

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

**Title :** Haloperidol USP (Item No. 41010790)

**Spec. No. :** SP-AK30-H11

**Reference(s) :** USP 36 p.3795-3796

**Rev. No. :** 03

**Other Requirements :** -----

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### USP 36

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)	The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard.
B. Ultraviolet absorption (197U)	Absorptivities at 245 nm, calculated on the dried basis, do not differ by more than 3.0%.
Melting range	Between 149 °C and 155 °C, determined after drying in vacuum at 60° for 3 hours.
Loss on drying	Not more than 0.5%.
Residue on ignition	Not more than 0.1%.
Limit of haloperidol related compound A	Not more than 1.0%.
Assay	98.0 – 102.0% of C <sub>21</sub> H <sub>23</sub> ClFNO <sub>2</sub> , calculated on the dried basis.

Prepared by : <i>Sunannee</i> , 30/05/16 Head of Raw Material Standard Section 1	Reviewed by : <i>rialapa</i> , 30/05/16 Director of Raw Material Standard Division	<i>Nichim</i> <i>Rungvongroj</i> , 04/06/16 Director of Regulatory Compliance and Documentation Division	Approved by : <i>Qsm</i> , 10/06/16 Director of Quality Assurance Department	Eff. Date 23/06/16
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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	P plan : for Identification $\sqrt{N} + 1$ : for other tests
Testing procedure	Tests to be performed as per current version of WI-AK30-H11.
Storage condition	Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective date
02	Up spec เป็น USP 34	01/11/12
03	Up spec เป็น USP 36 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 34 และ USP 36 เหมือนกัน	23/06/16

Prepared by : Sunamnee / 30/05/16 Head of Raw Material Standard Section I	Reviewed by : Nalaya / 30/05/16 Director of Raw Material Standard Division	Vichin Rungwongroj / 04/06/16 Director of Regulatory Compliance and Documentation Division	Approved by : Dum / 10/06/16 Director of Quality Assurance Department	Eff. Date 23/06/16
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