



The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER: RPP-SP-QC-RM-108

DOCUMENT TITLE: SPECIFICATION OF MANNITOL (PEARLITOL 25C) (ITEM NO. 44121680)

DOCUMENT NOTES:

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Control Information

Author: NATTAPORN_R

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Owner: NATTAPORN_R

Change Number: Packet-1195

| 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 (Change-20-090) | 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 dried 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; Not more than 3.2 ml of 0.02 M potassium permanganate VS is required to change the color of the solution. The green colors turns to pink, and the color persists at least 10 s. |
| 07 | Nickel | Not more than 1 $\mu\text{g/g}$. |
| 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 $\mu\text{S/cm}$ 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. <i>Escherichia coli</i> | Not more than 10^3 cfu/g. Not more than 10^2 cfu/g. Absence (1 g). |
| 13 | Particle size (By Laser diffraction) * | d (0.5) : 15 – 35 μm d (0.9) : Not more than 75 μm |

*According to GPO-In house Specification

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B. Packaging and Storage

Preserve in well-closed containers.

C. Reference

USP 42/NF37, Mannitol monograph, page 2686-2688.

D. Product Information

| | |
|---------------------|--|
| Approved source (s) | Refer to current version of Approved Vendor List (AVL) of MANNITOL (PEARLITOL 25C) (ITEM NO. 44121680). |
| 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 (PEARLITOL 25C) (ITEM NO. 44121680). |
| Retest period | 1 year. |

Signature Manifest

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All dates and times are in GMT +7.

RMS_MANNITOL (PEARLITOL 25C) (ITEM NO. 44121680)

Step 1. Preparer

| Name/Signature | Title | Date | Meaning/Reason |
|------------------------------------|----------------------|--------------------------|----------------|
| NATTAPORN RUANSON (NATTAPORN_R) | HEAD OF QC SECTION 1 | 15 Oct 2020, 07:10:29 PM | Complete |

Step 2. Reviewer

| Name/Signature | Title | Date | Meaning/Reason |
|--|--------------------------------|--------------------------|----------------|
| NOPPAWAN ANGKULSANSANEE (NOPPAWAN_A) | DIRECTOR OF COMP Q SYS DIV. | 15 Oct 2020, 08:07:20 PM | Approved |
| SUTAN OTAMO (SUTAN_O) | DIRECTOR OF QC DIVISION | 16 Oct 2020, 06:31:48 AM | Approved |
| SIVINEE WATTITHAM (SIVINEE_W) | DIRECTOR OF VALIDATION DIV. | 16 Oct 2020, 10:25:15 AM | Approved |

Step 3. Approver

| Name/Signature | Title | Date | Meaning/Reason |
|--------------------------------|------------|--------------------------|----------------|
| WILAK VANGKANONTA (WILAK_V) | QA MANAGER | 17 Oct 2020, 10:47:08 AM | Approved |

Step 4. Notify

| Name/Signature | Title | Date | Meaning/Reason |
|--|-----------------------------------|--------------------------|----------------|
| DONNAPA PUEKWATTANA (DONNAPA_P) | QA-IT&Doc | 17 Oct 2020, 10:47:08 AM | Email Sent |
| SIRILUK BUACHAROEN (SIRILUK_B) | HEAD OF IT QUALITY AND DOC SEC | 17 Oct 2020, 10:47:08 AM | Email Sent |
| SUTHASINEE PENGSR (SUTHASINEE_P) | QA IT&Doc | 17 Oct 2020, 10:47:08 AM | Email Sent |
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| WIMWIPA CHAWENGPAKDEEWET (WIMWIPA_C) | QA IT&Doc | 17 Oct 2020, 10:47:08 AM | Email Sent |
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