COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Mometasone Furoate USP (Item No. 41022315)	**Spec. No.** : SP-AK30-M010
Reference(s) : USP 37 p.3870-3871	**Rev. No.** : 01
Other Requirements : GPO Specification (R&D Institute)	**Page** : 1/2

USP 37	Description	: White to off-white powder.
	Melting point	: Melts at about 220 °C, with decomposition.
	Solubility	: Soluble in acetone and in methylene chloride.
	Identification	: A) Infrared Absorption. B) The retention time of Mometasone Furoate in the Sample solution corresponds to that of Mometasone Furoate in the Standard solution, both relative to the internal standard, as obtained in the Assay.
	Residue on ignition	: Not more than 0.1%.
	Heavy metals, Method II	: Not more than 30 µg/g.
	Organic impurities	: No secondary spot from the Sample solution is larger or more intense than the principal spot from Standard solution C; and the sum of the intensities of the secondary spots from the Sample solution is not more than 2.0%.
	Optical rotation, Specific rotation	: Between +56 ° and +62 °.
	Loss on drying	: Not more than 0.5%.
	Assay	: It contains not less than 97.0% and not more than 102.0% of mometasone furoate ($C_{27}H_{30}Cl_2O_6$), calculated on the dried basis.
GPO Specification	Particle size d(0.9)	: Not more than 10 µm.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
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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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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Mometasone Furoate USP (Item No. 41022315).
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-M010.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด (ทะเบียนตำรับยา Mometasone cream อ้างอิงตาม USP 37 และ GPO Specification)	27/09/17

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ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
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