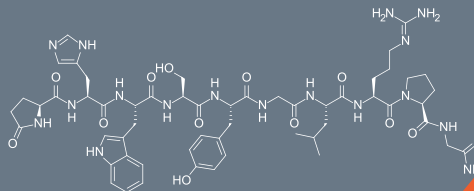


Gonadorelin

Quality Solutions

Category: Peptide



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

GONADORELIN HYDROCHLORIDE

Official as of 01-May-2018

USP Gonadorelin Hydrochloride RS	USP-1296803
USP Gonadorelin Acetate Related Compound A RS	USP-1296767

MONOGRAPH 2

GONADORELIN ACETATE

Official as of 01-Dec-2020

USP Gonadorelin Acetate RS	USP-1296756
USP Gonadorelin Acetate Related Compound A RS	USP-1296767
USP Goserelin System Suitability Mixture RS	USP-1297250

MONOGRAPH 3

GONADORELIN ACETATE

Official as of 31-Jul-2023

USP Gonadorelin Acetate RS	USP-1296756
USP [D-His2]-Gonadorelin RS	USP-1296701
USP [D-Tyr5]-Gonadorelin RS	USP-1296712
USP Gonadorelin Acetate Related Compound A RS	USP-1296767

MONOGRAPH 4

GONADORELIN FOR INJECTION

Official as of 01-May-2018

USP Gonadorelin Hydrochloride RS	USP-1296803
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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 01-May-2018

USP Endotoxin RS	USP-1235503
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<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

<503.1> TRIFLUOROACETIC ACID (TFA) IN PEPTIDES

Official as of 01-Dec-2017

USP Sodium Trifluoroacetate RS	USP-1615138
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<541> TITRIMETRY

Official as of 31-Dec-2012

<621> CHROMATOGRAPHY

Official as of 01-Oct-2023

<736> MASS SPECTROMETRY

Official as of 01-May-2018

<781> OPTICAL ROTATION

Official as of 01-Dec-2022

<79> PH

Official as of 01-Nov-2020

<921> WATER DETERMINATION

Official as of 01-May-2022

USP Sodium Tartrate Dihydrate RS	USP-1614909
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<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

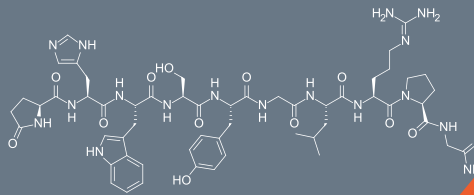
<1504> QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES

Official as of 01-Dec-2023

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INCLUDED EXCIPIENTS

ACETIC ACID

Official as of 01-Jan-2018

MANNITOL

Official as of 01-May-2020

USP Mannitol RS

[USP-1375105](#)

HYDROCHLORIC ACID

Official as of 01-Jan-2018

SODIUM CHLORIDE

Official as of 01-Jun-2023

SODIUM ACETATE

Official as of 01-Jun-2023

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.