



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title : Methylparaben USP (Methyl p-Hydroxybenzoate)  
(Item No. 41032380)

Spec. No : SP-AK30-M001

Reference(s) : USP 40 p. 7765-7766

Rev. No : 07

Other Requirements : GPO Specification

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USP 40

Test Parameters	Specifications
Description	White, crystalline powder or colorless crystals.
Solubility	Freely soluble in alcohol and in methanol; slightly soluble in water.
Identification	
A. Infrared absorption <197M>	Conforms to IR standard spectrum.
B. Melting range or temperature	125 °C-128 °C.
Color of solution	The Sample solution is clear and not more intensely colored than alcohol or the Comparison solution.
Acidity	Not more than 0.1 ml is required to produce a blue color.
Residue on ignition	Not more than 0.1%, determined on 1.0 g.
Organic impurities	
	p-Hydroxybenzoic acid : Not more than 0.5%.
	Unspecified impurities : Not more than 0.5%.
	Total impurities : Not more than 1.0%.
Assay	98.0%-102.0% of $C_8H_8O_3$ .

GPO spec

Test Parameters	Specifications
Packaging	Well-closed container, original from the manufacturer

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : Suannee, 19/01/18 Head of Raw Material Standard Section 1	Reviewed by : Sutharee, 19/01/18 Director of Raw Material Standard Division	VARIPIN, 22/01/18 Director of Regulatory Compliance and Documentation Division	Approved by : Vichin Rungnongkajit, 24/01/18 Director of Quality Assurance Department (A/ฉ.ค.ค.)	Eff. Date 20/03/18
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## Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Methylparaben USP (Methyl p-Hydroxybenzoate) (Item No. 41032380).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$ : for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-M001.
Storage condition	Preserve in well-closed containers.
Retest period	1 year after first testing date.

## History of changes

Rev. No.	Description	Effective date
06	Update spec. เป็น USP 37	20/03/15
07	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 37 และ USP 40 เหมือนกันจึง Update spec. จาก USP 37 เป็น USP 40	20/03/18

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ใช้ในการจัดซื้อ

Prepared by : Sunanee / 14/01/18 Head of Raw Material Standard Section 1	Reviewed by : Sutharee / 14/01/18 Director of Raw Material Standard Division	VARIPIN / 22/01/18 Director of Regulatory Compliance and Documentation Division	Approved by : Vichan Rungrat / 24/01/18 Director of Quality Assurance Department (Acting)	Eff. Date 20/03/18
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