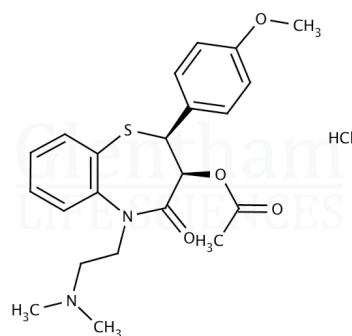


Certificate of Analysis

Product Name	Diltiazem hydrochloride, EP grade
Glentham Code	GP6533
CAS Number	33286-22-5
EINECS	251-443-3
MDL Number	MFCD00069252
Batch Number	002NXR

Molecular Weight	450.98
Molecular Formula	$C_{22}H_{26}N_2O_4S \cdot HCl$
Storage Temp.	+4°C



Property	Specification	Batch 002NXR
Physical Description	A white or almost white crystalline powder	White crystalline powder
Identification (IR)	To conform to standard	Conforms
Identification (TLC)	To pass test	Conforms
Identification	To pass tests C, D	Conforms
Solubility (5% in water)	Clear, colourless solution	Clear, colourless solution
pH (1% in water)	4.5 - 5.3	4.9
Specific Optical Rotation	+115 - +120 °	+118°
Impurity F	≤ 0.3%	0.0%
Any Unspecified Impurity	≤ 0.1%	0.02%
Total Impurities	≤ 0.3%	≤ 0.05%
Loss on Drying	≤ 0.5% (105°C, 2h)	0.2%
Heavy Metals	≤ 10ppm	Conforms
Sulphated Ash	≤ 0.1%	0.0%
Assay	98.5 - 101.0 %	99.4%
Pharmacopoeia Specification(s)	EP	Conforms

Specification Version	v1.0
Manufacture Date	2017-11-01
Re-Test Date	2028-12-03

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

This document was generated electronically and is therefore valid without signature. © Glentham Life Sciences Ltd, 2024