GPO องค์การเภสัชกรรม COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Miconazole Nitrate USP (Item No. 41022280)	**Spec. No.** : SP-AK30-M29
Reference(s): USP 41 page 2738	**Rev. No.** : 04
Other Requirements: -	**Page** : 1/2

USP 41

Description	:	White or practically white, crystalline powder, having not more than a slight odor.
Melting range	:	178 °C to 183 °C, with decomposition.
Solubility	:	Freely soluble in dimethyl sulfoxide; soluble in dimethylformamide; sparingly soluble in methanol; slightly soluble in alcohol, in chloroform, and in propylene glycol; very slightly soluble in water and in isopropyl alcohol; insoluble in ether.
Identification	:	A. Infrared Absorption. B. Ultraviolet Absorption <197U>.
Loss on drying	:	Not more than 0.5%.
Residue on ignition	:	Not more than 0.2%.
Organic impurities	:	The response of any individual peak, other than the main peak of the Sample stock solution, is not more than that of the main peak of the Sample solution (0.25%), and the sum of the responses of all peaks, other than the main peak of the Sample stock solution, is not more than twice the response of the main peak of the Sample solution (0.5%).
Assay	:	98.0% to 102.0% of Miconazole Nitrate ($C_{18}H_{14}Cl_4N_2O \cdot HNO_3$), calculated on the dried basis.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
J. Nappadech / 15/08/19	Tanmai Laboont / 19/08/19	/ 20/08/19	Vichien Ruengrongroj / 21/08/19	15/09/19
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 (Acting)	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Miconazole Nitrate USP (Item No. 41022280).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-M29.
Storage condition	Store at a condition stated on the label from the manufacturer or preserve in well-closed containers, protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำเอกสาร โดยอ้างอิงตาม BP 1993 p.433	22/04/98
02	ทบทวนเอกสาร โดยอ้างอิงตาม BP 2009 p. 1375-1377	19/10/09
03	ทบทวนเอกสาร โดยอ้างอิงตาม USP 37 (Change Request No. 58226)	09/03/17
04	Update โดยอ้างอิงตาม USP 41	15/09/19

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Prepared by :	Reviewed by :		Approved by :	Eff. Date
J. Kloppadech / 15/08/19	Tawmai / 19/08/19	/ 20/08/19	Vichien Ruengrongroj / 21/08/19	15/09/19
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 (Acting)	