

(14)



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Clotrimazole USP (Item No. 41020820)	Spec. No : SP-AK30-C57
Reference(s) : USP 36 p. 3070	Rev. No : 04
Other Requirements : GPO Specification	Page : 1/3

USP 36

Description	: White to pale yellow, crystalline powder.
Solubility	: Freely soluble in methanol, in acetone, in chloroform, and in alcohol; practically insoluble in water.
Identification	: A. Infrared absorption B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Residue on ignition	: Not more than 0.1%.
Heavy metals, <Method II>	: Not more than 10 ppm.
Organic impurities	
- Limit of imidazole	: Not more than 0.5% of imidazole.
- Limit of clotrimazole related compound A	: Not more than 0.5%.
Loss on drying	: Dry it at 105°C for 2 hours; it loses not more than 0.5% of its weight.
Assay	: It contains not less than 98.0% and not more than 102.0% of $C_{22}H_{17}ClN_2$, calculated on the dried basis.

GPO Specification

Particle size	: Not less than 95% by number of particles are less than 37 microns in size.
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Prepared by : J. Neppadech, 25/03/16	Reviewed by : Nalepa, 25/03/16	Approved by : (Acting) Prapavadee A., 25/03/16	Eff. Date 25/03/16
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department

เอกสารนี้เป็นของ
ใช้ภายในองค์กร



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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Clotrimazole USP (Item No. 41020820).
Sampling plan	$1 + \sqrt{N}$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C57.
Storage condition	Store at a condition stated on the label from the manufacturer or preserve in tight container.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Reviewed by	Effective Date
01	ประกาศใช้ครั้งแรก	ผอ. มาตรฐานวัตถุดิบ	-
02	Update ข้อกำหนดจาก USP23 และ GPO Specification เป็น USP29 และ GPO Specification	ผอ. มาตรฐานวัตถุดิบ	19/10/06
03	Update ข้อกำหนดจาก USP29 และ GPO Specification เป็น USP36 และ GPO Specification (หัวข้อทดสอบ Description จากเดิมระบุ "White crystalline powder." แต่ Rev. No. 03 ระบุเป็น "White to pale yellow, crystalline powder.")	ผอ. มาตรฐานวัตถุดิบ	19/11/15

Prepared by : S. Wappadeech, 25/03/16	Reviewed by : W. A. S., 25/03/16	Approved by : (Achana) P. Papanada C., 25/03/16	Eff. Date 25/03/16
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department



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Rev. No.	Description	Reviewed by	Effective Date
04	แก้ไขการพิมพ์ประวัติเอกสารอ้างอิงใน Rev. No. 03 ซึ่งไม่ได้กล่าวถึงการ update จาก USP23 เป็น USP29 (รายละเอียดการตรวจของ Rev. No. 04 ยังคงเหมือนกับ Rev. No. 03 คือ อ้างอิง USP36 และ GPO Specification)	ผอ.ก. มาตรฐานวัตถุดิบ	25/03/16

Prepared by : S. Noppadech, 25/03/16	Reviewed by : [Signature], 25/03/16	Approved by : (Acting) Prapawadee G., 25/03/16	Eff. Date 25/03/16
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department