



COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Icing Sugar USP/NF

Spec. No. : SP-AK30-I001

(Item No. 41021880)

Reference(s) : USP 41/NF 36 page 5632 – 5633 [under Confectioner's Sugar]

Rev. No. : 05

Other Requirements : GPO Specification

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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
Salmonella species and *Escherichia coli*.

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 :	Reviewed by :	Approved by :	Eff. Date
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Analysis Section 2	Analysis Division		



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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.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : F. Roppadech, 11/04/18 Head of Raw Material Standard Section 2	Reviewed by : S. Tantichanont, 11/04/18 Director of Raw Material Standard Division	VARIPIN, 20/04/18 Director of Regulatory Compliance and Documentation Division	Approved by : Vichin Kunwattanasri, 24/04/18 Director of Quality Assurance Department (Kunwattanasri)	Eff. Date 01/05/18
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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

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Ropphadech, 11/04/18 Head of Raw Material Standard Section 2 Umaporn N., 18/04/18 Head of Microbiological Analysis Section 2	Reviewed by : S. Tantithavorn, 11/04/18 Director of Raw Material Standard Division P. Pongy, 20/04/18 Director of Microbiological Analysis Division	Approved by : Vichien Kungwongroj, 24/04/18 Director of Quality Assurance Department (Arling)	Eff. Date 01/05/18
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