Desmopressin

Quality Solutions

Category: Peptide

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

Official and Proposed Documentary Standards and Associated Physical Materials



MONOGRAPH 1

| DESMOPRESSIN ACETATE Official as of 01-Mar-2021 | |
|--|--------------------|
| USP Desmopressin Acetate RS | <u>USP-1173202</u> |
| USP Oxytocin Identification RS | <u>USP-1491296</u> |

MONOGRAPH 2

| DESMOPRESSIN ACETATE INJECTION | |
|--------------------------------|--|
| Official as of 01-May-2018 | |
| | |

USP Desmopressin Acetate RS <u>USP-1173202</u>

MONOGRAPH 3

DESMOPRESSIN NASAL SPRAY SOLUTIONOfficial as of 31-Dec-2012

USP Desmopressin Acetate RS <u>USP-1173202</u>

INCLUDED GENERAL CHAPTERS

<1> INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS)— PRODUCT QUALITY TESTS | NEW Official as of 01-May-2024

<11> USP REFERENCE STANDARDS

Official as of 01-Nov-2020

<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS
Official as of 31-Dec-2012

<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS Official as of 31-Dec-2012

<<71> STERILITY TESTS

Official as of 31-Dec-2012

<85> BACTERIAL ENDOTOXINS TEST

Official as of O1-May-2018

USP Endotoxin RS USP-1235503

<503> ACETIC ACID IN PEPTIDES

Official as of 01-Dec-2017

USP Glacial Acetic Acid RS

USP-1005706

USP Sodium Acetate Trihydrate RS

USP-1613429

<621> CHROMATOGRAPHY

Official as of 01-Oct-2023

<736> MASS SPECTROMETRY

Official as of 01-May-2018

<788> PARTICULATE MATTER IN INJECTIONS

Official as of O1-May-2013

USP Particle Count RS USP-1500502

∠701\ DL

Official as of 01-Nov-2020

<921> WATER DETERMINATION

Official as of 01-May-2022

USP Sodium Tartrate Dihydrate RS <u>USP-1614909</u>

<1052> BIOTECHNOLOGY-DERIVED ARTICLES -AMINO ACID ANALYSIS

Official as of 01-May-2018

<1503> QUALITY ATTRIBUTES OF SYNTHETIC PEPTIDE DRUG SUBSTANCES

Official as of 01-Aug-2021

<1504> QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES

Official as of 01-Dec-2023

INCLUDED EXCIPIENTS

MAGNESIUM STEARATEOfficial as of 01-Aug-2016

 USP Palmitic Acid RS
 USP-1492007

 USP Stearic Acid RS
 USP-1621008

SODIUM CHLORIDE

Official as of 01-Jun-2023

LACTOSE MONOHYDRATE OFFICIAL AS OF 01-MAY-2020

| USP Dextrose RS | <u>USP-1181302</u> |
|----------------------------|--------------------|
| USP Fructose RS | <u>USP-1286504</u> |
| USP Lactose Monohydrate RS | <u>USP-1356701</u> |
| USP Sucrose RS | <u>USP-1623637</u> |

STERILE WATER FOR INJECTION

Official as of 01-May-2021

HYDROCHLORIC ACID

Official as of 01-Jan-2018

CORN STARCH

Official as of 01-Jun-2023



Desmopressin

Quality Solutions

Category: Peptide

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Official and Proposed Documentary Standards and Associated Physical Materials



| POTATO STARCH Official as of 01-Jun-2023 | |
|---|--------------------|
| CITRIC ACID MONOHYDRATE Official as of 01-May-2020 | |
| USP Citric Acid RS | <u>USP-1134368</u> |
| ANHYDROUS CITRIC ACID Official as of 01-May-2020 | |
| USP Citric Acid RS | <u>USP-1134368</u> |
| CROSCARMELLOSE SODIUM Official as of 01-May-2022 | |
| USP Croscarmellose Sodium RS | <u>USP-1150659</u> |

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