SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	EZETIMIBE - USP	**CAS No:**	163222-33-1
Batch No.	2605001	**Manufactured by**	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	**Date of Analysis**	20/05/2026
Batch Quantity	-	**Retest Date**	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White or almost white, hygroscopic powder	White hygroscopic powder
2	Solubility	Freely soluble in alcohol, soluble in acetonitrile, Insoluble in aqueous solvents and non-polar solvents like hexane.	Complies
3	Identification (IR)	The IR spectrum of the sample should be concordant with the IR spectrum of the Ezetimibe reference/Working standard.	Complies
4	Identification by - HPLC	The retention time ratio of the major peak of the sample solution to that of the Ezetimibe peak from the system suitability solution in the test for Organic impurities (Method-2) is between 0.97 and 1.03.	Complies
5	Water by KF Titrator (% w/w)	Not more than 0.6	0.10
6	Specific optical rotation (°)	-25.0° to -30.0°	-29.1
7	Residue on Ignition (% w/w)	Not more than 0.2	0.08
8	Organic Impurities by HPLC (%) Method-I Desfluoroaniline analog	NMT 0.2	Not detected
9	Organic Impurities by HPLC (%) Method-I o-Fluorobenzene isomer	NMT 0.2	Not detected
10	Organic Impurities by HPLC (%) Method-I m-Fluoroaniline analog	NMT 0.2	Not detected
11	Organic Impurities by HPLC (%) Method-I Ezetimibe ketone	NMT 0.1	Less than 0.05
12	Organic Impurities by HPLC (%) Method-I Any unspecified impurity	NMT 0.10	0.06
13	Organic Impurities by HPLC (%) Method-I Total impurities	NMT 0.6	0.06
14	Organic Impurities by HPLC (%) Method-II S,S,S-Ezetimibe	NMT 0.2	Not detected

Sr No	Test	Acceptance Criteria	Results
15	Organic Impurities by HPLC (%) Method-II R,R,R-Ezetimibe	NMT 0.1	Not detected
16	Organic Impurities by HPLC(%) Method-II R,R,S-Ezetimibe	NMT 0.4	0.05
17	Organic Impurities by HPLC (%) Method-II S,S,R-Ezetimibe	NMT 0.1	Not detected
18	Organic Impurities by HPLC (%) Method-II R,S,R-Ezetimibe	NMT 0.1	Not detected
19	Organic Impurities by HPLC (%) Method-II Total chiral impurities	NMT 0.5	0.05
20	Organic Impurities by HPLC (%) Method-II Total impurities (Sum of all impurities from Method-I and Method-II)	NMT 0.9	0.11
21	Assay By HPLC (% w/w, on anhydrous and solvent free basis)	Not less than 98.0 and not more than 102.0	100.0
22	Residual solvents by GC-HS (ppm) Method-I Methanol	Not more than 3000	Not detected
23	Residual solvents by GC-HS (ppm) Method-I Isopropyl alcohol	Not more than 5000	441
24	Residual solvents by GC-HS (ppm) Method-I Acetonitrile	Not more than 410	1
25	Residual solvents by GC-HS (ppm) Method-I Dichloromethane	Not more than 600	Not detected
26	Residual solvents by GC-HS (ppm) Method-I Toluene	Not more than 890	Not detected
27	Residual solvents by GC-HS (ppm) Method-I n-Hexane	Not more than 290	Not detected
28	Residual solvents by GC-HS (ppm) Method-I Dimethyl sulfoxide	Not more than 5000	Not detected
29	Residual solvents by GC-HS (ppm)	Not more than 1000	Not detected

Sr No	Test	Acceptance Criteria	Results
	Method-I Hexamethyldisilane		
30	Method-II (DIEPA Content)	Not more than 100	Not detected
31	Method-III (Benzene content)	Not more than 2	Not detected

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

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

Swapnroop Drugs And Pharmaceuticals Quality Assurance Aurangabad