The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER:	RPP-SP-QC-RM-023
DOCUMENT TITLE:	SPECIFICATION OF PEARLITOL SD 200 MANNITOL USP ITEM NO. 44121700
DOCUMENT NOTES:	

Document Information

Revision:	04	Vault:	RPP STP_SP-rel
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Date Information

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Control Information

Author:	NATTAPORN_R	Previous Number:	SP-QC-RM-023
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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	9 Mar 2015

02	• Change Item name from "MANNITOL USP" to "PEARLITOL SD 200 (MANNITOL USP)" follow change no. 58-AT32-001
	• Change limit of microbial enumeration test and test for specified microorganism for better clarification with same limit
	  • TAMC: from 10^3 cfu/g to 1000 cfu/g
	  • TYMC: from 10^2 cfu/g to 100 cfu/g
	  • *Escherichia coli*: from Absence to Absence (1 g)
		30 Apr 2015

03	Periodic review and revise specification as per USP40/NF35 (USP40/NF35 is equivalent to USP37/NF32)	27 Jun 2017
04	Periodic review and revise specification as per USP42/NF37 (USP42/NF37 is equivalent to USP37/NF32)	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description	White, crystalline powder or free-flowing granules, odorless.
02	Solubility	Freely soluble in water, soluble in alkaline solutions; slightly soluble in pyridine, very slightly soluble in alcohol; practically insoluble in ether.
03	Identification	The IR absorption spectrum of sample preparation exhibits maxima at the same wavelengths as that of Mannitol reference standard preparation.
04	Assay	Not less than 97.0% and not more than 102.0% of Mannitol ($C_6H_{14}O_6$), calculated on the anhydrous basis.
05	Related substances a. Sorbitol b. Sum of isomalt and maltitol c. Unspecified impurities d. Total impurities	 Not more than 2.0%. Not more than 2.0%. Not more than 0.10% for each impurity. Not more than 2.0%.
06	Reducing sugars	Not more than 0.1%, expressed as glucose.
07	Nickel	Not more than 1 µg/g.
08	Melting range or temperature	165°C- 170°C.
09	Appearance of solution	The sample solution is clear and colorless: its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension, and it is not more intensely colored than the Standard solution.
10	Loss on drying	Not more than 0.5 %.
11	Conductivity	Not more than 20 µS/cm at 25°C.
12	Microbial enumeration tests and tests for specified microorganisms a. Total aerobic microbial count (TAMC) b. Total combined molds and yeasts count (TMYC) c. *Escherichia coli*	 Not more than 1000 cfu/g. Not more than 100 cfu/g. Absence (1 g).

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B. Packaging and Storage

Preserve in well-closed containers.

C. Reference

- USP 42/NF37, Mannitol monograph, page 2686-2688.
- BP 1998, Mannitol monograph, page 843. (Assay).

D. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Pearlitol SD 200 (Mannitol USP) (Item No. 44121700).
Sampling plan	Identification: Every container. Other tests : $\sqrt{N}+1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Mannitol USP (Item No. 44121700).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

Pls review RPP-SP-QC-RM-023

Step 1. Preparer

Name/Signature	Title	Date	Meaning/Reason
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NALINEE NEAMSRIPETCH (NALINEE_N)	QC Pharmacist	08 Jul 2019, 09:17:06 AM	Complete

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Step 3. Approver

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Step 4. Notify

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SIRILUK BUACHAROEN (SIRILUK_B)	HEAD OF IT QUALITY AND DOC SEC	08 Jul 2019, 09:48:18 PM	Email Sent
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TASSANA PRAWISAT (TASSANA_P)	QA IT&Doc	08 Jul 2019, 09:48:18 PM	Email Sent
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Review: RPP-SP-QC-RM-023 04 SPECIFICATION OF PEARLITOL SD 200 MANNITOL USP ITEM NO.44121700

Review

Name/Signature	Title	Date	Meaning/Reason
SUTAN OTAMO (SUTAN_O)	DIRECTOR OF QC DIVISION 2	08 Jun 2021, 07:29:23 AM	Reviewed
NATTAPORN RUANSON (NATTAPORN_R)	HEAD OF IT QUALITY AND DOC SEC	08 Jun 2021, 08:02:49 AM	Reviewed
NALINEE NEAMSRIPETCH (NALINEE_N)	QC-RM Pharmacist	28 Jun 2021, 07:38:06 PM	Reviewed