## Mannitol Quality Solutions

Category: Osmotic Diuretics

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USP can support your development and manufacturing activities on Osmotic Diuretics-based medicines with these existing and upcoming standards.



| MONOGRAPH 1 MANNITOL IN SODIUM CHLORIDE INJECTION   |                    | <621> CHROMATOGRAPHY - NEW  |                    |
|---|--------------------|---|--------------------|
| Official as of 1-May-2018   |                    | Official as of 01-Dec-2024  |                    |
| USP Mannitol RS   | <u>USP-1375105</u> | <731> LOSS ON DRYING  |                    |
| MONOGRAPH 2   |                    | Official as of 01-Nov-2020  |                    |
| MANNITOL INJECTION<br>Official as of 1-May-2018   |                    | <741> MELTING RANGE OR TEMPERATURE<br>Official as of 01-Aug-2018              |                    |
| USP Mannitol RS   | <u>USP-1375105</u> | <781> OPTICAL ROTATION -NEW   |                    |
| MONOGRAPH 3   |                    | Official as of 01-Dec-2024  |                    |
| MANNITOL<br>Official as of 1-May-2020   |                    | <788> PARTICULATE MATTER IN INJECTION<br>Official as of 01-May-2013           | IS                 |
| USP Mannitol RS   | <u>USP-1375105</u> | USP Particle Count RS   | <u>USP-1500502</u> |
| MONOGRAPH 4   |                    |   |                    |
| MANNITOL COMPOUNDED INJECTION - NE<br>Official as of 1-Dec-2024   | EW                 | <791> PH Official as of 01-Aug-2024   |                    |
| USP Mannitol RS   | <u>USP-1375105</u> | <797> PHARMACEUTICAL COMPOUNDING-   | _                  |
| INCLUDED GENERAL CHAPTERS   |                    | STERILE PREPARATIONS<br>Official as of 01-May-2024                            |                    |
| <1>INJECTIONS AND IMPLANTED DRUG PRODUCTS<br>(PARENTERALS)—PRODUCT QUALITY TESTS<br>Official as of 01-May-2024              |                    | <b>&lt;852&gt; ATOMIC ABSORPTION SPECTROSCO</b><br>Official as of 01-Aug-2022 | РҮ                 |
| <11> USP REFERENCE STANDARDS<br>Official as of 01-Nov-2020  |                    | <1229.2> MOIST HEAT STERILIZATION OF A<br>Official as of 01-Aug-2022          | QUEOUS LIQUIDS     |
| <61> MICROBIOLOGICAL EXAMINATION O<br>PRODUCTS: MICROBIAL ENUMERATION<br>Tests Official as of 31-Dec-2012                   | FNONSTERILE        |   |                    |
| <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE<br>PRODUCTS: TESTS FOR SPECIFIC MICROORGANISMS<br>Official as of 31-Dec-2012 |                    |   |                    |
| <71> STERILITY TESTS<br>Official as of 31-Dec-2012  |                    |   |                    |
| <85> BACTERIAL ENDOTOXINS TEST<br>Official as of 01-May-2018  |                    |   |                    |
| USP Endotoxin RS  | <u>USP-1235503</u> |   |                    |
| <191> IDENTIFICATION TESTS—GENERAL<br>Official as of 01-May-2021  |                    |   |                    |
| <197> SPECTROSCOPIC IDENTIFICATION T<br>Official as of 01-Sep-2021  | ESTS               |   |                    |



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| WATER FOR INJECTION<br>Official as of 1-Nov-2018     |                    |
|--|--------------------|
| USP 1,4-Benzoquinone RS                              | <u>USP-1056504</u> |
|  |                    |
| <b>GELATIN</b><br>Official as of 1-Nov-2020          |                    |
| USP Gelatin RS                                       | <u>USP-1288485</u> |
|  |                    |
| HYDROCHLORIC ACID<br>Official as of 1-Jan-2018       |                    |
|  |                    |
| <b>SODIUM HYDROXIDE</b><br>Official as of 1-Jan-2018 |                    |
|  |                    |

**FERRIC OXIDE** Official as of 1-Jun-2023

| INCLUDED EXCIPIENTS                                  |                    |
|--|--------------------|
| WATER FOR INJECTION<br>Official as of 1-Nov-2018     |                    |
| USP 1,4-Benzoquinone RS                              | <u>USP-1056504</u> |
|  |                    |
| GELATIN<br>Official as of 1-Nov-2020                 |                    |
| USP Gelatin RS                                       | <u>USP-1288485</u> |
| HYDROCHLORIC ACID<br>Official as of 1-Jan-2018       |                    |
| <b>SODIUM HYDROXIDE</b><br>Official as of 1-Jan-2018 |                    |
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