Sirolimus Quality Solutions

Category: Immunosuppresants

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

Official and Proposed Documentary Standards and Associated Physical Materia

MONOGRAPH 1

| SIROLIMUS COMING SOON Published in PF 49(4) 05-Jul-2023 | |
|--|--------------------|
| USP Sirolimus RS | <u>USP-1612765</u> |
| USP Sirolimus System Suitability Mixture RS I NEW | <u>USP-1612743</u> |

MONOGRAPH 2

| SIROLIMUS TABLETS COMING SOON Published in PF 49(4) 05-Jul-2023 | |
|--|--------------------|
| USP Sirolimus RS | <u>USP-1612765</u> |
| USP Sirolimus System Suitability Mixture RS I NEW | <u>USP-1612743</u> |

RELATED EXCIPIENTS STANDARDS

TITANIUM DIOXIDE Official as of 01-Jun-2023

RELATED EXCIPIENTS STANDARDS

HYPROMELLOSE Official as of 01-May-2023

RELATED EXCIPIENTS STANDARDS

| POVIDONE Official as of 01-Jun-2023 | |
|---|--------------------|
| USP Povidone RS | <u>USP-1551503</u> |

RELATED EXCIPIENTS STANDARDS

| LACTOSE MONOHYDRATE Official as of 01-May-2020 | |
|--|--------------------|
| USP Fructose RS | <u>USP-1286504</u> |
| USP Dextrose RS | <u>USP-1181302</u> |
| USP Sucrose RS | <u>USP-1623637</u> |
| USP Lactose Monohydrate RS | <u>USP-1356701</u> |

RELATED EXCIPIENTS STANDARDS

| ANHYDROUS LACTOSE Official as of 01-May-2020 | |
|---|--------------------|
| USP Anhydrous Lactose RS | <u>USP-1356676</u> |
| USP Dextrose RS | <u>USP-1181302</u> |
| USP Sucrose RS | <u>USP-1623637</u> |
| USP Fructose RS | <u>USP-1286504</u> |

RELATED EXCIPIENTS STANDARDS

| CROSPOVIDONE Official as of 01-May-2020 | |
|---|--------------------|
| USP Crospovidone RS | <u>USP-1150706</u> |

RELATED EXCIPIENTS STANDARDS

| SODIUM LAURYL SULFATE Official as of 01-May-2021 | |
|--|--------------------|
| USP Sodium Lauryl Sulfate RS | <u>USP-1614363</u> |

RELATED EXCIPIENTS STANDARDS

| BUTYLATED HYDROXYTOLUENE Official as of 01-May-2021 | |
|---|--------------------|
| USP Butylated Hydroxytoluene RS | <u>USP-1082708</u> |
| | |

RELATED EXCIPIENTS STANDARDS

| POLYVINYL ALCOHOL Official as of 01-Aug-2023 | |
|--|--------------------|
| USP Methyl Acetate RS | <u>USP-1424051</u> |
| USP Methyl Alcohol RS | <u>USP-1424109</u> |
| USP Polyvinyl Alcohol RS | <u>USP-1548065</u> |

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| CROSCARMELLOSE SODIUM Official as of 01-May-2022 | |
|--|--------------------|
| USP Croscarmellose Sodium RS | <u>USP-1150659</u> |

RELATED EXCIPIENTS STANDARDS

| MANNITOL Official as of 01-May-2020 | |
|--|--------------------|
| USP Mannitol RS | <u>USP-1375105</u> |

RELATED EXCIPIENTS STANDARDS

| SHELLAC Official as of 01-May-2020 | |
|---------------------------------------|--------------------|
| USP Aleuritic Acid RS | <u>USP-1012799</u> |
| USP Refined Bleached Shellac RS | <u>USP-1600303</u> |
| USP Regular Bleached Shellac RS | <u>USP-1600314</u> |

RELATED EXCIPIENTS STANDARDS

| MICROCRYSTALLINE CELLULOSE Official as of 01-Dec-2019 | |
|--|--------------------|
| USP Microcrystalline Cellulose RS | <u>USP-1098388</u> |

RELATED EXCIPIENTS STANDARDS

| SUCROSE Official as of 01-Jun-2023 | |
|---------------------------------------|--------------------|
| USP Sucrose RS | <u>USP-1623637</u> |

RELATED EXCIPIENTS STANDARDS

| PROPYLENE GLYCOL Official as of 01-May-2020 | |
|---|--------------------|
| USP Ethylene Glycol RS | <u>USP-1265515</u> |
| USP Diethylene Glycol RS | <u>USP-1193265</u> |
| USP Propylene Glycol RS | <u>USP-1576708</u> |

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