COPY No. 2

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 2016 p. I-527 to I-528	**Rev. No.** : 08
Other Requirements : GPO Specification	**Page** : 1/2

BP 2016

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. Conform to *FT-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%.
Heavy metals	Not more than 20 ppm, Test C.	
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
Bacterial endotoxins	Not more than 8.8 Endotoxin Units per mg.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sunanee / 04/05/16 Head of Raw Material Standard Section 1	Nalapa / 04/05/16 Director of Raw Material Standard Division	Wichien Rueangsongraj / 13/05/16 Director of Regulatory Compliance and Documentation Division	A. Yamyat / 18/05/16 Director of Quality Assurance Department	24/05/16

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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	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
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.

History of changes

Rev. No.	Description	Effective date
07	Up date spec เป็น BP 2011 เพื่อให้สอดคล้องกับ Spec ของ Finished product Chlorpheniramine maleate injection ตาม CR no.55078	17/09/12
08	Up spec เป็น BP 2016 เนื่องจากเอกสารอายุมากกว่า 3 ปี ต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน อ้างอิง CR No. AN80-59088	24/05/16

ใช้ในการอัดฟิล์ม

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suvannee / 04/05/16 Head of Raw Material Standard Section 1	Wadaporn / 04/05/16 Director of Raw Material Standard Division	Vichien Ruengwongroj / 17/05/16 Director of Regulatory Compliance and Documentation Division	A. Yoompat / 18/05/16 Director of Quality Assurance Department	24/05/16