

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. : 05
Other Requirements : GPO Specification	Page : 1/3

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	4.5 to 6.0.
B. Infrared absorption spectrophotometry	Conforms to IR standard spectrum.
C. Chloride Test	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	<p>- Examine in ultraviolet light at 254 nm. Any spot in the chromatogram obtained with <i>Test solution (a)</i>, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with <i>Reference solution (b)</i> (0.5%).</p> <p>- Spray with dimethylaminobenzaldehyde solution R1. Any spot in the chromatogram obtained with <i>Test solution (a)</i> that has not been visualized in ultraviolet light at 254 nm is not more than intense than the spot in the chromatogram obtained with <i>Reference solution (c)</i> (0.5%).</p>
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 $C_{14}H_{22}ClN_3O_2 \cdot HCl$, calculated with reference to the anhydrous substance.

Prepared by : Sundee, 12/10/20 Head of Raw Material Standard Section 1	Reviewed by : Sundee, 12/10/20 Director of Raw Material Standard Division	Reviewed by : Sundee, 12/10/20 Director of Microbiological Analysis Division	Reviewed by : Sundee, 12/10/20 Director of Drug Registration and Pharmacovigilance Division	Approved by : Yampan, 15/10/20 Director of Quality Assurance Department (Acting)	Eff. Date 30/11/20
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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	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-M28/1.
Storage condition	Store protected from light.
Retest period	1 year after first testing date.

Prepared by : <i>Sunam...</i> 12/10/20	Reviewed by : <i>...</i> 12/10/20	Approved by : <i>...</i> 15/10/20	Eff. Date 30/11/20
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 1	Director of Raw Material Standard Division	Director of Quality Assurance Department (Acting)


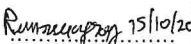
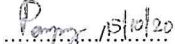
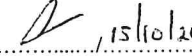
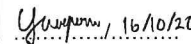
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History of changes

Rev. No.	Description	Effective date
03	อ้างอิง spec. เป็น BP 2011	28/02/12
04	Update spec. เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน อ้างอิง CR No. AN80- 59092	24/05/16
05	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน อ้างอิงตาม BP 2016 เพื่อให้สอดคล้องกับ Metoclopramide injection ซึ่งขึ้นทะเบียนตาม Monograph BP 2016	30/11/20

Prepared by :  12/10/20 Head of Raw Material Standard Section 1	Reviewed by :  15/10/20 Director of Raw Material Standard Division	Reviewed by :  15/10/20 Director of Microbiological Analysis Division	Reviewed by :  15/10/20 Director of Drug Registration and Pharmacovigilance Division	Approved by :  16/10/20 Director of Quality Assurance Department (Acting)	Eff. Date 30/11/20
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