COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Naproxen USP (Item No. 41011020)	**Spec. No.**	: SP-AK30-N11
Reference(s) : USP 39 p. 4992-4993 (same as USP 43)	**Rev. No.**	: 04
Other Requirements : GPO Specification	**Page**	: 1/2

USP 39

Test Items	Specification
Description	White to off white, practically odorless, crystalline powder.
Solubility	Soluble in chloroform, in dehydrated alcohol and in alcohol; sparingly soluble in ether; practically insoluble in water.
Identification A. Infrared absorption <197K> B. Ultraviolet absorption <197U>	 The IR absorption spectrum of sample exhibits the same spectrum as standard. Absorptivities at 271 nm, calculated on the dried basis, do not differ by more than 3%.
Specific rotation	Between +83.0° and +89.5°, on dried.
Loss on drying	Not more than 0.5%.
Chromatographic purity	- The Rf value of the principal spot in the chromatogram of the Test solution corresponds to that of the Standard solution. - Any other spot obtained from the Test solution does not exceed in size or intensity the principal spot obtained from the 100-µg per ml Comparison solution (0.5%) and the sum of the intensities of any secondary spots, similarly compared does not exceed 2.0%.
Assay	98.5% to 101.5% of $C_{14}H_{14}O_3$, calculated on the dried basis.

GPO Spec.

Test Items	Specification	
Heavy metals	Not more than 0.002%, Method II.	
Tapping volume	Not more than 21 ml ; 5.0-g portion tapped down 20 times at 3-mm drop height and at a rate of 250 drops/minute.	
Residual solvents*	Methanol	: Not more than 200 ppm.
	Toluene	: Not more than 250 ppm.

Remark : Residual solvents* for Divi's Laboratories Limited/ India

Prepared by :	Reviewed by :		Approved by :	Eff. Date
(Acting) Thunyatorn / 15/11/21	Suwannee / 15/11/21	/ 16/11/21	Tumnee / 16/11/21	15/01/22
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Naproxen USP (Item No. 41011020).
Sampling plan	1. N Plan ($\sqrt{N} + 1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-N11.
Storage condition	Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	อ้างอิง spec. เป็น USP 36	28/08/13
03	Update spec. เป็น USP 39 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 36 และ USP 39 เหมือนกัน	23/06/16
04	1) เพิ่มหัวข้อ Residual solvent ตามผลประเมินเบื้องต้นคำขอแก้ไขเปลี่ยนแปลงทะเบียนตำรับยา (แบบ ย. 5) ตำรับ Naproxen tablet 250 mg เรื่องเพิ่มแหล่งวัตถุดิบตัวยาสำคัญ 2) เอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยข้อกำหนดของ USP 43 กับ USP 39 เหมือนกัน	15/01/22

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