THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Propranolol Hydrochloride USP (Item No. 41011260)	**Spec. No.** : SP-AK30-P008
Reference(s) : USP 41 p. 3493	**Rev. No.** : 06
Other Requirements : GPO Specification	**Page** : 1/2

USP 41

Test Items	Specification
Description	White to off-white, crystalline powder, odorless.
Solubility	Soluble in water and in alcohol; slightly soluble in chloroform; practically insoluble in ether.
Identification A. Infrared absorption <197M> B. HPLC C. Chloride Test	 Conforms to FT-IR standard spectrum. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. A white, curdy precipitate is formed which is insoluble in nitric acid but is soluble in slight excess ammonia.
Melting range or temperature	Between 162 °C and 165 °C, Class Ia.
Specific rotation	Between -1.0° and +1.0°.
Loss on drying	Not more than 0.5%.
Residue on ignition	Not more than 0.1%.
Assay	98.0 – 101.5% of Propranolol HCl ($C_{16}H_{21}NO_2 \cdot HCl$), calculated on the dried basis.

GPO Specification

Test Items	Specification
Particle size	Not less than 65.0% by number of particles are smaller than 10 µm in size, and not less than 95.0% by number of the particles are smaller than 37 µm in size ; measuring the particle size of powder by microscope (Image analysis technique).

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 30/07/19	Tanmee Lukrornrat / 31/07/19	/ 31/07/19	Wichien Ruengwongroj / 01/08/19	30/10/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	

GPO COPY No. 2

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Propranolol Hydrochloride USP (Item No. 41011260)
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-P008.
Storage condition	Preserve in well-closed containers. Store at 25 °C, excursions permitted between 15 °C and 30 °C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
04	อ้างอิง spec. เป็น USP 36	16/06/14
05	เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยยังคงเนื้อหาเดิม USP 36 เพื่อให้สอดคล้องกับ Finished product spec. และสอดคล้องกับที่ยื่นขึ้นทะเบียน	28/04/17
06	Update spec. เป็น USP 41 โดยเนื้อหาของ USP 36 และ USP 41 เหมือนกัน เนื่องจากตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป	30/10/19

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