# **Betamethasone** Quality Solutions

Category: Steroid

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

# Official and Proposed Documentary Standards and Associated Physical Materials

## **MONOGRAPH 1**

<b>BETAMETHASONE VALERATE</b>   NEW Official as of 01-Aug-2024	
USP Betamethasone RS	<u>USP-1066009</u>
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Betamethasone Valerate Related Compound A RS	<u>USP-1069018</u>
USP Betamethasone Valerate Related Compound D RS	<u>USP-1069049</u>
USP Betamethasone Valerate System Suitability Mixture RS	<u>USP-1069095</u>

#### **MONOGRAPH 2**

<b>BETAMETHASONE SODIUM PHOSPHATE</b> Official as of 01-May-2020	
USP Betamethasone Sodium Phosphate RS	<u>USP-1068004</u>
MONOCRAPH 2	

#### MONOGRAPH 3

# BETAMETHASONE SODIUM PHOSPHATE AN BETAMETHA-<br/>SONE ACETATE INJECTABLE SUSPENSION<br/>Official as of 01-May-2018USP Betamethasone Acetate RSUSP-1067001USP Betamethasone Sodium Phosphate RSUSP-1068004

## MONOGRAPH 4

BETAMETHASONE DIPROPIONATE Official as of 01-May-2020	
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>
USP Betamethasone Dipropionate RS	<u>USP-1067704</u>

## MONOGRAPH 5

BETAMETHASONE Official as of 01-May-2020	
USP Betamethasone RS	<u>USP-1066009</u>

# MONOGRAPH 6

<b>BETAMETHASONE ACETATE</b> Official as of 01-Dec-2023	
USP Betamethasone RS	<u>USP-1066009</u>
USP Dexamethasone Acetate RS	<u>USP-1176506</u>
USP Betamethasone Acetate RS	<u>USP-1067001</u>
USP Betamethasone Acetate Related Compound C RS	<u>USP-1067034</u>
USP Betamethasone Acetate Related Compound D RS	<u>USP-1067045</u>

### MONOGRAPH 7

<b>BETAMETHASONE VALERATE LOTION</b> Official as of 01-Aug-2017	
USP Betamethasone RS	<u>USP-1066009</u>
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Betamethasone Valerate Related Compound A RS	<u>USP-1069018</u>
MONOGRAPH 8	
<b>BETAMETHASONE DIPROPIONATE CREAM</b> Official as of 31-Dec-2012	
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>
USP Betamethasone Dipropionate RS	<u>USP-1067704</u>
MONOGRAPH 9	
BETAMETHASONE SODIUM PHOSPHATE IN Official as of 01-May-2018	IJECTION
USP Betamethasone Sodium Phosphate RS	<u>USP-1068004</u>
MONOGRAPH 10	
<b>BETAMETHASONE DIPROPIONATE OINTM</b> Official as of 31-Dec-2012	ENT
USP Beclomethasone Dipropionate RS	<u>USP-1067704</u>
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>

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



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MONOGRAPH 11 BETAMETHASONE VALERATE OINTMENT Official as of 01-May-2017	
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Betamethasone RS	<u>USP-1066009</u>
USP Betamethasone Valerate Related Compound A RS	<u>USP-1069018</u>
MONOGRAPH 12	
<b>CLOTRIMAZOLE AND BETAMETHASONE D</b> <b>CREAM</b> Official as of 31-Dec-2012	IPROPIONATE
USP Clotrimazole RS	<u>USP-1141002</u>
USP Clotrimazole Related Compound A RS	<u>USP-1141024</u>
USP Betamethasone Dipropionate RS	<u>USP-1067704</u>
MONOGRAPH 13	
<b>BETAMETHASONE ORAL SOLUTION</b> Official as of 31-Dec-2012	
USP Betamethasone RS	<u>USP-1066009</u>
MONOGRAPH 14	
<b>BETAMETHASONE DIPROPIONATE LOTION</b> Official as of 31-Dec-2012	
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>
USP Betamethasone Dipropionate RS	<u>USP-1067704</u>
MONOGRAPH 15	
BETAMETHASONE VALERATE CREAM Official as of 01-May-2017	
USP Betamethasone RS	<u>USP-1066009</u>
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Betamethasone Valerate Related Compound A RS	<u>USP-1069018</u>
MONOGRAPH 16	
GENTAMICIN SULFATE AND BETAMETHAS	ONE VALERATE

GENTAMICIN SULFATE AND BETAMETHASONE VALERATE OINTMENT Official as of 31-Dec-2012	
USP Gentamicin Sulfate RS	<u>USP-1289003</u>
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>

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## MONOGRAPH 17

GENTAMICIN SULFATE AND BETAMETHASONE VALERATE TOPICAL SOLUTION Official as of 31-Dec-2012	
USP Gentamicin Sulfate RS	<u>USP-1289003</u>
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>

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MONOGRAPH 18

GENTAMICIN SULFATE AND BETAMETHASONE ACETATE OPHTHALMIC SOLUTION Official as of 31-Dec-2012	
USP Betamethasone Acetate RS	<u>USP-1067001</u>
USP Gentamicin Sulfate RS	<u>USP-1289003</u>

**MONOGRAPH 19** 

GENTAMICIN SULFATE AND BETAMETHASONE VALERATE OTIC SOLUTION Official as of 31-Dec-2012	
USP Betamethasone Valerate RS	<u>USP-1069007</u>
USP Gentamicin Sulfate RS	<u>USP-1289003</u>
USP Beclomethasone Dipropionate RS	<u>USP-1048506</u>

**MONOGRAPH 20** 

BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE INJECTABLE SUSPENSION Official as of 01-May-2018	
USP Betamethasone Acetate RS	<u>USP-1067001</u>
USP Betamethasone Sodium Phosphate RS	<u>USP-1068004</u>

**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

<51> ANTIMICROBIAL EFFECTIVENESS TESTING Official as of 01-May-2018

<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE **PRODUCTS: MICROBIAL ENUMERATION TESTS** Official as of 31-Dec-2012



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<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS		<921> WATER DETERMINATION Official as of 01-May-2022	
Official as of 31-Dec-2012		USP Sodium Tartrate Dihydrate RS	<u>USP-1614909</u>
<81> ANTIBIOTICS—MICROBIAL ASSAYS Official as of 01-Jan-2024		INCLUDED EXCIPIENTS	
<85> BACTERIAL ENDOTOXINS TEST Official as of 01-May-2018		STERILE WATER FOR INJECTION Official as of 01-May-2021	
USP Endotoxin RS	<u>USP-1235503</u>	MINERAL OIL Official as of 01-May-2020	
<191> IDENTIFICATION TESTS—GENERAL Official as of 01-May-2021		USP Mineral Oil RS	<u>USP-1443952</u>
<197> SPECTROSCOPIC IDENTIFICATION TESTS		USP Naphthalene RS	<u>USP-1457083</u>
Official as of 01-Sep-2021 <b>201&gt; THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION</b>		SODIUM HYDROXIDE Official as of 01-Jan-2018	
<b>TEST</b> Official as of 01-May-2018		WHITE PETROLATUM Official as of 31-Dec-2012	
USP Bacitracin Zinc RS	<u>USP-1048007</u>	PROPYLENE GLYCOL	
USP Neomycin Sulfate RS	<u>USP-1458009</u>	Official as of 01-May-2020	
USP Polymyxin B Sulfate RS	<u>USP-1547007</u>	USP Diethylene Glycol RS	<u>USP-1193265</u>
<281> RESIDUE ON IGNITION Official as of 31-Dec-2012		USP Ethylene Glycol RS	<u>USP-1265515</u>
		USP Propylene Glycol RS	<u>USP-1576708</u>
<466> ORDINARY IMPURITIES Official as of 01-Oct-2018			
<621> CHROMATOGRAPHY Official as of 01-Oct-2023			
<698> DELIVERABLE VOLUME Official as of 01-Dec-2020			
<b>&lt;731&gt; LOSS ON DRYING</b> Official as of 01-Nov-2020			
<b>&lt;755&gt; MINIMUM FILL</b> Official as of 01-Dec-2020			
<b>&lt;781&gt; OPTICAL ROTATION</b> Official as of 01-Dec-2022			
<788> PARTICULATE MATTER IN INJECTIONS Official as of 01-May-2013			
USP Particle Count RS	<u>USP-1500502</u>		
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