Certificate of Analysis

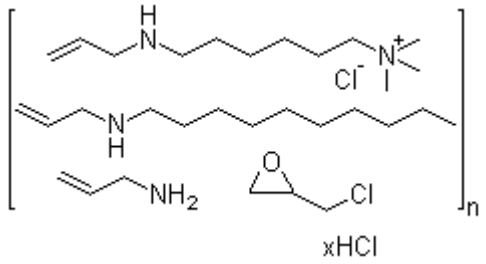
Colesevelam Hydrochloride

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 # S506F24001

Code # 3686



Date of Mfg: 10/2024
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}	Complies
Loss on Drying (with on 1.0 g at 105°C for 3 h)	≤ 10.0%	6.22%
Residue on Ignition (with 1.0 g of sample)	≤ 0.10%	0.03%
Chloride Content (on dried basis)	Between 16.0 % and 22.0%	17.8%
Swell Index	Between 2.0 and 7.5	4.7
Glycocholate binding Capacity by HPLC (ODB)	2.0g/g and 2.5g/g	2.2g/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%	0.9%
Residual Solvents (GC)		
Methanol	≤ 3000ppm	92ppm
Ethyl acetate	≤ 5000ppm	Not detected
Organic Impurities by GC		
1 -Methoxydecane	≤ 0.05%	BQL
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	81µm