COPY No.2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Furosemide USP (For injection dosage form) (Item No. 41032020)	**Spec. No.** : SP-AK30-F14/1
Reference(s) : USP 39 p.4059-4060	**Rev. No** : 05
Other Requirements : GPO Specification	**Page** : 1/2

USP 39

Test Items	Specification	
Description	White to slightly yellow, odorless, crystalline powder.	
Solubility	Freely soluble in acetone, in dimethylformamide, and in solutions of alkali hydroxides; soluble in methanol; sparingly soluble in alcohol; slightly soluble in ether; very slightly soluble in chloroform; practically insoluble in water.	
Identification A. Infrared absorption (197K) B. Ultraviolet absorption (197U) C. Chemical Test	The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard. Absorptivities at 271 nm, calculated on the dried basis, do not differ by more than 3.0%. A red to red-violet color is produced.	
Loss on drying	Not more than 1.0%.	
Residue on ignition	Not more than 0.1%.	
Heavy metals	Not more than 0.002%, Method II.	
Organic impurities	The sum of the peak areas of peaks eluting before furosemide at 254 nm.	: Not more than 0.5%.
	The sum of the peak areas of peaks eluting after furosemide at 272 nm.	: Not more than 0.5%.
Assay	98.0 – 101.0% of $C_{12}H_{11}ClN_2O_5S$, calculated on the dried basis.	

GPO Specification

Test Items	Specification
Bacterial endotoxins	Not more than 3.6 USP Endotoxin units per mg of furosemide.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Suwannee /13/05/16	Benjawan Woonklee /13/05/16	/13/05/16	Umaporn /16/05/16 (Acting)	Vichien Rungvongraj /26/05/16	Prapanadda /6/06/16 (Acting)	23/06/16
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 1	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Furosemide USP (For injection dosage form) (Item No. 41032020).
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-F14/1.
Storage condition	Preserve in well-closed, light resistance container. 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	Up spec เป็น USP 34	30/01/12
05	Up spec เป็น USP 39 เนื่องจากเอกสารมีอายุมากกว่า 3 ปีจึงต้องทบทวน โดยเนื้อหาของ USP 34 และ USP 39 เหมือนกัน	23/06/16

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

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