GPO COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Era gel (Pregelatinized Starch USP/NF) (Item No. 41010570)	**Spec. No.** : SP-AK30-E003
Reference(s) : USP 42/NF 37 p. 6001 - 6002	**Rev. No.** : 05
Other Requirements : ---	**Page** : 1/2

USP 42/NF 37

Test Items	Specification	
Description	Fine, white to off-white powder, odorless.	
Solubility	Slightly soluble to soluble in cold water; insoluble in alcohol.	
Identification	A water slurry of it is colored orange-red to deep blue by *Iodine TS.*	
Residue on ignition	Not more than 0.5%, determined on a 2.0-g test specimen.	
Iron	Not more than 20 ppm.	
Limit of sulfur dioxide	Not more than 2.7 ml of 0.01 N Iodine VS is consumed. (Not more than 80 ppm.)	
pH	4.5 - 7.0.	
Loss on drying	Not more than 14.0% of its weight.	
Oxidizing substances	No distinct blue, brown, or purple color is observed.	
Microbial enumeration tests and Tests for specified microorganisms.	*Salmonella species*	Absence.
	Escherichia coli	Absence.
	The total aerobic microbial count	Not exceed 1000 cfu/g.
	The total combined molds and yeasts count	Not exceed 100 cfu/g.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	15/06/20

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Title : Era gel (Pregelatinized Starch USP/NF) (Item No. 41010570)	**Spec. No.** : SP-AK30-E003
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Era gel (Pregelatinized Starch USP/NF) (Item No. 41010570)
Sampling plan	1. N Plan ($\sqrt{N}+1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-E003.
Storage condition	Preserve in well-closed containers. No storage requirements specified.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	Update spec. เป็น USP 36/NF 31	16/06/14
04	Update spec. เป็น USP 39/NF 34 โดยเนื้อหาของ USP 36/NF 31 และ USP 39/NF 34 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องดำเนินการทบทวน	28/02/17
05	Update spec. เป็น USP 42/NF 37 โดยเนื้อหาของ USP 42/NF 37 และ USP 39/NF 34 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องดำเนินการทบทวน	15/06/20

Prepared by :		Reviewed by :			Approved by :	Eff. Date
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Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	