GPO องค์การเภสัชกรรม COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Diluted Isosorbide Dinitrate USP (40% in Lactose) (Item No. 41010500)	**Spec. No.** : SP-AK30-I20
Reference(s) : USP 41 p. 2267 - 2269	**Rev. No.** : 06
Other Requirements : GPO Specification	**Page** : 1/2

USP 41

Test Items	Specification	
Description	Ivory-white, odorless powder.	
Identification A. Infrared absorption 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 Assay.	
Loss on drying	Not more than 1.0%.	
Organic impurities	Isosorbide mononitrate related compound A	: Not more than 0.15%.
	Isosorbide mononitrate	: Not more than 0.15%.
	Any individual unspecified impurity	: Not more than 0.10%.
	Total impurities	: Not more than 1.0%.
Assay	95.0% – 105.0% of the labeled amount of Isosorbide dinitrate ($C_6H_8N_2O_8$) (equivalent to 38.0% - 42.0% of $C_6H_8N_2O_8$).	

GPO Specification

Test Items	Specification
Heavy metals	Not more than 10 ppm, Method II.
Particle size	Not less than 90.0% by number of particles are less than 37 μm in size; measuring the particle size of powder by microscope. (Image analysis technique)
Tapping volume	Between 7.0 ml and 10.0 ml, 5.0-g portion tapped down 20 times at 3-mm drop height and at a rate of 250 drops/minute.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 21/10/19 Head of Raw Material Standard Section 1	Taemnei Lonkhant / 22/10/19 Director of Raw Material Standard Division	/ 28/10/19 Director of Drug Registration and Pharmacovigilance Division	Vichien Rungruangroj / 28/10/19 Director of Quality Assurance Department (Acting)	15/12/19

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Diluted Isosorbide Dinitrate USP (40% in Lactose) (Item No. 41010500)
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-I20.
Storage condition	To be stored in tight container.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
04	Update spec. เป็น USP 36 เพื่อให้สอดคล้องกับ FP spec.	10/01/14
05	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยยังคง USP 36 เนื่องจาก FP spec. ที่ยื่นขึ้นทะเบียนไว้เป็น USP 36	28/02/17
06	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป	15/12/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee , 21/10/19	[illegible] , 22/10/19	[illegible] , 28/10/19	[illegible] , 28/10/19	15/12/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department [illegible]	