GoserelinQuality Solutions

Category: Peptide



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

Official and Proposed Documentary Standards and Associated Physical Materials

Authorized Distributor

MONOGRAPH 1

GOSERELIN ACETATE Official as of 01-Dec-2020	
USP Goserelin Acetate RS	<u>USP-1297205</u>
USP Goserelin Related Compound A RS	<u>USP-1297216</u>
USP Goserelin System Suitability Mixture RS	<u>USP-1297250</u>

MONOGRAPH 2

GOSERELIN IMPLANTS Official as of 01-Aug-2017	
USP Goserelin Acetate RS	<u>USP-1297205</u>
USP Goserelin Related Compound A RS	<u>USP-1297216</u>
USP Glacial Acetic Acid RS	<u>USP-1005706</u>
USP Endotoxin RS	<u>USP-1235503</u>

INCLUDED GENERAL CHAPTERS

<11> USP REFERENCE STANDARDS

Official as of 01-Nov-2020

<71> STERILITY TESTS

Official as of 31-Dec-2012

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Official as of O1-May-2018

USP Endotoxin RS <u>USP-1235503</u>

<503> ACETIC ACID IN PEPTIDES

USP Sodium Acetate Trihydrate RS

Official as of 01-Dec-2017

USP Glacial Acetic Acid RS	<u>USP-1005706</u>

USP-1613429

<621> CHROMATOGRAPHY

Official as of 01-Oct-2023

<711> DISSOLUTION

Official as of O1-May-2023

USP Dissolution Performance Verification
Standard- Prednisone RS

USP-1222818

<761> NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Official as of 01-May-2018

<781> OPTICAL ROTATION

Official as of O1-Dec-2022

<905> UNIFORMITY OF DOSAGE UNITS

Official as of O1-Aug-2023

<921> WATER DETERMINATION

Official as of O1-May-2022

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

<1052> BIOTECHNOLOGY-DERIVED ARTICLES- AMINO ACID ANALYSIS

Official as of O1-May-2018

<1503> QUALITY ATTRIBUTES OF SYNTHETIC PEPTIDE DRUG SUBSTANCES

Official as of O1-Aug-2021

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

Official as of 01-Dec-2023

INCLUDED EXCIPIENTS

DL-LACTIDE AND GLYCOLIDE (50:50) COPOLYMER 12000 ACID

Published in PH 48(3) 31-Jul-2022

USP dl-Lactide and Glycolide (50:50) Copolymer 12000 Acid RS - NEW

USP-1224300

DL-LACTIDE AND GLYCOLIDE (50:50) COPOLYMER 12000 ETHYL ESTER

Published in PH 48(6) 31-Jan-2023

USP dl-Lactide and Glycolide (50:50) Copolymer 12000 Ethyl Ester RS - NEW

<u>USP-1224311</u>

DL-LACTIDE AND GLYCOLIDE (50:50) COPOLYMER 46000

Published in PH 48(5) 30-Nov-2023

USP DL-Lactide and Glycolide (50:50) Copolymer 46000 Acid RS - NEW

<u>USP-1224322</u>

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