

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Methylpyrrolidone USP/NF (Item No. 41032780)	Spec. No. : SP-AK30-M012
Reference(s) : USP40/NF35 p. 7767-7768	Rev. No. : 01
Other Requirements : -	Page : 1/2

USP40/NF35	Description	: A clear, colorless to very slightly yellow liquid.
	Solubility	: Miscible with water and with most organic solvents including alcohol, ketones, and aromatic and chlorinated hydrocarbons.
	Identification	: Infrared Absorption.
	Heavy metals	: Not more than 10 ppm.
	Organic impurities	: Not more than 0.1% of any individual impurity; and not more than 0.3% of total impurities.
	Alkalinity	: Not more than 8.0 mL of 0.02 M hydrochloric acid is required.
	Clarity of solution	: The Sample shows the same clarity as that of water, or its opalescence is not more pronounced than that of the Reference suspension.
	Color of solution	: The Sample is not more intensely colored than the Comparison solution.
	Water content	: Not more than 0.1%.

Prepared by : J. Noppadech, 17/08/17 Head of Raw Material Standard Section 2	Reviewed by : Yuwaporn, 17/08/17 Director of Raw Material Standard Division	Approved by : VARIPIN, 17/08/17 Director of Regulatory Compliance and Documentation Division	Eff. Date Vichian Kungwong, 18/08/17 Director of Quality Assurance Department (Acting) 21/08/17
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Methylpyrrolidone USP/NF (Item No. 41032780).
Sampling plan	P plan : For identification. $\sqrt{N} + 1$ plan : For other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-M012.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in light-resistant containers.
Retest period	2 years after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด โดยอ้างอิงตาม USP40/NF35	21/08/17

Prepared by : J. Noppradechy 17/08/17 Head of Raw Material Standard Section 2	Reviewed by : Yunwattana 4. / 17/08/17 Director of Raw Material Standard Division	Approved by : VAKIPIN 17/08/17 Director of Regulatory Compliance and Documentation Division	Eff. Date 21/08/17 Director of Quality Assurance Department (Acting)
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