COPY No. 3

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.** : 06
Other Requirements : GPO Specification	**Page** : 1/3

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%.	
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 Furosemide ($C_{12}H_{11}ClN_2O_5S$), calculated on the dried basis.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Sirinee 08/07/19	Benjawan Ubonklee 08/07/19	09/07/19	09/07/19	23/07/19	24/07/19	15/08/19
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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GPO Specification

Test Items	Specification
Heavy metals	Not more than 20 ppm, Method II.
Bacterial endotoxins	Not more than 3.6 USP Endotoxin units per mg of furosemide.

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	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-F14/1.
Storage condition	To be stored in well-closed, light-resistant containers. Store at 25 °C, excursions permitted between 15 °C and 30 °C.
Retest period	1 year after first testing date.

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Prepared by :		Reviewed by :			Approved by :	Eff. Date
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History of changes

Rev. No.	Description	Effective date
04	Update spec. เป็น USP 34	30/01/12
05	Update spec. เป็น USP 39 เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 34 และ USP 39 เหมือนกัน	23/06/16
06	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยคงเนื้อหาเดิม USP 39	15/08/19

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ใช้ในการจัดซื้อ

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