Certificate of Analysis

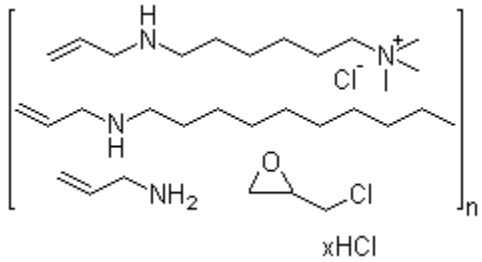
Colesevelam Hydrochloride

CAS # 182815-44-7

MF # $(C_{13}H_{27}N)_n \cdot (C_{12}H_{27}ClN_2)_n \cdot (C_3H_7N)_n \cdot (C_3H_5ClO)_n \cdot xHCl$

Batch # S506F26001

Code # 4086



Date of Mfg: 01/2026
Date of Retest: 03/2028
Country of Origin: India

TESTS	SPECIFICATIONS	RESULT
Appearance	White, off-white to pale yellow powder	Pale yellow powder
Solubility	Insoluble in water, 0.1N HCl, Methylene Chloride, acetonitrile and methanol	Complies
Identification		
By Ninhydrin test	Particles in solution appear violet in color	Complies
By FTIR	The infrared absorbance of the test preparation exhibit maxima at between 1448 and 1470cm^{-1} 1500 and 1650cm^{-1} 2800 and 2950 cm^{-1} & 3180 and 3500cm^{-1}	The infrared absorbance of the test preparation exhibits maxima at 1467cm^{-1}, 1630 cm^{-1}, 2926 cm^{-1} and 3429 cm^{-1}.
Loss on Drying (with on 1.0 g Sample at 105°C for 3 h)	≤ 10.0%	5.28%
Residue on Ignition (with 1.0 g of sample)	≤ 0.10%	0.02%
Chloride Content (on dried basis)	Between 16.0 % and 22.0%	20.7%
Swell Index	Between 2.0 and 7.5	4.5

Glycocholate binding Capacity by HPLC (ODB)	2.0g/g and 2.5g/g	2.3g/g
Limit of Epichlorohydrin by GC	≤ 0.34%	Not detected
Limit of water soluble Amines	≤ 0.5%	0.0%
Limit of allylamine by TLC	≤ 0.05%	BQL
Limit of Bromide by IC	≤ 1.0%	0.8%
Residual Solvents (GC)		
Methanol	≤ 3000ppm	Not detected
Ethyl acetate	≤ 5000ppm	Not detected
Organic Impurities by GC		
1 -Methoxydecane	≤ 0.05%	0.001%
1,6-Dibromohexane	≤ 0.05%	Not detected
1 -Bromodecane	≤ 0.05%	Not detected
Particle size distribution by Malvern (dry method technique)		
D (0.9)	≤ 100µm	71µm

Additional information
BQL: Below Quantification Limit
LOQ: Limit of Quantification
LOQ of Bromide is 0.3 %
LOQ of Methanol is 60.6 ppm
LOQ of Ethyl acetate is 50.1 ppm
General LOQ limit is 0.004%