COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Chlorpheniramine Maleate USP (Item No. 41020760)	**Spec. No.** : SP-AK30-C012
Reference(s): USP 42 page 949 to 950	**Rev. No.** : 06
Other Requirements: GPO Specification	**Page** : 1/2

USP 42

Test Parameter	Requirement	
Description	White, odorless, crystalline powder.	
Solubility	Freely soluble in water; soluble in alcohol and in chloroform; slightly soluble in ether and in benzene.	
Identification	A. Infrared Absorption.	
	B. The retention times of the maleic acid and chlorpheniramine peaks of the Sample solution correspond to those of the Standard solution, as obtained in the Assay.	
Assay	98.0% to 102.0% of Chlorpheniramine Maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$), calculated on the dried basis.	
Residue on ignition	Not more than 0.2%.	
Organic impurities	Diamine analog	Not more than 0.2%.
	Chlorpheniramine related compound B	Not more than 0.1%.
	Chlorpheniramine related compound C	Not more than 0.1%.
	Chlorpheniramine nitrile	Not more than 0.1%.
	Any other unspecified impurity	Not more than 0.10%.
	Total impurities	Not more than 0.5%.
Optical rotation	-0.10° to +0.10°.	
Loss on drying	Not more than 0.5%.	

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GPO Specification

Test Parameter	Requirement
Fineness	Passed through sieve number 100 is not less than 40.0% by weight of the powder.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
Benjawan Ubonklee /15/10/20	Tamma Lumlumnt /15/10/20	/19/10/20	/19/10/20	15/11/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard 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 Supplier List of Chlorpheniramine Maleate USP (Item No. 41020760).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C012.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
03	Update ข้อกำหนดตาม USP 35 และ GPO Specification	19/06/13
04	Update ข้อกำหนดตาม USP 36 และ GPO Specification	19/08/14
05	Update ข้อกำหนดตาม USP 41 และ GPO Specification	15/12/19
06	Update ข้อกำหนดตาม USP 42 และ GPO Specification	15/11/20

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