GPO COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Chlorphenamine Maleate BP (For injection dosage form) (Item No. 41031400)	**Spec. No.** : SP-AK30-C003
Reference(s) : BP 2021 p. I-552 to I-553	**Rev. No.** : 10
Other Requirements : GPO Specification	**Page** : 1/3

BP 2021

Test Items	Specification	
Description	White or almost white crystalline powder, odorless.	
Solubility	Freely soluble in water, soluble in ethanol (96%).	
Identification A. Melting point B. Infrared absorption spectrophotometry C. Optical rotation	 130 °C to 135 °C. Conforms to IR standard spectrum. Between -0.10° and +0.10°.	
Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY_6.	
Optical rotation	Between -0.10° and +0.10°, determined on solution S.	
Related substances	Impurity A	Not more than 0.2%.
	Impurity B	Not more than 0.1%.
	Impurity C	Not more than 0.1%.
	Impurity D	Not more than 0.1%.
	Unspecified impurity	Not more than 0.10%.
	Total impurities	Not more than 0.5%.
Loss on drying	Not more than 0.5%.	
Sulfated ash	Not more than 0.1%.	
Assay	98.0-101.0% of $C_{20}H_{23}ClN_2O_4$, calculated on dried basis.	

GPO Specification

Test Items	Specification
Heavy metals	Not more than 20 ppm, Test C.
Bacterial endotoxins	Not more than 8.8 Endotoxin Units per mg.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
(Acting) Thanyaton / 20/12/21	Rungnapa D. / 20/12/21	Suwannee / 20/12/21	Pongsy / 21/12/21	/ 21/12/21	(Acting) Tanmi Lumlert / 29/12/21	24/01/22
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 Strategy Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Chlorphenamine Maleate BP (For injection dosage form) (Item No. 41031400).
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-C003.
Storage condition	Preserve in tight, light resistance containers.
Retest period	1 year after first testing date.

Prepared by :		Reviewed by :			Approved by : (Acting)	Eff. Date
(Acting) Thunyatorn / 20/12/21	Russaporn P. / 20/12/21	Suwanee / 20/12/21	/ 21/12/21	/ 21/12/21	Tanmai Lamlert / 27/12/21	24/01/22
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 Strategy Division	Director of Quality Assurance Department	

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History of changes

Rev. No.	Description	Effective date
07	Update spec. เป็น BP 2011 เพื่อให้สอดคล้องกับ spec. ของ Finished product Chlorpheniramine maleate injection ตาม CR No.55078	17/09/12
08	Update spec. เป็น BP 2016 เนื่องจากเอกสารอายุมากกว่า 3 ปี ต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน อ้างอิง CR No. AN80-59088	24/05/16
09	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน อ้างอิงตาม BP 2016 เพื่อให้สอดคล้องกับ Chlorpheniramine injection ซึ่งขึ้นทะเบียนตาม Monograph BP 2016 (วัตถุดิบ Chlorpheniramine maleate (for injectable dosage form) BP 2016 เทียบเท่ากับ BP 2020	24/11/20
10	Update spec. เป็น BP 2021 อ้างอิง CR No. 1500001201 เพื่อให้สอดคล้องกับ Chlorpheniramine injection	24/01/22

Prepared by :		Reviewed by :			Approved by :	Eff. Date
(Acting) Thanyatorn 20/12/21	Rewadee 20/12/21	Suwannee, 20/12/21	21/12/21	21/12/21	(Acting) 27/12/21	24/01/22
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 Strategy Division	Director of Quality Assurance Department	