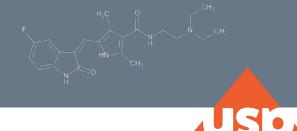
Sunitinib

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Official and Proposed Documentary Standards and Associated Physical Materials

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MONOGRAPH 1

| SUNITINIB MALATE COMING SOON Published in PF 49(6) 01-Nov-2023 | | |
|---|--------------------|--|
| USP Sunitinib Malate RS I NEW | <u>USP-1642358</u> | |
| ANALYTICAL REFERENCE MATERIALS | i . | |
| USP Desimidazoline Sunitinib PAI I NEW | <u>USP-1A05030</u> | |
| USP Sunitinib N-Oxide PAI I NEW | <u>USP-1A05050</u> | |
| USP Desethyl Sunitinib PAI I NEW | <u>USP-1A05060</u> | |
| USP Sunitinib Amide PAI I COMING SOON | <u>USP-1A05040</u> | |

| RELATED EXCIPIENTS STAN | DVDDC |
|-------------------------|-------|

TITANIUM DIOXIDE

Official as of O1-Jun-2023

RELATED EXCIPIENTS STANDARDS

HYPROMELLOSE

Official as of 01-May-2019

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> |

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