



COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Deoiled enzyme-modified soy lecithin (Item No. 41022070)	Spec. No. : SP-AK30-L004
Reference(s) : GPO Specification (R&D Institute)	Rev. No. : 01
Other Requirements : -	Page : 1/2

GPO Specification

Description	: Light yellow to tan powder.
Acetone-insoluble matter	: Not less than 50.0%.
Acid value	: Not more than 36.
Hexane-insoluble matter	: Not more than 0.3%.
Water (Karl-Fischer)	: Not more than 1.5%.
Total aerobic microbial count	: Not more than 10^3 cfu/g.
Total combined yeasts/moulds count	: Not more than 10^2 cfu/g.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Rappadech, 26/09/17 Head of Raw Material Standard Section 2	Reviewed by : Yungworn, 26/09/17 Director of Raw Material Standard Division Vasirpin, 03/10/17 Director of Regulatory Compliance and Documentation Division	Approved by : Vithin Kungwongroj, 03/10/17 (Nithing) Director of Quality Assurance Department	Eff. Date 15/10/17
Ungpan N., 26/09/17 Head of Microbiological Analysis Section 2	P.p., 26/09/17 Director of Microbiological Analysis Division		



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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Lecithin (Item No. 41022070).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other Tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-L004.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด โดยอ้างอิงตามข้อกำหนดจากสถาบันวิจัยและพัฒนา [Spec. No. RMS-QC-79N58010P; Rev. No. 00]	15/10/17

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ใช้ในการจัดซื้อ

Prepared by : J. R. P. P. P. P. 26/09/17 Head of Raw Material Standard Section 2 Umporn H. 26/09/17 Head of Microbiological Analysis Section 2	Reviewed by : Yunwiporn 26/09/17 Director of Raw Material Standard Division Pong 26/09/17 Director of Microbiological Analysis Division	Approved by : Vichit Rungvongzai 03/10/17 (Acting) Director of Quality Assurance Department	Eff. Date 15/10/17
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