

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Polyethylene Glycol 1500 USP/NF (Item No. 41022970)	Spec. No. : SP-AK30-P70
Reference(s): USP 42/NF 37 page 5882 - 5884 [Polyethylene Glycol]	Rev. No. : 02
Other Requirements: GPO Specification [Manufacturer's Specification: Clariant]	Page : 1/2

USP 42/NF 37

Test Parameters	Requirement
Description	Practically odorless, white, waxy, plastic material having a consistency similar to beeswax, or as creamy white flakes, beads, or powders.
Solubility	Freely soluble in water; soluble in acetone, in alcohol, in chloroform, in ethylene glycol monoethyl ether, in ethyl acetate, and in toluene; insoluble in ether and in hexane.
Assay	The average molecular weight is not less than 90.0% and not more than 110.0% of the labeled nominal value.
Residue on ignition	Not more than 0.1%.
Limit of free ethylene oxide and 1,4-dioxane	Not more than 10 µg/g of ethylene oxide and not more than 10 µg/g of 1,4-dioxane.
pH	4.5 - 7.5.
Completeness and color of solution	Not more than slightly hazy.

GPO Specification

Test Parameter	Requirement
Solidification point	44 °C - 48 °C.
Water [By KF]	Not more than 0.5%.
Viscosity	36 - 42 mPa s (cps), 50% solution, at 20 °C.

Prepared by : <i>J. Ropadech</i> / 23/12/19 Head of Raw Material Standard Section 2	Reviewed by : <i>Tarnie</i> <i>Lukorn</i> / 23/12/19 Director of Raw Material Standard Division	Approved by : <i>Vichin</i> <i>Rungwong</i> / 25/12/19 Director of Quality Assurance Department (Aching)	Eff. Date 15/01/20
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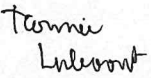

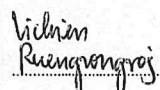
Title: Polyethylene Glycol 1500 USP/NF (Item No. 41022970)	Spec. No. : SP-AK30-P70
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Polyethylene Glycol 1500 USP/NF (Item No. 41022970).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-P70.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
00	จัดทำข้อกำหนด โดยอ้างอิงตาม GPO Specification [Manufacturer's Specification: Clariant]	29/08/03
01	Update ตาม USP 38/NF 33 และ GPO Specification [Manufacturer's Specification: Clariant]	24/03/16
02	Update ตาม USP 42/NF 37 และ GPO Specification [Manufacturer's Specification: Clariant]	15/01/20

Prepared by : J. Noppadech / 23/12/19 Head of Raw Material Standard Section 2	Reviewed by : <div style="display: flex; justify-content: space-between;"> <div>  Director of Raw Material Standard Division </div> <div>  Director of Drug Registration and Pharmacovigilance Division </div> </div>	Approved by : <div style="display: flex; justify-content: space-between;"> <div>  Director of Quality Assurance Department (Acting) </div> <div> Eff. Date 15/01/20 </div> </div>
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