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C19076306/1

Certificate of Analysis

Name of Product :	BEDAQUILINE FUMARATE		
Product Code :	116620	Date of Manufacture :	01-MAR-2019
Batch Number :	A19CB1127	Retest date :	28-FEB-2021
Manufacturing Site :	Geel		

Test	Specification	Result
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)	99.7 % (w/w)
Chromatographic Purity		
R601094	<= 0.80 %	0.21 %
Unspecified impurity	<= 0.10 %	<0.05 %
Total impurities	<= 1.0 %	0.2 %
Melting Temperature	204 degree C to 216 degree C	208 degree C
Residual Solvents		
2-propanol	<= 5000 ppm	303 ppm
Particle Size		
d50	<= 25 µm	12 µm
d90	<= 45 µm	23 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, Lodariyal Taluka-Sanad, Survey No. 47, Paiki Sub Plot No. 1, Ahmedabad, Gujarat - 382220, India

Conclusion: **Approved**

Ref batch 119BCW0016.

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 09-OCT-2019 and originally electronically signed for approval by Hilde Van Dijck (HVANDIJC) on 24-JUN-2019. 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 Vandenbossche, Senior Director, Quality.