. It meets the requirements of the tests for absence of <i>Salmonella</i> species and <i>Escherichia coli</i> .
Loss on drying	: Not more than 1.0%.
Optical Rotation, Specific Rotation	: Not less than +62.6 °, corresponding to not less than 95.0% of sucrose ( $C_{12}H_{22}O_{11}$ ), calculated on the dried basis.

Prepared by : <u>S. Rappodech, 17/04/18</u> Head of Raw Material Standard Section 2  <u>Umaporn N., 18/04/18</u> Head of Microbiological Analysis Section 2	Reviewed by : <u>S. Tantachaneerat, 18/04/18</u> Director of Raw Material Standard Division  <u>Pongy, 20/04/18</u> Director of Microbiological Analysis Division	Approved by : <u>Varipin, 20/04/18</u> Director of Regulatory Compliance and Documentation Division  <u>Wingungras, 24/04/18</u> Director of Quality Assurance Department (Acting)	Eff. Date  01/05/18
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Spec. No. : SP-AK30-I001

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Assay

: It contains not less than 95.0% of sucrose ( $C_{12}H_{22}O_{11}$ ), calculated  
on the dried basis.

GPO Specification

Fineness

: For information.

Prepared by : F. Ropadech, 11/04/18 Head of Raw Material Standard Section 2	Reviewed by : S. Tantichaweevat, 11/04/18 Director of Raw Material Standard Division	VARIPIN, 20/04/18 Director of Regulatory Compliance and Documentation Division	Approved by : Vichian Kungumroj, 24/04/18 Director of Quality Assurance Department (Atchana)	Eff. Date 01/05/18
Umangon M., 18/04/18 Head of Microbiological Analysis Section 2	Pongy, 20/04/18 Director of Microbiological Analysis Division			

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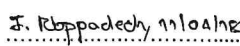
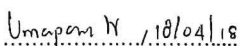
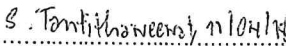
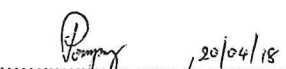
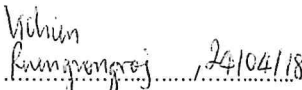
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### Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Icing Sugar USP/NF (Item No. 41021880).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-I001, WI-AK62-T41, WI-AK62-T14 and WI-AK62-T11.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	2 years after first testing date.

### History of changes

Rev. No.	Description	Effective Date
04	ทบทวนเอกสาร โดยอ้างอิงตาม USP 34/NF 29 และ GPO Specification	19/03/12
05	ทบทวนเอกสาร โดยอ้างอิงตาม USP 41/NF 36 และ GPO Specification	01/05/18

<b>Prepared by :</b>  S. Koppodech 11/04/18 Head of Raw Material Standard Section 2   Umaphan N. 18/04/18 Head of Microbiological Analysis Section 2	<b>Reviewed by :</b>  S. Tantithanon 11/04/18 Director of Raw Material Standard Division   P. Pong 20/04/18 Director of Microbiological Analysis Division	<b>Approved by :</b>  Vichin Kumpangroj 24/04/18 Director of Quality Assurance Department (Ateliny)	<b>Eff. Date</b> 01/05/18
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