GPO COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Chlorpromazine Hydrochloride USP (For injection dosage form) (Item No. 41031420)	**Spec. No.**	: SP-AK30-C24/1
Reference(s) : USP 41 p. 906	**Rev. No.**	: 05
Other Requirements : GPO Specification	**Page**	: 1/2

USP 41

Test Items	Specification
Description	White or slightly creamy white, odorless, crystalline powder.
Solubility	Very soluble in water, freely soluble in alcohol and in chloroform; insoluble in ether and in benzene.
Identification A. Infrared absorption <197K> B. Thin layer chromatography C. Chloride Test	 Conforms to IR standard spectrum. The principal spot found in the test for *Other alkylated phenothiazines* corresponds in R_f to the spot from the Standard solution. A white, curdy precipitate is formed which is insoluble in nitric acid but is soluble in a slight excess of ammonia.
Melting range	Between 195 °C and 198 °C.
Loss on drying	Not more than 0.5%.
Residue on ignition	Not more than 0.1%.
Other alkylated phenothiazines	The area and intensity of any spot, other than the principal spot, from the solution of Chlorpromazine Hydrochloride are not greater than those of the spot from the Diluted standard solution (0.5%).
Assay	98.0 – 101.5% of $C_{17}H_{19}ClN_2S \cdot HCl$, calculated on the dried basis.

GPO Specification

Test Items	Specification
Bacterial endotoxin	Not more than 6.9 USP Endotoxin Units per mg of Chlorpromazine HCl.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Suwannee, 25/07/19	Benjawan Ubonklee, 26/07/19	Tarinee Lalueni, 26/07/19	19/08/19	19/08/19	Vichian Ruengpongyuj, 20/08/19	30/10/19
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 Regulatory Compliance and Documentation 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 Chlorpromazine Hydrochloride USP (For injection dosage form) (Item No. 41031420).
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-C24/1.
Storage condition	Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	อ้างอิง spec. เป็น BP 2011	17/10/11
04	Update spec. เป็น BP 2016 อ้างอิง CR No. AN80-59089 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน	24/05/16
05	Update spec. เป็น USP 41 อ้างอิงมติที่ประชุม Site transfer	30/10/19

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Head of Raw Material Standard Section I	Head of Microbiological Analysis Section I	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	30/10/19