

Certificate of Analysis

Name of Product : BEDAQUILINE FUMARATE
 Product Code : 116620 Date of Manufacture : 01-OCT-2019
 Batch Number : A19JB3154 Retest date : 30-SEP-2024
 Manufacturing Site : Geel

<u>Test</u>	<u>Specification</u>	<u>Result</u>
Appearance	White to almost white powder	Pass
Identification		
IR	Complies with reference spectrum	Pass
Assay "as is"	98.0 % (w/w) to 102.0 % (w/w)	99.6 % (w/w)
Chromatographic Purity		
R601094	<= 0.80 %	0.25 %
Unspecified impurity	<= 0.10 %	<0.05 %
Total impurities	<= 1.0 %	0.2 %
Melting Temperature	204 degree C to 216 degree C	211 degree C
Residual Solvents		
2-propanol	<= 5000 ppm	188 ppm
Particle Size		
d50	<= 25 µm	13 µm
d90	<= 45 µm	24 µm
Residue on Ignition/Sulfated Ash	<= 0.1 %	0.0 %
Heavy Metals	<= 20 ppm	Pass

Information

Specification Report : DS-SPE-29239 (1.0)

Unmilled material produced by Dishman Carbogen Amcis Limited
 Survey No: 47 & 48, Paiki Sub Plot No: 1,
 Village: Lodariyal, Taluka: Sanand
 Dist. Ahmedabad-382 220
 Gujarat State, India

Conclusion: Approved

Certificate of Analysis

Name of Product :	BEDAQUILINE FUMARATE	Date of Manufacture :	01-OCT-2019
Product Code :	116620	Retest date :	30-SEP-2024
Batch Number :	A19JB3154		
Manufacturing Site :	Geel		

Ref batch 119BCW0081.

This batch has been manufactured, including packaging and quality control, in accordance with the GMP requirements and complies with the requirements in the above Specification Report.

This certificate of analysis has been created on 10-FEB-2021 and originally electronically signed for approval by Greet Walbers (GWALBERS) on 07-DEC-2020. This certificate is produced by a validated Laboratory Information Management System and therefore bears no handwritten signature. The release of this certificate is under the supervision of Claude Vandebossche, Senior Director, Quality.