

Certificate of Analysis

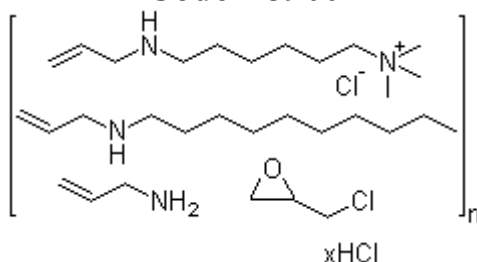
Colesevelam Hydrochloride

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 # 3900



Date of Mfg: 10/2024
Date of Retest: 03/2028
Country of Origin: India

TESTS

Appearance
 Solubility

Identification

By Ninhydrin test
 By FTIR

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

Residue on Ignition
 (with 1.0 g of sample)

Chloride Content
 (on dried basis)

Swell Index

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

RESULT

Pale yellow powder

Complies

The infrared absorbance of the
 test preparation exhibits
 maxima at 1467cm⁻¹,
 1628 cm⁻¹, 2926 cm⁻¹
 and 3429 cm⁻¹.

6.22%

0.03%

17.8%

4.7

Glycocholate binding

Capacity by HPLC (ODB)	2.0g/g and 2.5g/g	2.2g/g
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	$\leq 1.0\%$	0.9%
Residual Solvents (GC)		
Methanol	$\leq 3000\text{ppm}$	92ppm
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)	$\leq 100\mu\text{m}$	81 μm

Additional information

BQL: Below Quantification Limit

LOQ: Limit of Quantification

LOQ of Bromide is 0.3 %

General LOQ limit is 0.004%

LOQ of Methanol is 60.6 $\mu\text{g/mL}$

LOQ of Ethyl acetate is 50.1 $\mu\text{g/mL}$