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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Item NO. 41022133

TITLE : Meropenem and Sodium Carbonate Sterile Bulk	**SPEC. NO. :** SP-AQ13-CRM01
REFERENCE(S) : USP 37 p.3713-3714	**REV. NO. :** 01
OTHER REQUIREMENTS : GPO Specification	**PAGE :** 1/2

USP37

Constituted solution	
- Completeness and clarity of solution	The solid dissolves completely, leaving no visible residue as undissolved matter, the constituted solution is not significantly less clear than an equal volume of the diluent or of purified water contained in a similar vessel and examined similarly.
- Particulate matter (visual inspection)	The solution is essentially free from particles of foreign matter.
Identification (HPLC)	Conforms to standard HPLC chromatogram.
pH	7.3 - 8.3, in a solution containing 50 mg/mL.
Loss on drying	9.0 - 12.0% w/w.
Bacterial endotoxins	Not more than 0.125 USP Endotoxin Unit/mg of meropenem.
Sterility	No microbial growth is observed.

GPO Specification

Description	White to light yellow powder.
Identification (FT-IR)	Conforms to reference IR spectrum.
Particulate matter (light OBS)	Particles size ≥ 10 µm : ≤ 6,000 particles/g. Particles size ≥ 25 µm : ≤ 600 particles/g.
Assay of meropenem	70.0 - 78.0% w/w of meropenem ($C_{17}H_{25}N_3O_5S$).
Content of sodium	6.0 - 7.4% w/w of sodium (Na).
Meropenem impurity I	Not more than 0.5%.
Meropenem impurity II	Not more than 0.4%.

Prepared by		Reviewed by			Approved by	Eff. Date
Kanyaporn 05/10/17	Benjawan Ubonklee, 06/10/17	9/10/17	09/10/17	10/10/17	Vichian Rungruangyos 16/10/17 (Acting)	16/10/17
Director of Beta-lactam Antibiotics QC Group	Head of Microbiological Analysis Section 1	Manager of Beta-lactam Antibiotics Plant	Director of Microbiological Analysis Division	Beta-lactam Antibiotics Plant QA Manager	Director of Quality Assurance Department	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

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Product Information

Approved source(s)	Refer to current version of Approved Vendor List of Meropenem.
Sampling procedure	Current version of WI-AQ13-001.
Testing procedure	Tests to be performed as per current version of WI-AQ13-CRM01,WI-AK61-T11, WI-AK61-T14.
Storage conditions	To be stored in tight containers. (Where specific storage conditions are stated on the labels from the manufacturers, the materials should be stored in the conditions stated on the labels).
Retest period	1 year after first testing date.

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REVISION HISTORY

Rev. No.	Summary of change	Editor	Effective date
01	The first issuance of document.	-	16/10/17

Prepared by		Reviewed by			Approved by	Eff. Date
Kanyaporn, 05/10/17	Benjawan Ubonklee, 06/10/17	9/10/17	10/10/17	10/10/17	Wichain Rungwongsri (Acting) 16/10/17	16/10/17
Director of Beta-lactam Antibiotics QC Group	Head of Microbiological Analysis Section 1	Manager of Beta-lactam Antibiotics Plant	Director of Microbiological Analysis Division	Beta-lactam Antibiotics Plant QA Manager	Director of Quality Assurance Department	