

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Pyrazinamide USP (Item No. 41011280)	Spec. No : SP-AK30-P32
Reference(s) : USP 40 p. 5919-5920	Rev. No : 04
Other Requirements : GPO Specification	Page : 1/2

USP 40

Test Items	Specification
Description	White to practically white, odorless or practically odorless, crystalline powder.
Solubility	Sparingly soluble in water; slightly soluble in alcohol, in ether and in chloroform.
Identification	
A. Infrared Absorption <197M>	The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard.
B. Ultraviolet Absorption <197U>	Absorptivities at 268 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.
C. Chemical Test	The odor of ammonia is perceptible.
Melting range	Between 188 °C and 191 °C.
Water Determination	Not more than 0.5%, Method I.
Residue on ignition	Not more than 0.1%.
Heavy metals	Not more than 0.001%, Method II.
Assay	99.0% to 101.0% of $C_5H_5N_3O$, calculated on the anhydrous basis.

GPO Specification

Test Items	Specification
Tapping volume	5.0-g portion occupies between 8 ml and 16 ml when tapped down 20 times at 3-mm drop height and at a rate of 250 drops/minute.
Fineness	Pass through sieve No. 60 : Not less than 90%.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Swannee, 12/12/17 Head of Raw Material Standard Section I	Reviewed by : Sutharee, 13/12/17 Director of Raw Material Standard Division	VARIPIN, 15/12/17 Director of Regulatory Compliance and Documentation Division	Approved by : Vibhinn Kunwongwong, 15/12/17 Director of Quality Assurance Department (วิบูลย์)	Eff. Date 29/12/17
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Pyrazinamide USP (Item No. 41011280)
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-P32.
Storage condition	Preserve in well closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	อ้างอิง spec. เป็น USP 36	20/02/15
04	เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยข้อกำหนดตาม USP 36 และ USP 40 เหมือนกัน ดังนั้นจึง Update spec. เป็น USP 40	29/12/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Suvannee, 12/12/17 Head of Raw Material Standard Section 1	Reviewed by : Smitharee, 13/12/17 Director of Raw Material Standard Division	Approved by : VAREAN, 15/12/17 Director of Regulatory Compliance and Documentation Division	Eff. Date 29/12/17
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