COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Ibuprofen USP [25 microns, for suspension] (Item No. 41021878)	**Spec. No.** : SP-AK30-I24
Reference(s): USP 39 page 4267 - 4268	**Rev. No.** : 03
Other Requirements: GPO Specification	**Page** : 1/3

USP 39

Test Parameters	Requirement
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.
	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%.
Chromatographic purity - Any individual impurity	Not more than 0.3%.
- Total impurities	Not more than 1.0%.
Limit of Ibuprofen related compound C	Not more than 0.1%.
Assay	97.0% to 103.0% of Ibuprofen ($C_{13}H_{18}O_2$), calculated on the anhydrous basis.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 08/09/20	Tarinee Lwanbrunt / 09/09/20	/ 09/09/20	Vichien Ruengrongroj / 10/09/20	01/10/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department	

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GPO Specification

Test Parameters	Requirement
Heavy metals <Method II>	Not more than 0.002%.
Particle size [by Image Analysis]	Not less than 50.0% by number of particle that are smaller than 37 microns in size.
Ibuprofen related compound J	For information.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Klappadech / 08/09/20	/ 09/09/20	/ 09/09/20	10/09/20	01/10/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Ibuprofen USP [25 microns, for suspension] (Item No. 41021878).
Sampling plan	For Identification : 100%. For Other Tests : 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. Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	ประกาศใช้ครั้งแรก (USP 32)	19/10/09
02	update โดยอ้างอิงตาม USP 36 และ GPO Specification	19/06/15
03	Update โดยอ้างอิงตาม USP 39 และ GPO Specification ซึ่งมีการเปลี่ยนแปลง ดังนี้ 1. ปรับหัวข้อ Heavy metals มาอยู่ใน GPO Specification เนื่องจากไม่ระบุใน monograph 2. เพิ่มการทดสอบ Ibuprofen related compound J [GPO Specification]	01/10/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Rappadech / 08/09/20	Tawee Lubroom / 09/09/20	/ 09/09/20	Vichien Rungvongroj / 10/09/20	01/10/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	