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COPY No. 1

# 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 36 p. 4000-4001

**Rev. No. :** 05

**Other Requirements :** GPO Specification

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### USP 36

Test Items	Specification
Description	Ivory-white, odorless powder.
Identification	Examined by Infrared absorption. The IR absorption spectrum of sample exhibits maxima only at the same wavelengths as that of a similar preparation from the residue obtained from Diluted Isosorbide Dinitrate WS.
Loss on drying	Not more than 1.0%.
Heavy metals	Not more than 0.001%, Method II.
Assay	95.0 – 105.0% of the labeled amount of $C_6H_8N_2O_8$ (equivalent to 38.0-42.0% of $C_6H_8N_2O_8$ ).

### GPO Spec

Test Items	Specification
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 : Sunanee, 10/12/16 Head of Raw Material Standard Section I	Reviewed by : Yunaporn, 20/12/16 Director of Raw Material Standard Division	Vichien Kungwongroj, 23/12/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. Y. K., 26/12/16 Director of Quality Assurance Department	Eff. Date 28/02/17
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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	P plan : for Identification. $\sqrt{N} + 1$ : for other tests.
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 ปีจึงต้องทบทวน โดยยังคง USP 36 เนื่องจาก FP spec และที่ยืนยันทะเบียนไว้เป็น USP 36	28/02/17

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