Brivaracetam

Quality Solutions

Category: Psychiatrics

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

Official and Proposed Documentary Standards and Associated Physical Materials



MONOGRAPH 1

BRIVARACETAM Published in PF 49(6) 31-Jan-2024	
USP Brivaracetam RS	<u>USP-1078030</u>
USP Brivaracetam Related Compound A RS	<u>USP-1078041</u>
USP Brivaracetam Related Compound B RS	<u>USP-1078052</u>
USP Brivaracetam Related Compound C RS	<u>USP-1078063</u>
MONOGRAPH 2	
BRIVARACETAM TABLETS Published in PF 49(6) 31-Jan-2024	
USP Brivaracetam RS	<u>USP-1078030</u>
USP Brivaracetam Related Compound A RS	<u>USP-1078041</u>
USP Brivaracetam Related Compound D RS NEW	<u>USP-1078074</u>
MONOGRAPH 3	
BRIVARACETAM INJECTION Published in PF 49(6) 31-Jan-2024	
USP Brivaracetam RS	<u>USP-1078030</u>
USP Brivaracetam Related Compound A RS	<u>USP-1078041</u>
USP Brivaracetam Related Compound D RS NEW	<u>USP-1078074</u>
MONOGRAPH 4	

BRIVARACETAM ORAL SOLUTION Published in PF 49(6) 31-Jan-2024	
USP Brivaracetam RS	<u>USP-1078030</u>
USP Brivaracetam Related Compound A RS	<u>USP-1078041</u>
USP Brivaracetam Related Compound D RS NEW	<u>USP-1078074</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



<71> STERILITY TESTS Official as of 31-Dec-2012		
<85> BACTERIAL ENDOTOXINS TEST Official as of 01-May-2018		
USP Endotoxin RS	<u>USP-1235503</u>	
<197> SPECTROSCOPIC IDENTIFICATION TESTS Official as of 01-Sep-2021		
<201> THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST Official as of 01-May-2018		
USP Bacitracin Zinc RS	<u>USP-1048007</u>	
USP Neomycin Sulfate RS	<u>USP-1458009</u>	
USP Polymyxin B Sulfate RS	<u>USP-1547007</u>	
<281> RESIDUE ON IGNITION Official as of 31-Dec-2012		

<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE

PRODUCTS: TESTS FOR SPECIFIED

MICROORGANISMS

<701> DISINTEGRATION Official as of 01-May-2020

<785> OSMOLALITY AND OSMOLARITY Official as of 01-Dec-2020

<788> PARTICULATE MATTER IN INJECTIONS Official as of 01-May-2013

USP Particle Count RS

<791> PH Official as of 01-Nov-2020

<905> UNIFORMITY OF DOSAGE UNITS Official as of 01-Aug-2023

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Official and Proposed Documentary Standards and Associated Physical Materials



<921> WATER DETERMINATION Official as of 01-May-2022	
USP Sodium Tartrate Dihydrate RS	<u>USP-1614909</u>
INCLUDED EXCIPIENTS	
PURIFIED WATER Official as of 01-Nov-2018	
ANHYDROUS CITRIC ACID Official as of 01-May-2020	
USP Citric Acid RS	<u>USP-1134368</u>
TITANIUM DIOXIDE Official as of 01-Jun-2023	
TALC Official as of 01-May-2022	
SUCRALOSE Official as of 01-Dec-2023	
USP Sucralose RS	<u>USP-1623626</u>
SORBITOL Official as of 01-May-2021	
USP Sorbitol RS	<u>USP-1617000</u>
MAGNESIUM STEARATE Official as of 01-Aug-2016	
USP Palmitic Acid RS	<u>USP-1492007</u>
USP Stearic Acid RS	<u>USP-1621008</u>
SODIUM ACETATE Official as of 01-Jun-2023	

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

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