Albuterol Quality Solutions

Category: Pulmonary

• H₂SO₄

2

Authorized Distributor

MONOGRAPH 1

ALBUTEROL SULFATE Official as of 1-May-2020	
USP Albuterol Sulfate RS	<u>USP-1012633</u>
USP Albuterol Related Compound A RS	<u>USP-1012644</u>

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

MONOGRAPH 2

ALBUTEROL Official as of 1-May-2020	
USP Albuterol RS	<u>USP-1012600</u>

MONOGRAPH 3

ALBUTEROL EXTENDED-RELEASE TABLETS Official as of 1-May-2020	
USP Albuterol Sulfate RS	<u>USP-1012633</u>
USP Albuterol Related Compound B RS	<u>USP-1012655</u>
USP Levalbuterol Related Compound C RS	<u>USP-1358810</u>
USP Levalbuterol Related Compound D RS	<u>USP-1358820</u>
USP Albuterol Related Compound E RS	<u>USP-1012689</u>

MONOGRAPH 4

ALBUTEROL TABLETS Official as of 1-May-2023	
USP Albuterol Sulfate RS	<u>USP-1012633</u>
USP Albuterol Related Compound B RS	<u>USP-1012655</u>
USP Levalbuterol Related Compound C RS	<u>USP-1358810</u>
USP Levalbuterol Related Compound D RS	<u>USP-1358820</u>
USP Albuterol Related Compound E RS	<u>USP-1012689</u>
USP Levalbuterol Related Compound H RS	<u>USP-1358864</u>

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.



MONOGRAPH 5

IPRATROPIUM BROMIDE AND ALBUTEROL SULFATE INHALATION SOLUTION

Official as of 1-May-2021	
USP Albuterol Sulfate RS	<u>USP-1012633</u>
USP Ipratropium Bromide RS	<u>USP-1347507</u>
USP Ipratropium Bromide Related Compound B RS	<u>USP-1347529</u>
USP Ipratropium Bromide Related Compound CRS	<u>USP-1347530</u>
USP Levalbuterol Related Compound D RS	<u>USP-1358820</u>

MONOGRAPH 6

ALBUTEROL INHALATION SOLUTION - NEW To Be Officialas of 1-May-2025	/
USP Albuterol Sulfate RS	<u>USP-1012633</u>
USP Levalbuterol Related Compound D RS	<u>USP-1358820</u>
USP Levalbuterol Related Compound H RS	<u>USP-1358864</u>
USP Albuterol Related Compound I RS	<u>USP-1012564</u>
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
4-HYDROXY 3 -HYDROXYMETHYLBENZAL- DEHYDE- NEW	<u>USP-1A10560</u>

* Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.



Small Molecules

www.labmix24.com

Albuterol Quality Solutions

Category: Pulmonary

• H₂SO₄

2

Authorized Distributor

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

INCLUDED GENERAL CHAPTERS

<11> USP REFERENCE STANDARDS Official as of 01-Nov-2020

<71> STERILITY TESTS Officialas of 31-Dec-2012

<197> SPECTROSCOPIC IDENTIFICATION TESTS Official as of 01-Sep-2021

<281> RESIDUE ON IGNITION Official as of 31-Dec-2012

<621> CHROMATOGRAPHY - NEW Official as of 01-Dec-2024

<711> DISSOLUTION Official as of 1-May-202

USP Dissolution Performance Verification Standard-Prednisone RS

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

<791> PH Official as of 01-Aug-2024

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

<191> IDENTIFICATION TESTS—GENERAL Official as of 01-May-2021

<788> PARTICULATE MATTER IN INJECTIONS Official as of 01-May-2013	
USP Particle Count RS	<u>USP-1500502</u>
2021 WATER DETERMINATION	

4921> WATER DETERMINATION Official as of 1-May-2022	
USP Sodium Tartrate Dihydrate RS	<u>USP-1614909</u>

INCLUDED EXCIPIENTS

STERILE WATER FOR INHALATION Official as of 01-May-2021

SODIUM CHLORIDE Official as of 1-Jun-2023

SULFURIC ACID Official as of 1-Jun-2023

USP-1222818

LACTOSE MONOHYDRATE Official as of 1-May-2020	
USP Dextrose RS	<u>USP-1181302</u>
USP Fructose RS	<u>USP-1286504</u>
USP Lactose Monohydrate RS	<u>USP-1356701</u>
USP Sucrose RS	<u>USP-1623637</u>

MAGNESIUM STEARATE Official as of 1-Aug-2016	
USP Palmitic Acid RS	<u>USP-1492007</u>
USP Stearic Acid RS	<u>USP-1621008</u>



www.labmix24.com