Johnson&Johnson

CERTIFICATE OF ANALYSIS

FOR ANALYTICAL PURPOSES ONLY

REFERENCE STANDARD: **JNJ-16175328-AEP** **LOT:** **A19DD1366**
CoA NUMBER: AD-RSCoA-JNJ-16175328-AEP-A19DD1366
VERSION NUMBER: V4

TYPE OF STANDARD:	Drug Substance API	RE-EVALUATION DATE:	30-Jun-2027
INTENDED USE:	Quantitative	EFFECTIVE DATE:	13-Aug-2025
SALT FACTOR: F	1.209		
SALT FACTOR: F'	1.209		
PURITY (P):	0.998	STORAGE CONDITION(S):	Room temperature
CHIRAL PURITY (Pc):	0.998		
REMARKS:	n.a.		

CHEMICAL NAME:	3-Quinolineethanol, 6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-beta-phenyl-,(alphaS,betaR)-,(2E)-2-butenedioate		
OTHER COMPOUND ID:	R403323 / Bedaquiline fumarate		
		MANUFACTURING DATE:	01-Apr-2019
MOLECULAR FORMULA:	$C_{32}H_{31}BrN_2O_2.C_4H_4O_4$	MANUFACTURER LOT:	A19DD1366
MOLECULAR WEIGHT:	671.59	MANUFACTURER:	Janssen Pharmaceutica NV
MOLECULAR WEIGHT PARENT:	555.52	MANUFACTURER ADDRESS:	Turnhoutseweg 30, B-2340 Beerse

ANALYTICAL TEST RESULTS:

TESTS PERFORMED	RESULTS (UNITS)
Appearance	White powder
IR identification	Complies with reference spectrum
NMR identification	Confirms the structure, stereochemistry not confirmed, salt confirmed
Water determination Karl Fisher	< 0.1 % w/w
GC residual solvent determination	< 500 ppm
HPLC impurity	0.23 % w/w
Residue on ignition	< 0.1 % w/w
Heavy metals	< 20 ppm
Melting point	209 °C
Stereoisomeric impurity HPLC	< 0.1 % w/w

PURITY CALCULATION: P = (100 - % water content - % residual solvent - % chromatographic impurity - % inorganic impurities) / 100
Pc = (100 - % water content - % residual solvent - % chromatographic impurity - % inorganic impurities - % stereoisomeric impurities) / 100

APPROVED BY:
NAME: Sien Keysers

Sien Keysers

Electronically signed by: Sien Keysers
Reason: I am certifying this document
Date: Aug 13, 2025 14:17:11 GMT+2

DEPARTMENT: AMSC – Analytical Method & Stability Center

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