COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Metoclopramide HCl (For injection dosage form) BP (Item No. 41032400)	**Spec. No.** : SP-AK30-M28/1
Reference(s) : BP 2016 p. II-278-279	**Rev. No.** : 04
Other Requirements : GPO Specification	**Page** : 1/2

BP 2016

Test Items	Specification
Description	White or almost white crystalline powder, odorless.
Solubility	Very soluble in water, freely soluble in alcohol, sparingly soluble in methylene chloride.
Identification A. The pH of Solution S B. Infrared absorption spectrophotometry C. Chloride Test	 4.5 to 6.0. Conforms to *FT-IR standard spectrum*. Dilute 1 ml of Solution S to 2 ml of water, Acidify with dilute nitric acid and add 0.4 ml of silver nitrate solution R1. Shake and allow to stand. A curdled, white precipitate is formed. Suspend the precipitate in 2 ml of water and add 1.5 ml of ammonia. The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
Appearance of solution	Solution S is clear and colorless.
Related substances	- Examine in ultraviolet light at 254 nm. Any spot in the chromatogram obtained with *Test solution (a),* apart from the principal spot, is not more intense than the spot in the chromatogram obtained with *Reference solution (b)* (0.5%). - Spray with dimethylaminobenzaldehyde solution R1. Any spot in the chromatogram obtained with *Test solution (a)* that has not been visualized in ultraviolet light at 254 nm is not more than intense than the spot in the chromatogram obtained with *Reference solution (c)* (0.5%).
Heavy metals	Not more than 20 ppm, Test A.
Water	4.5% to 5.5%.
Sulfated ash	Not more than 0.1%.
Assay	99.0 – 101.0% of $C_{14}H_{22}ClN_3O_2$,HCl, calculated with reference to the anhydrous substance.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 04/05/16	Nalapa / 04/05/16	Vichien Rungvongroj / 17/05/16	A. Y. Rapt / 18/05/16	24/05/16
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

GPO COPY No. 2

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GPO Specification

Test Items	Specification
Bacterial endotoxins	Not more than 2.5 USP Endotoxin Units per mg of Metoclopramide.

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Metoclopramide HCl (Injection grade) BP (Item No. 41032400).
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-M28/1.
Storage condition	Store protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	อ้างอิง spec เป็น BP 2011	28/02/12
04	Up spec เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน อ้างอิง CR No. AN80- 59092	24/05/16

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