

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Dry Vitamin D3, type 100 CWS (Item No. 41011650)

Spec. No. : SP-AK30- V12

Reference(s) : GPO Specification (BASF/ Denmark)

Rev. No. : 02

Other Requirements : -----

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GPO Specification

Test Items	Specification
Description	Light yellow, free flowing, fine granular powder.
Identification	The retention time of the major peak in the chromatogram of the Sample preparation corresponds to principal peak in the chromatogram of the Standard preparation, as obtained in the Assay.
Loss on drying	Not more than 8.0%.
Assay	90,000 – 110,000 IU/g, calculated on dried basis.
Expiry date	The expiry date is beyond the date of material receipt at GPO warehouse for at least two years.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanee, 18/05/16 Head of Raw Material Standard Section 1	Reviewed by : Walaen, 18/05/16 Director of Raw Material Standard Division	Vichin Ruenwongroj, 30/05/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. Y. K. K., 30/05/16 Director of Quality Assurance Department	Eff. Date 23/06/16
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Dry Vitamin D3, type 100 CWS (Item No. 41011650).
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-V12.
Storage condition	Stored in tightly closed container and avoid the moisture and light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรกเป็น Manufacturer's specification (BASF/ Denmark)	30/09/11
02	เอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน เนื้อหาเหมือนเดิม	23/06/16

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanree, 18/05/16 Head of Raw Material Standard Section 1	Reviewed by : Nalapa, 18/05/16 Director of Raw Material Standard Division	Approved by : Nikhun Ruangvongroj, 27/05/16 Director of Regulatory Compliance and Documentation Division	Eff. Date A. Y. K. P., 30/05/16 Director of Quality Assurance Department 23/06/16
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