

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Polyethylene Glycol 8000 USP/NF [PEG 8000 USP/NF, Macrogol 6000 JP] (Item No. 41022980)		Spec. No. : SP-AK30-P010
Reference(s): USP 42/NF 37 page 5882 - 5884 [Polyethylene Glycol]		Rev. No. : 05
Other Requirements: GPO Specification [JP 16 page 1052 - 1053]		Page : 1/3

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.
Approximate congealing temperature	60 °C.
Assay	The average molecular weight is not less than 87.5% and not more than 112.5% 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.
Viscosity	470 - 900 centistokes.

Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Ropadech / 19/12/19	Thornier / 19/12/19	Wichin Ruengprongroj / 20/12/19	15/01/20
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
Standard Section 2	Standard Division	Department (Aching)	
	Director of Drug Registration and Pharmacovigilance Division		

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Other Requirements: GPO Specification [JP 16 page 1052 - 1053] **Page :** 2/3

GPO Specification

Test Parameter	Requirement
Identification	Dissolve 0.05 g of sample in 5 mL of dilute hydrochloric acid, add 1 mL of barium chloride TS, shake, and filter, if necessary. To the filtrate add 1 mL of a solution of phosphomolybdic acid n-hydrate (1 in 10): a yellow-green precipitate is formed.

Prepared by : <u>S. Koppadech / naha</u> Head of Raw Material Standard Section 2	Reviewed by : <u>Tanmee</u> <u>Unboonit</u> , 10/12/19 Director of Raw Material Standard Division	Approved by : <u>Wichien</u> <u>Rungrongroj</u> , 20/12/19 Director of Quality Assurance Department (Acting)	Eff. Date 15/01/20
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Polyethylene Glycol 8000 USP/NF [PEG 8000 USP/NF, Macrogol 6000 JP] (Item No. 41022980).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-P010.
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
02	อ้างอิงตาม JP 16	19/08/14
03	อ้างอิงตามตำรายาที่รัฐมนตรีประกาศ โดยอ้างอิงตาม USP 38/NF 33 และเปลี่ยนชื่อจาก Macrogol 6000 JP เป็น PEG 8000 USP/NF	29/01/16
04	เพิ่มชื่อ "(PEG 8000 USP/NF, Macrogol 6000 JP)" [เดิม "Polyethylene Glycol 8000 USP/NF" เป็น "Polyethylene Glycol 8000 USP/NF (PEG 8000 USP/NF, Macrogol 6000 JP)"]	25/02/16
05	Update ตาม USP 42/NF 37 และทดสอบ Identification ตาม GPO Specification	15/01/20

Prepared by : <u>J. Klopadech / 19/12/19</u> Head of Raw Material Standard Section 2	Reviewed by : <u>tanwae</u> <u>unhornt / 20/12/19</u> Director of Raw Material Standard Division	Approved by : <u>Vichien Rungwongroj / 20/12/19</u> Director of Quality Assurance Department (Acting)	Eff. Date 15/01/20
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