

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 2023, p. I-1390 to I-1391	Rev. No. : 05
Other Requirements : GPO specification	Page : 1 / 2

BP 2023

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).

GPO specification

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

Prepared by Thanyatorn S./12/09/23 Head of Raw Material Standard Section 1	Reviewed by Suwannee / 12/09/23 Director of Raw Material Standard Division	Approved by Umaporn N. / 13/09/23 Director of Quality System Development Division	Eff. Date 22/09/23
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Diluted Isosorbide-5-mononitrate BP (40% in Lactose) (Item No. 41010515).
Sampling plan	1. 100% Identification. 2. N Plan ($\sqrt{N} + 1$) : 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	Update spec. เป็น BP 2017 โดยเนื้อหาของ BP 2017 และ BP 2013 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จำเป็นต้องทบทวน	01/04/18
05	Update spec. เป็น BP 2023 โดยเนื้อหาของ BP 2023 และ BP 2017 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จำเป็นต้องทบทวน	22/09/23

Prepared by Thanyarat S. / 12/09/23 Head of Raw Material Standard Section 1	Reviewed by Gunawanee / 12/09/23 Director of Raw Material Standard Division	Approved by Chunpan N. / 13/09/23 Director of Quality System Development Division	Approved by Chafin T. / 21/09/23 Director of Quality Assurance Department	Eff. Date 22/09/23
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