

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Metoclopramide HCl BP (For injection dosage form) (Item No. 41032400)	Spec. No. : SP-AK30-M28/1
Reference(s) : BP 2021 p. II-293 to II-294	Rev. No. : 06
Other Requirements : GPO Specification	Page : 1/3

BP 2021

Test Items	Specification
Description	White or almost white crystalline powder, odorless.
Solubility	Very soluble in water, freely soluble in ethanol (96%), sparingly soluble in methylene chloride.
Identification	
A. pH	4.5 to 6.0 for solution S.
B. Infrared absorption spectrophotometry	Conforms to IR standard spectrum.
C. Chloride Test	Conforms to BP 2021.
Appearance of solution	Solution S is clear and colourless.
Impurity E	Any spot due to impurity E in the chromatogram obtained with Test solution is not more intense than the corresponding spot in the chromatogram obtained with Reference solution (0.5%).
Related substances	Unspecified impurity : Not more than 0.10%.
	Total impurities : Not more than 0.2%.
Water	4.5% to 5.5%.
Sulfated ash	Not more than 0.1%.
Assay	99.0% – 101.0% (anhydrous substance).

GPO Specification

Test Items	Specification
Heavy metals	Not more than 20 ppm, Test A.
Bacterial endotoxins	Not more than 2.5 USP Endotoxin Units per mg of Metoclopramide.

Prepared by : (Acting) Pharmacist, 14/03/22 Head of Raw Material Standard Section 1	Reviewed by : Pharmacist, 14/03/22 Head of Microbiological Analysis Section 1	Reviewed by : Pharmacist, 14/03/22 Director of Raw Material Standard Division	Reviewed by : Pharmacist, 16/03/22 Director of Microbiological Analysis Division	Reviewed by : Pharmacist, 24/03/22 Director of Regulatory Strategy Division	Approved by : (Acting) Pharmacist, 24/03/22 Director of Quality Assurance Department	Eff. Date 15/04/22
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Metoclopramide HCl BP (For Injection dosage grade) (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 : (Acting) Thanyaporn, 14/03/22 Head of Raw Material Standard Section 1	Reviewed by : Swannee, 14/3/22 Director of Raw Material Standard Division	Reviewed by : Pany, 16/03/22 Director of Microbiological Analysis Division	Reviewed by : Pany, 24/03/22 Director of Regulatory Strategy Division	Approved by : (Noting) Thanyaporn, 25/03/22 Director of Quality Assurance Department	Eff. Date 15/04/22
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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
06	Update spec. เป็น BP 2021 อ้างอิง CR No. 1500001312	15/04/22

Prepared by : ศาสตราจารย์ พญ.วิมล / 14/03/22 Head of Raw Material Standard Section 1	Reviewed by : สุวามรี / 14/03/22 Director of Raw Material Standard Division	Reviewed by : พญ. / 16/03/22 Director of Microbiological Analysis Division	Reviewed by : / 24/03/22 Director of Regulatory Strategy Division	Approved by : (Active) / 25/03/22 Director of Quality Assurance Department	Eff. Date 15/04/22
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