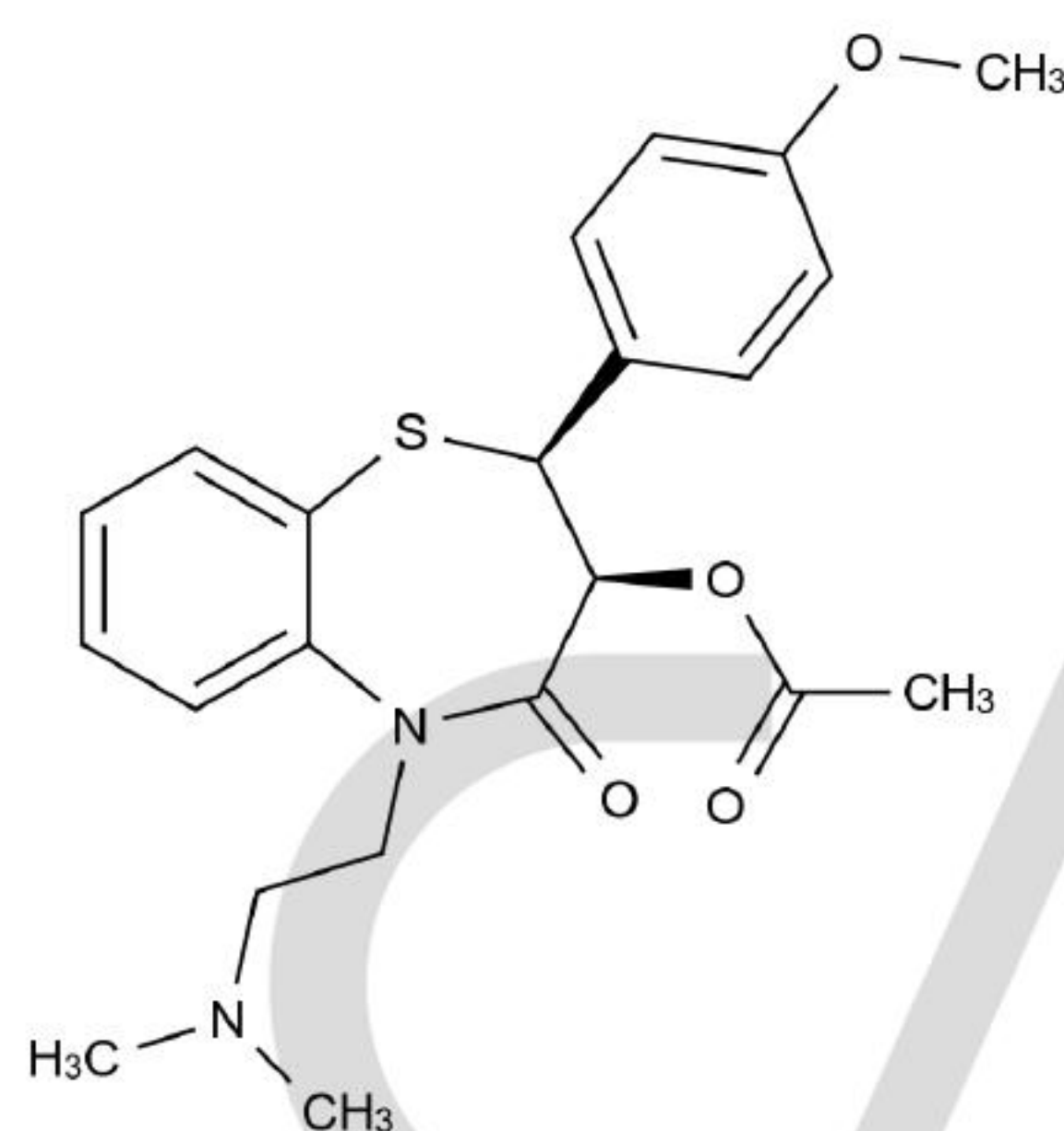


Certificate of Analysis

Reference Material & Standard

Product Name:	Diltiazem	Catalogue Number:	CCAD302220
Synonyms:	N/A	Lot Number:	1209-RF-0124
CAS Number:	42399-41-7	Expiry Date:	Dec 08, 2028
Molecular Formula:	C ₂₂ H ₂₆ N ₂ O ₄ S	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	414.52		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.572%
Loss On Drying	TGA	0.4625%
Assay		99.1%
Uncertainty		±2.0%

Comment:

1. The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$$

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by:

Lisa

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Dec 09, 2024

Date: Dec 09, 2024

Date: Dec 09, 2024

