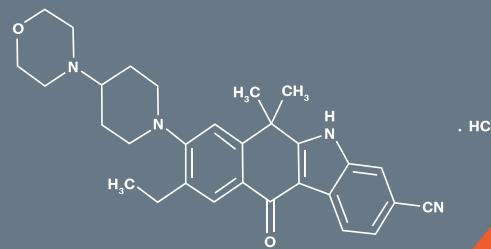


Alectinib

Quality Solutions

Category: Oncology-Kinase Inhibitor



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



MONOGRAPH 1

ALECTINIB HYDROCHLORIDE

PF 51(1) 02-Jan-2025 to 31-Mar-2025

USP Alectinib Hydrochloride RS

[USP-1012775](#)

INCLUDED GENERAL CHAPTERS

GC <11> USP REFERENCE STANDARDS

Official as of 01-Nov-20

GC <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS

Official as of 01-May-25

GC <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS

Official as of 31-Dec-12

MONOGRAPH 2

ALECTINIB CAPSULES

PF 51(1) 02-Jan-2025 to 31-Mar-2025

USP Alectinib Hydrochloride RS

[USP-1012775](#)

INCLUDED EXCIPIENTS

MAGNESIUM STEARATE

Official as of 01-Aug-16

USP Palmitic Acid RS

[USP-1492007](#)

USP Stearic Acid RS

[USP-1621008](#)**GC <477> USER-DETERMINED REPORTING THRESHOLDS**

Official as of 01-May-24

GC <621> CHROMATOGRAPHY

Official as of 01-Dec-24

PURIFIED WATER

Official as of 01-Nov-2018

USP 1,4-Benzoquinone RS

[USP-1056504](#)**GC <711> DISSOLUTION**

Official as of 01-May-23

TITANIUM DIOXIDE

Official as of 01-Jun-23

MICROCRYSTALLINE CELLULOSE

Official as of 1-Dec-2019

USP Microcrystalline Cellulose RS

[USP-1098388](#)**GC <191> IDENTIFICATION TESTS-GENERAL**

Official as of 1-May-21

GC <197> SPECTROSCOPIC IDENTIFICATION TESTS

Official as of 01-Sep-21

GC <281> RESIDUE ON IGNITION

Official as of 31-Dec-12

GC <921> WATER DETERMINATION

Official as of 1-May-22

LACTOSE MONOHYDRATE

Official as of 01-Dec-24

USP Dextrose RS

[USP-1181302](#)

USP Fructose RS

[USP-1286504](#)

USP Lactose Monohydrate RS

[USP-1356701](#)

USP Sucrose RS

[USP-1623637](#)

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