

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diluted Isosorbide-5-mononitrate BP(40% in Lactose)

Spec. No : SP-AK30-I30

(Item No. 41010515)

Reference(s): BP 2013 p. 1215-1216

Rev. No : 03

Other Requirements: GPO Specification

Page

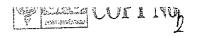
: 1/3

BP 2013

Test Items	Specification		
Description	White crystalline powder.		
Identification			
A: Infrared Absorption	Conform to standard spectrum.		
B: Thin layer chromatography	Complies with Lactose.		
C: Melting point	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 nitra		
Impurities B and C (HPLC)	Impurity B (Isosorbide dinitrate)	: Not more than 0.5%.	
TAMP OF THE PARTY	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 ₆ H ₉ NO ₆)		



			A	Eff. Date
Prepared by:	Reviewed by:	_	Approved by:	Lii. Date
Surannee, 30/09/15		a-R ,07/10/15	Praparade a. , 07/10/15	30/10/15
Head of Raw Material	Director of Kaw Material	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	,
Standard Section 1	Standard Division	and Documentation Division	I Lopes Market	L.,



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diluted Isosorbide-5-mononitrate BP(40% in Lactose)

Spec. No : SP-AK30-I30

(Item No. 41010515)

Reference(s): BP 2013 p. 1215-1216

Rev. No

: 03

Other Requirements: GPO Specification

Page

: 2/3

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

Prepared by:	Reviewed by :		Approved by	Eff. Date
	Walapa 130/09/15	GiR, 07/10/15	Praparadu 6. 07/10/15	30/10/15
Head of Raw Material	Director of Raw Material	Director of Regulatory Compliance		
Standard Section 1	Standard Division	and Documentation Division	Department	



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diluted Isosorbide-5-mononitrate BP(40% in Lactose)

Spec. No : SP-AK30-I30

(Item No. 41010515)

Rev. No : 03

Reference(s): BP 2013 p. 1215-1216

Other Requirements: GPO Specification

Page : 3/3

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	ปรับชยาย spec ค่า d(0.9) จาก NMT 250 µm เป็น NMT 300 µm ได้รับการอนุมัติตาม CR no 58380	30/10/15

Prepared by:	Reviewed by:		Approved by:	Eff. Date
Suvannee, 20/09/15	malen 10 09 15	a- R 07/16/15	Praparadu 6 , 07/10/15	30/10/15
Head of Raw Material	Director of Raw Material	Director of Regulatory Compliance	Director of Quality Assurance	
Standard Section 1	Standard Division	and Documentation Division	Department	

