# **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

<b>BIVALIRUDIN  </b> 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

<b>BIVALIRUDIN FOR INJECTION  </b> 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

<b>MANNITOL</b> 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

<b>POLYETHYLENE GLYCOL 3350</b> 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.



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