

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Gelatin granules BP (Item No. 41010770)	Spec. No. : SP-AK30-G002
Reference(s) : BP 2016 p. I1070-I1071	Rev. No. : 03
Other Requirements : -----	Page : 1/2

BP 2016

Test Items	Specification	
Description	Faintly yellow granules, slight odor.	
Solubility	Soluble in hot water, in 6 N acetic acid and in a hot mixture of glycerin and water; insoluble in cold water.	
Identification		
A. Chemical Test	A violet color is produced.	
B. Chemical Test	The contents immediately flow out for non-gelling grades and do not flow out immediately for gelling grades.	
pH	3.8 to 7.6 for solution S.	
Conductivity	Maximum 1 mS.cm ⁻¹ , determined on a 1.0% solution at 30±1.0 °C.	
Sulfur dioxide	Maximum 50 ppm.	
Peroxides	Maximum 10 ppm.	
Gel strength (Bloom value)	80-120% of the nominal value stated on the label for the gelling grade.	
Iron	Maximum 30 ppm.	
Chromium	Maximum 10 ppm.	
Zinc	Maximum 30 ppm.	
Loss on drying	Maximum 15.0%.	
Microbial contamination	Total aerobic microbial count	: Not exceed 1000 cfu/g.
	Total combined yeasts and molds counts	: Not exceed 100 cfu/g.
	<i>Salmonella species</i>	: Absence.
	<i>Escherichia coli</i>	: Absence.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Gelatin granules BP (Item No. 41010770).
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-G002.
Storage condition	Protect from heat and moisture.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	อ้างอิง spec เป็น BP 2013	15/05/13
03	Up spec เป็น BP 2016 โดยเนื้อหาของ BP 2013 และ BP 2016 เหมือนกัน เนื่องจากเอกสารมีอายุมากกว่า 3 ปีจึงต้องทบทวน	23/06/16

Prepared by : Sunanee / 13/06/16 Head of Raw Material Standard Section 1	Reviewed by : Valaya / 13/06/16 Director of Raw Material Standard Division	Reviewed by : Vichien Ruengsong / 14/06/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. Y. / 23/06/16 Director of Quality Assurance Department	Eff. Date 23/06/16
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