

Certificate of Analysis

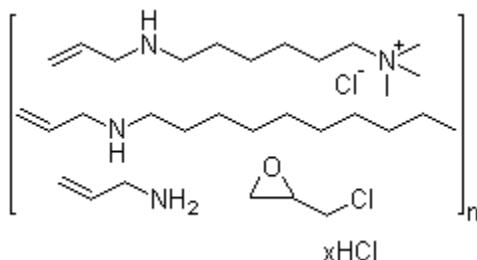
Colesevelam Hydrochloride

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 # S506F23004

Code # 3214



Date of Mfg: 07/2023
Date of Retest: 04/2028
Country of Origin: India

TESTS

Appearance
 Solubility

Identification

By Ninhydrin test
 By FTIR

Loss on Drying (with
 on 1.0 g at 105°C for 3 h)

Residue on Ignition
 (with 1.0 g of sample)

Chloride Content
 (on dried basis)

Swell Index

Glycocholate binding

Capacity by HPLC (ODB)

SPECIFICATIONS

white, off-white to pale yellow powder
 Insoluble in water, 0.1N HCl, Methylene
 Chloride, acetonitrile and methanol

Particles in solution appear violet in color
 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

≤ 10.0%

≤ 0.10%

Between 16.0 % and 22.0%

Between 2.0 and 7.5

2.0g/g and 2.5g/g

RESULT

pale yellow powder

Complies

Complies

Complies

5.6%

0.06%

21.0%

7.1

2.2g/g



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Limit of Epichlorohydrin by GC	$\leq 0.34\%$	Not detected
Limit of water soluble Amines	$\leq 0.5\%$	0.0%
Limit of allylamine by TLC	$\leq 0.05\%$	BQL
Limit of Bromide by IC	$\leq 1.0\%$	0.8%
Residual Solvents (GC)		
Methanol	$\leq 3000\text{ppm}$	240ppm
Ethyl acetate	$\leq 5000\text{ppm}$	Not detected
Organic Impurities by GC		
1 -Methoxydecane	$\leq 0.05\%$	BQL
1,6-Dibromohexane	$\leq 0.05\%$	Not detected
1 -Bromodecane	$\leq 0.05\%$	Not detected
Particle size distribution by Malvern (dry method technique)		
D (0.9)	$\leq 100\mu\text{m}$	85 μm