

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Diluted Isosorbide-5-mononitrate BP(40% in Lactose) (Item No. 41010515)	<b>Spec. No :</b> SP-AK30-I30
<b>Reference(s) :</b> BP 2013 p. 1215-1216	<b>Rev. No :</b> 03
<b>Other Requirements :</b> GPO Specification	<b>Page :</b> 1/3

### BP 2013

Test Items	Specification	
Description	White crystalline powder.	
Identification	A : Infrared Absorption B : Thin layer chromatography C : Melting point	
	Conform to standard spectrum. Complies with Lactose. Between 89°C to 91°C.	
Impurity A (TLC)	Impurity A: any spot due to impurity A is not more intense than the principal spot in the chromatogram obtained with the reference solution (0.5%, calculated as potassium nitrate).	
Impurities B and C (HPLC)	Impurity B (Isosorbide dinitrate)	: Not more than 0.5%.
	Impurity C(Isosorbide 2-nitrate)	: Not more than 0.5%.
Assay	95.0 – 105.0% w/w of the labeled amount. (equivalent to 38.0-42.0% of $C_6H_9NO_6$ )	

เอกสารนี้เป็นเอกสาร  
ใช้ในการจัดซื้อ

Prepared by : Sunanee / 30/09/15 Head of Raw Material Standard Section 1	Reviewed by : Wadee / 30/09/15 Director of Raw Material Standard Division	Approved by : Praparat / 07/10/15 Director of Regulatory Compliance and Documentation Division	Approved by : Praparat / 07/10/15 Director of Quality Assurance Department	Eff. Date 30/10/15
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### GPO Specification

Test Items	Specification
Particle size - Laser diffraction, Malvern d (0.9)	: Not more than 300 µm.

### Method Parameters for Particle size Analysis using Malvern Mastersizer 2000.

No	Parameter	Specification
1	Condition	Dry Dispersion (Air pressure 3 bar)
2	Absorption	0.1 (For slightly colored powders.)
3	Particle Refractive Index (RI)	1.520 (For organic compounds.)
4	Weighted residual	< 2%
5	Obscuration	1-3%
6	Analysis model	General purpose
7	Particle Shape	Irregular-particles have angular shapes (default)
8	Measurement Integration time	≥ 3000 ms/ sample and measure 10 times/ sample
9	Measurement background time	≥ 10 seconds
10	Result units	Volume

เอกสารนี้ควบคุม  
ใช้ในการผลิต

Prepared by : Sunanee, 30/09/15 Head of Raw Material Standard Section 1	Reviewed by : W. A. P., 30/09/15 Director of Raw Material Standard Division	Approved by : G. R., 07/10/15 Director of Regulatory Compliance and Documentation Division	Eff. Date 30/10/15
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Diluted Isosorbide-5-mononitrate BP (40% in Lactose) (Item No. 41010515)
Sampling plan	P plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-I30.
Storage condition	Store protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	Up Specเป็น BP 2013	31/10/14
03	ปรับขยาย spec ค่า d(0.9) จาก NMT 250 $\mu$ m เป็น NMT 300 $\mu$ m ได้รับการอนุมัติตาม CR no 58380	30/10/15

Prepared by : Suannee , 30/09/15 Head of Raw Material Standard Section 1	Reviewed by : Malee , 30/09/15 Director of Raw Material Standard Division	C-R , 07/10/15 Director of Regulatory Compliance and Documentation Division	Approved by : Prapanadee G. , 07/10/15 Director of Quality Assurance Department	Eff. Date 30/10/15
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เอกสารนี้เป็นเอกสาร  
ใช้ภายในองค์กร