(93)

COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Ibuprofen USP [25 micron, for suspension] (Item No. 41021878)	**Spec. No** : SP-AK30-I24
Reference(s) : USP 36 p. 3875-3876	**Rev. No** : 02
Other Requirements : GPO Specification	**Page** : 1/3

USP 36

Description : White to off-white, crystalline powder, having a slight, characteristic odor.

Solubility : Very soluble in alcohol, in methanol, in acetone, and in chloroform; slightly soluble in ethyl acetate; practically insoluble in water.

Identification : A. Infrared Absorption

B. Ultraviolet Absorption <197U>

Solution: 250 µg per mL.

Medium: 0.1 N sodium hydroxide.

Respective absorptivities at 264 nm and 273 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

C. The chromatogram of the Assay preparation obtained as directed in the Assay exhibits a major peak for ibuprofen, the retention time of which, relative to that of the internal standard, corresponds to that exhibited in the chromatogram of the Standard preparation, obtained as directed in the Assay.

Water <Method I> : Not more than 1.0%.

Residue on ignition : Not more than 0.5%.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
S. Noppadech, 26/05/15	Walaya, 26/05/15	Li R 28/05/15	Prapanradee C. (Actg.) 28/05/15	19/06/15
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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	Heavy metals <Method II>	: Not more than 0.002%.
	Chromatographic purity	
	- any individual impurity	: Not more than 0.3%,
	- the sum of all the individual impurities	: Not more than 1.0%.
	Limit of ibuprofen related compound C	: Not more than 0.1%.
	Assay	: It contains not less than 97.0% and not more than 103.0% of $C_{13}H_{18}O_2$, calculated on the anhydrous basis.
GPO Specification	Particle size [by Image Analysis]	: Not less than 50.0% by number of particle that are smalle than 37 micron in size.

เอกสารใช้ภายในกลุ่ม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
อ. Noppadech 28/05/15	Nalapa 26/05/15	28/05/15	Praparadu C. (Actng) 28/05/15	19/06/15
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Ibuprofen USP [25 micron, for suspension] (Item No. 41021878).
Sampling plan	$1 + \sqrt{N}$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-I24.
Storage condition	Store at a condition stated on the label from the manufacturer or preserve in tight container.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Reviewed by	Effective Date
01	ประกาศใช้ครั้งแรก (USP 32)	ผอก. มาตรฐานวัตถุดิบ	19/10/09
02	Update ข้อกำหนดตาม USP 36 และ GPO Specification	ผอก. มาตรฐานวัตถุดิบ	19/06/15

Prepared by :	Reviewed by :		Approved by :	Eff. Date
K. Noppadech 26/05/15	Malapa 26/05/15	28/05/15	Prapawadee Actiw 28/05/15	19/06/15
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