

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Diluted Isosorbide-5-mononitrate BP (40% in Lactose)
(Item No. 41010515)

Spec. No. : SP-AK30-I30

Reference(s) : BP 2017 p. I-1312 to I-1314

Rev. No. : 04

Other Requirements : GPO Specification

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BP 2017

Test Items	Specification
Description	A white or almost white, crystalline powder.
Identification	
A : Infrared absorption spectrophotometry	Conforms to IR standard spectrum.
B : Thin-layer chromatography	The principal spot in the chromatogram obtained with the Test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a) for lactose.
C : Melting point	Between 89 °C to 91 °C.
Impurity A (TLC)	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% w/w.
	Impurity C (Isosorbide-2-nitrate) : Not more than 0.5% w/w.
Assay	95.0 – 105.0% w/w of the content of 1,4 : 3,6-dianhydro-D-glucitol 5-nitrate stated on the labeled (equivalent to 38.0-42.0% w/w of C ₆ H ₉ NO ₆).

Prepared by : S. Wanmee / 31/01/18 Head of Raw Material Standard Section 1	Reviewed by : S. Tanthongrat / 31/01/18 Director of Raw Material Standard Division	Approved by : V. R. P. / 31/01/18 Director of Regulatory Compliance and Documentation Division	Eff. Date 01/04/18
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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 coloured powders).
3	Particle refractive index	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 : S. Wannee, 31/01/18 Head of Raw Material Standard Section 1	Reviewed by : S. Tantakhanon, 31/01/18 Director of Raw Material Standard Division	Approved by : Vichien Rungnongre, 05/02/18 Director of Quality Assurance Department (Acting)	Eff. Date 01/04/18
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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 : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-I30.
Storage condition	Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	Update spec. เป็น BP 2013	31/10/14
03	ปรับขยาย spec. ค่า d(0.9) จาก NMT 250 μ m เป็น NMT 300 μ m ได้รับการอนุมัติตาม CR No. 58380	30/10/15
04	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2017 และ BP 2013 เหมือนกัน	01/04/2018

Prepared by : S. Tanthanasri / 31/01/18 Head of Raw Material Standard Section 1	Reviewed by : S. Tanthanasri / 31/01/18 Director of Raw Material Standard Division	Approved by : V. Rungtongroj / 05/02/18 Director of Regulatory Compliance and Documentation Division	Eff. Date 01/04/18
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