

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

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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.		
pН	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 Particles size $\geq 10 \ \mu m : \leq 6,000 \ particles/g$. (light OBS) Particles size $\geq 25 \ \mu m : \leq 600 \ particles/g$.				
Assay of meropenem	70.0 - 78.0% w/w of meropenem (C ₁₇ H ₂₅ N ₃ O ₅ S).			
Content of sodium	6.0 - 7.4% w/w of sodium (Na).			
Meropenem impurity I	Not more than 0.5%.			
Meropenem impurity II	npurity II Not more than 0.4%.			

Prepared by Kanyapara, 05/10/17	Benjawan actados	Reviewed by	Pl. l.	PSi 10/10/17	Approved by	Eff . Date
Director of Beta-	Ubunkles, 06/70/17 Head of	7 ,9/10/17 Manager of	Director of	ferrenessed as intelligentel	(Aultrace) Director of	16/10/17
lactam Antibiotics QC Group	Microbiological Analysis Section 1	Beta-lactam Antibiotics Plant	Microbiological Analysis Division	Antibiotics Plant OA Manager	Quality Assurance	ใม่ควบคุ

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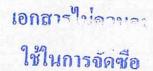
OTHER REQUIREMENTS: GPO Specification

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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.			



REVISION HISTORY

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

Prepared by Kanyopsin, 05/10/17	Benjawan Ubanklee, o Wolat	Reviewed by	Popy postiolis	PS:: 1.10/10/17	Approved by Violatin Rungwicky 16/10/17	Eff. Date 16/10/17
Director of Beta-	Head of	Manager of	Director of	Beta-lactam	(Aulity) Director of	
lactam Antibiotics	Microbiological	Beta-lactam	Microbiological	Antibiotics Plant	Quality Assurance	
QC Group	Analysis Section 1	Antibiotics Plant	Analysis Division	QA Manager	Department	