

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION



COPY No. 2

Title : Minoxidil USP
(Item No. 41022290)

Spec. No : SP-AK30-M009

Reference(s) : USP 39 p.4896-4897

Rev. No : 03

Other Requirements : -

Page : 1/2

USP39

Description	: White to off-white crystalline powder; odorless.
Melting range	: Melts in the approximate range of between 248 °C and 268 °C, with decomposition.
Solubility	: Soluble in alcohol and in propylene glycol; sparingly soluble in methanol; slightly soluble in water; practically insoluble in chloroform, in acetone, in ethyl acetate, and in hexane.
Identification	: Infrared Absorption.
Residue on ignition	: Not more than 0.5%.
Heavy metals	: Not more than 20 ppm.
Organic impurities	: The total percentage of impurities is not more than 1.5%.
Loss on drying	: Not more than 0.5%.
Assay	: It contains not less than 97.0% and not more than 103.0% of minoxidil ($C_9H_{15}N_3O$), calculated on the dried basis.

Prepared by :	Reviewed by :	Approved by :	Eff. Date
<u>J. Wappadechy 25/05/17</u>	<u>Yuvaporn 15/05/17</u> <u>VARIPIN 26/05/17</u>	<u>Vichien Rungwongroj 29/05/17</u>	20/06/17
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
Standard Section 2	Standard Division	Department (Acting)	

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION



COPY No. 2

Title : Minoxidil USP (Item No. 41022290)	Spec. No : SP-AK30-M009
Reference(s) : USP 39 p.4896-4897	Rev. No : 03
Other Requirements : -	Page : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Minoxidil USP (Item No. 41022290).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other Tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-M009.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in a well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำเอกสาร โดยอ้างอิงตาม USP 34	03/11/11
02	ทบทวนเอกสาร ยังคงอ้างอิงตาม USP 34	25/02/16
03	Update โดยอ้างอิงตาม USP 39	20/06/17

Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Noppadetch, 25/05/17 Head of Raw Material Standard Section 2	Yunwarom, 16/05/17 Director of Raw Material Standard Division	VARIPIN, 26/05/17 Director of Regulatory Compliance and Documentation Division	Vithin Rungnongroj, 29/05/17 Director of Quality Assurance Department (Acting) 20/06/17