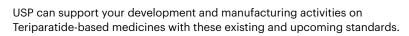
Teriparatide

Quality Solutions

Category: Peptide





Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

TERIPARATIDE NEW Official as of 01-Apr-2024	
USP Teriparatide RS	USP-1643962

MONOGRAPH 2

LEUPROLIDE ACETATE Official as of 01-May-2018	
USP Teriparatide RS	<u>USP-1643962</u>
USP Endotoxin RS	<u>USP-1235503</u>
ANALYTICAL REFERENCE MATERIALS (ARM)	
[MetO8]-Teriparatide	<u>USP-1643970</u>
[MetO18]-Teriparatide	<u>USP-1643971</u>
[MetO8,18]-Teriparatide	<u>USP-1643972</u>

INCLUDED GENERAL CHAPTERS

<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 US	SP-1235503
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<111> DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS

Official as of 01-Aug-2020

01-May-2024. For publications related to Teriparatide in PF online after this date, please visit the integrated USP-NF/PF online.

<621> CHROMATOGRAPHY

<788> PARTICULATE MATTER IN INJECTIONS

Official as of 01-May-2013

USP Particle Count RS USP-1500502

<791> PH

<921> WATER DETERMINATION

Official as of O1-May-2022

USP Sodium Tartrate Dihydrate RS USP-1614909

<1032> DESIGN AND DEVELOPMENT OF BIOLOGICAL ASSAYS Official as of 31-Dec-2012

<1503> QUALITY ATTRIBUTES OF SYNTHETIC PEPTIDE DRUG **SUBSTANCES**

Official as of 31-Dec-2012

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

Official as of 31-Dec-2012

INCLUDED EXCIPIENTS

PURIFIED WATER

Official as of O1-Nov-2018

MANNITOL

Official as of 01-May-2020

USP Mannitol RS USP-1375105

METACRESOL

Official as of 01-May-2020

USP Metacresol RS USP-1395204

USP Phenol RS USP-1524806

ACETIC ACID

SODIUM HYDROXIDE

Official as of O1-Jan-2018

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

Official and Proposed Documentary Standards and Associated Physical Materials



HYDROCHLORIC ACID Official as of 01-Jan-2018

ANHYDROUS SODIUM ACETATE

* Documents in PF Online are not official and not suitable to demonstrate compliance. They may never become official.

01-May-2024. For publications related to **Teriparatide** in *PF* online after this date, please visit the integrated *USP-NF/PF* online.

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