# **Exenatide Quality Solutions**

Category: Peptide



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

#### Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

**Authorized Distributor** 

<b>EXENATIDE</b> Official as of 01-Dec-2017	
USP Exenatide RS	<u>USP-1269105</u>
USP [N-Acetyl-His1]-Exenatide RS	<u>USP-1269045</u>
USP [Met(O)14]-Exenatide RS	<u>USP-1269009</u>
USP [Glu13]-Exenatide (1 mg) RS	<u>USP-1268998</u>

MONOGRAPH 2

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**USP Exenatide RS** USP-1269105

**INCLUDED GENERAL CHAPTERS** 

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

#### <11> USP REFERENCE STANDARDS

Official as of 01-Nov-2020

#### <7> LABELING

Official as of 01-Sep-2023

#### <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	<u>USP-1005706</u>
USP Sodium Acetate Trihydrate RS	USP-1613429

#### <503.1> TRIFLUOROACETIC ACID (TFA) IN PEPTIDES

Official as of 01-Dec-2017

USP Sodium Trifluoroacetate RS USP-1615138

#### <621> CHROMATOGRAPHY

Official as of 01-Oct-2023

#### <736> MASS SPECTROMETRY

Official as of 01-May-2018

### <787> SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC **PROTEIN INJECTIONS**

Official as of 01-May-2021

**USP Particle Count RS** USP-1500502

#### <788> PARTICULATE MATTER IN INJECTIONS

Official as of O1-May-2013

**USP Particle Count RS** USP-1500502

Official as of O1-Nov-2020

#### <921> WATER DETERMINATION

Official as of O1-May-2022

USP Sodium Tartrate Dihydrate RS USP-1614909

#### <1052> BIOTECHNOLOGY-DERIVED ARTICLES - AMINO ACID **ANALYSIS**

Official as of O1-May-2018

#### <1065> ION CHROMATOGRAPHY

Official as of O1-Aug-2016

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

Official as of 01-Aug-2021

#### <1504> QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THECHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES

Official as of 01-Dec-2023

**INCLUDED EXCIPIENTS** 

#### **MANNITOL**

Official as of 01-May-2020

**USP Mannitol RS** USP-1375105

#### **CARBOXYMETHYLCELLULOSE SODIUM**

Official as of 01-Jan-2018

### **ACETIC ACID**

Official as of 01-Jan-2018

#### SUCROSE

USP Sucrose RS USP-1623637

#### STERILE WATER FOR INJECTION

Official as of 01-May-2021

Disclaimer: USP Quality Solution Sheets are provided as a convenience and for informational purposes only. Labmix24 makes reasonable efforts to provide correct information but assumes no liability for the completeness, timeliness or accuracy of the information contained in each QSS. It is the responsibility of the user to verify the information. The US Pharmacopeia remains the official source of this information.

