COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Calcium Gluconate Monohydrate USP (Item No. 41030720) (for injectable dosage form)

Spec. No. : SP-AK30-C002

Reference(s) : USP 39 p. 2877-2879 (same as USP 43)

Rev. No. : 10

Other Requirements : GPO specification

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USP 39

Test Parameters	Specifications
Description	White, crystalline, odorless, tasteless granules or powder.
Solubility	Freely soluble in boiling water, sparingly and slowly soluble in water, insoluble in alcohol.
Identification A. Calcium B. Infrared absorption	 Upon the addition of ammonium oxalate TS, a white precipitate is formed. This precipitate is insoluble in 6 N acetic acid but dissolves in hydrochloric acid. Conforms to the spectrum of USP Calcium Gluconate Monohydrate RS.
Arsenic	Not more than 3 ppm, Method I.
Chloride	Not more than 0.005%.
Sulfate	Not more than 0.005%.
Heavy metals	Not more than 10 ppm, Method II.
Limit of Iron	Not more than 5 ppm.
Limit of Magnesium and alkali metals	Not more than 0.4%; the weight of the residue does not exceed 2 mg.
Limit of Phosphates	Not more than 0.01%; after 10 minutes any color in the Sample solution is not more intense than that in the Standard solution.
Limit of Oxalate	Not more than 0.01%.
Reducing substances	Not more than 1.0%.
Loss on drying	Not more than 1.0%.
Assay	99.0% to 101.0% of $C_{12}H_{22}CaO_{14},H_2O$, calculated on the dried basis.

GPO Specification

Test Parameters	Specifications
Bacterial endotoxins	Less than 167 IU/g.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
06/10/20	12/10/20	07/10/20	12/10/20	12/10/20	14/10/20	25/11/20
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 1	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Calcium Gluconate Monohydrate USP (Item No. 41030720) (for injectable dosage form)
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-C002.
Storage condition	To be stored in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
07	ประกาศใช้เป็นครั้งแรก Specเป็น BP2009	15/10/10
08	Update spec. เป็น BP2014 เนื้อหาของ BP2009 และ BP2014 เหมือนกัน	29/05/15
09	Update spec. เป็น USP 39 เพื่อให้สอดคล้องกับ FP อ้างอิง CR No. AN80-59241	25/10/16
10	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน อ้างอิงตาม USP 39 เพื่อให้สอดคล้องกับ Calcium gluconate injection ซึ่งขึ้นทะเบียนตาม Monograph USP 39 (วัตถุดิบ Calcium Gluconate Monohydrate (for injectable dosage form) USP 39 เทียบเท่ากับ USP 43	25/11/20

Prepared by :		Reviewed by :			Approved by :	Eff. Date
04/10/20	...../.....	09/10/20	17/10/20	12/10/20	14/10/20	25/11/20
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 1	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	