

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

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

### USP 41

Test Items	Specification
Description	Ivory-white, odorless powder.
Identification	
A. Infrared absorption	Conforms to IR standard spectrum.
B. HPLC	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 $\mu m$ 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.

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : Sudhanee, 21/10/19 Head of Raw Material Standard Section 1	Reviewed by : Tanyee, 22/10/19 Director of Raw Material Standard Division	Approved by : Vichin, 28/10/19 Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/12/19
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**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 :** 2/2**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

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by : Suvanee, 21/10/19 Head of Raw Material Standard Section 1	Reviewed by : Tunthai Limwong, 22/10/19 Director of Raw Material Standard Division	Approved by : Vichin Ruengroeng, 28/10/19 Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/12/19
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