



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	BEDAQUILINE FUMARATE	CAS No:	845533-86-0
Batch No.	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR2031

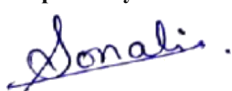
Sr No	Test	Acceptance Criteria	Results
1	Description	White to cream colored powder	White color powder
2	Solubility	Soluble in Tetrahydrofuran, freely soluble in N, N-Dimethyl formamide and practically insoluble in water.	Complies
3	Identification – By IR	IR spectrum of the sample should be concordant with the IR spectrum of the Reference/working standard, obtained in the same manner.	Complies
4	Identification – By UV	The sample has maximum absorption at 226nm wavelength.	Complies
5	Identification – By HPLC	The retention time of the major peak in the chromatogram of test preparation corresponds to that in the chromatogram of standard preparation as obtained under assay by HPLC.	Complies
6	X-Ray Diffraction	X-Ray diffractogram of the test should exhibit 2θ values at 6.1°, 10.4°, 12.0°, 14.1°, 16.9°, 18.9°, 20.5°, 20.8°, 21.5° and 23.2° with ±0.2° /20.8°, 21.5° and 23.2° with ±0.2°	Complies
7	Loss on drying (%W/W, dried at 105°C for 3hrs)	Not more than 1.0	0.54
8	Specific optical rotation (°)	-132 to -137	-133.2
9	Residue on ignition (%W/W)	Not more than 0.2	0.03
10	Fumaric acid content by titration method (% w/w, on dried basis)	Between 16.0 to 18.0	17.03
11	Enantiomer by HPLC method (%W/W)	Not more than 0.15	Not detected
12	Assay by HPLC method (% w/w, on dried basis)	Between 98.0 and 102.0	100.3
13	Organic impurities by HPLC method (% w/w) BDQRC-1 (BDQ-SC)	Not more than 0.15	Not detected
14	Organic impurities by HPLC method (% w/w) BDQRC-2 (O-Desmethyl Bedaquiline)	Not more than 0.15	Not detected
15	Organic impurities by HPLC method (% w/w) BDQRC-3	Not more than 0.15	0.03

Sr No	Test	Acceptance Criteria	Results
	(Desbromo Bedaquiline)		
16	Organic impurities by HPLC method (% w/w) BDQRC-4 (Bedaquiline N-Oxide)	Not more than 0.15	0.03
17	Organic impurities by HPLC method (% w/w) BDQRC-5 (Diastereomer)	Not more than 0.15	0.02
18	Organic impurities by HPLC method (% w/w) BDQRC-6 (2-Naphthyl Bedaquiline)	Not more than 0.15	0.01
19	Organic impurities by HPLC method (% w/w) BDQRC-7 (BDQ-III)	Not more than 0.15	Not detected
20	Organic impurities by HPLC method (% w/w) Any unspecified impurity	Not more than 0.10	0.03
21	Organic impurities by HPLC method (% w/w) Total impurities	Not more than 1.00	0.18
22	Residual solvents by GC-HS (ppm) (Method-I) 1,4 Dioxane	Not more than 380	Not detected
23	Residual solvents by GC-HS (ppm) (Method-I) Acetone	Not more than 2000	Not detected
24	Residual solvents by GC-HS (ppm) (Method-I) Acetonitrile	Not more than 410	Not detected
25	Residual solvents by GC-HS (ppm) (Method-I) Dimethyl formamide	Not more than 880	Not detected
26	Residual solvents by GC-HS (ppm) (Method-I) Ethanol	Not more than 2000	Not detected
27	Residual solvents by GC-HS (ppm) (Method-I) Hexane	Not more than 290	Not detected
28	Residual solvents by GC-HS (ppm) (Method-I) Isopropyl alcohol	Not more than 5000	153
29	Residual solvents by GC-HS (ppm) (Method-I) Methanol	Not more than 2000	48
30	Residual solvents by GC-HS (ppm) (Method-I) n-heptane	Not more than 1500	Not detected
31	Residual solvents by GC-HS (ppm) (Method-I) Tetrahydrofuran	Not more than 720	Not detected
32	Residual solvents by GC-HS (ppm) (Method-I) Toluene	Not more than 890	15
33	Residual solvents by GC-HS (ppm) (Method-II) • Methylene dichloride	Not more than 600	Not detected
34	Residual solvents by GC-HS (ppm) (Method-III)	Not more than 5000	Not detected

Sr No	Test	Acceptance Criteria	Results
	• Triethyl amine		
35	Residual solvents by HPLC (ppm) (Method-IV) • Acetic acid	Not more than 5000	Not detected
36	Particle size by Malvern d (0.1)	Not more than 3 μm	0.767
37	Particle size by Malvern d (0.5)	Not more than 6 μm	1.93
38	Particle size by Malvern d (0.9)	Not more than 10 μm	4.61

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026
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