Bivalirudin Quality Solutions

Category: Peptide



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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

BIVALIRUDIN NEW To Be Official 01-Dec-2023	
USP Bivalirudin RS I New	<u>USP-1076013</u>
USP Asp9-Bivalirudin RS I New	<u>USP-1076024</u>
USP [des-Glu13]-Bivalirudin RS I New	<u>USP-1076035</u>

MONOGRAPH 2

BIVALIRUDIN FOR INJECTION NEW To Be Official 01-Dec-2023	
USP Bivalirudin RS I New	<u>USP-1076013</u>
USP Asp9-Bivalirudin RS I New	<u>USP-1076024</u>

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

RELATED EXCIPIENTS STANDARDS

MANNITOL Official as of 01-May-2020	
USP Mannitol RS	<u>USP-1375105</u>
RELATED EXCIPIENTS STANDARDS	
SODIUM HYDROXIDE Official as of 01-Jan-2018	

RELATED EXCIPIENTS STANDARDS

SODIUM ACETATE Official as of 01-Jun-2023

RELATED EXCIPIENTS STANDARDS

ACETIC ACID Official as of 01-Jan-2018

RELATED EXCIPIENTS STANDARDS

POLYETHYLENE GLYCOL 3350 Official as of 01-Dec-2020	
USP Ethylene Glycol RS	<u>USP-1265515</u>
USP Polyethylene Glycol 3350 RS	<u>USP-1546547</u>
USP Diethylene Glycol RS	<u>USP-1193265</u>

01-Dec-2023. For publications related to **Bivalirudin** in *PF* online after this date, please visit the integrated *USP-NF/PF* online.



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.

www.labmix24.com