

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

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

<b>Prepared by :</b> J. Neppadech / 15108ha Head of Raw Material Standard Section 2	<b>Reviewed by :</b> Tarnia Lukmanee, 19/04/19 Director of Raw Material Standard Division	<b>Approved by :</b> Vichin Ruengrongroj, 21/08/19 Director of Quality Assurance Department (Acting)	<b>Eff. Date</b> 15/09/19
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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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