THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Haloperidol USP (Item No. 41010790)	**Spec. No.** : SP-AK30-H11
Reference(s) : USP 41 p. 2019 - 2020	**Rev. No.** : 04
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USP 41

Test Items	Specification	
Description	White, crystalline powder.	
Solubility	Soluble in chloroform; sparingly soluble in alcohol; slightly soluble in ether; practically insoluble in water.	
Identification A. Infrared absorption <197K> B. HPLC	Conforms to 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 test for Organic impurities.	
Loss on drying	Not more than 0.5%.	
Residue on ignition	Not more than 0.1%.	
Organic impurities	Haloperidol related compound B	: Not more than 0.3%.
	Haloperidol related compound A	: Not more than 0.2%.
	Any other individual impurity	: Not more than 0.10%.
	Total impurities	: Not more than 0.5%.
Assay	98.0 – 102.0% of Haloperidol ($C_{21}H_{23}ClFNO_2$), calculated on the dried basis.	

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sunwanee / 09/08/19 Head of Raw Material Standard Section 1	Tammee Lunbrown / 09/08/19 Director of Raw Material Standard Division	/ 15/08/19 Director of Regulatory Compliance and Documentation Division	Vichian Ruengrongroj / 16/08/19 Director of Quality Assurance Department (Acting)	15/09/19

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Haloperidol USP (Item No. 41010790)
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-H11.
Storage condition	Preserve in tight, light-resistant containers. Store at room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	Update spec. เป็น USP 34	01/11/12
03	Update spec. เป็น USP 36 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 34 และ USP 36 เหมือนกัน	23/06/16
04	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/ BP 2016 ขึ้นไป	15/09/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 09/08/19	Tumma Limbanmit / 09/08/19	/ 15/08/19	Vichien Ruengwongroj / 16/08/19	15/09/19
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)	