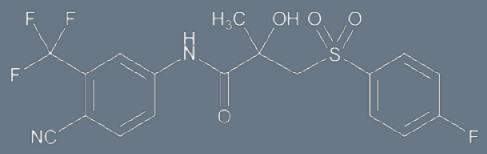
Small Molecules

Bicalutamide

Quality Solutions

Category: Oncology



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

Authorized Distributor

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

BICALUTAMIDE Official as of 01-May-2020	
USP Bicalutamide RS	USP-1071202
USP Bicalutamide Related Compound A RS	USP-1071213

MONOGRAPH 2

BICALUTAMIDE TABLETS Official as of 01-Sep-2023	
USP Bicalutamide RS	USP-1071202
USP Bicalutamide Related Compound B RS	USP-1071224
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
USP Bicalutamide Sulfide PAI | *NEW*	USP-1A08320
USP Deoxybicalutamide PAI | *NEW*	USP-1A07540

INCLUDED GENERAL CHAPTERS

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

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

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

<621> CHROMATOGRAPHY Official as of 01-Oct-2023

<711> DISSOLUTION Official as of 01-May-2023	
USP Dissolution Performance Verification Standard Prednisone RS	USP-1222818

<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY Official as of 01-Dec-2022

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

<921> WATER DETERMINATION Official as of 01-May-2022	
USP Sodium Tartrate Dihydrate RS	USP-1614909

INCLUDED EXCIPIENTS

LACTOSE MONOHYDRATE Official as of 01-May-2020	
USP Dextrose RS	USP-1181302
USP Fructose RS	USP-1286504
USP Lactose Monohydrate RS	USP-1356701
USP Sucrose RS	USP-1623637

CROSPOVIDONE Official as of 01-May-2020	
USP Crospovidone RS	USP-1150706

POLYETHYLENE GLYCOL Official as of 01-Feb-2020

SILICON DIOXIDE Official as of 01-Jun-2023

SODIUM STARCH GLYCOLATE Official as of 01-May-2020	
USP Sodium Starch Glycolate Type A RS	USP-1614669
USP Sodium Starch Glycolate Type B RS	USP-1614670

** 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.*