

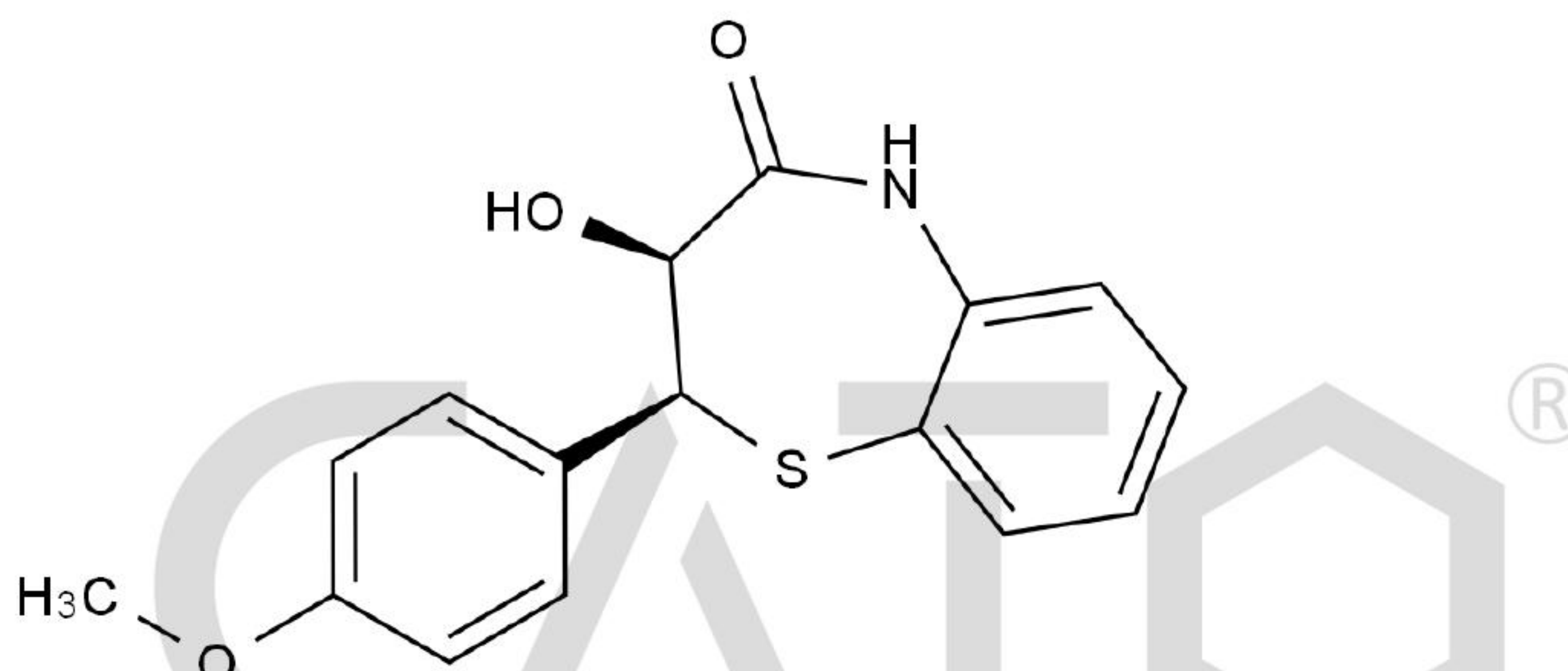
Certificate of Analysis

Reference Material & Standard

Product Name:	Diltiazem EP Impurity E	Catalogue Number:	C4X-13685
Synonyms:	N/A	Lot Number:	0211-RG-0072
CAS Number:	42399-49-5	Expiry Date:	Feb 10, 2028
Molecular Formula:	C ₁₆ H ₁₅ NO ₃ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	301.36	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&UV&HNMR	Confirmed
Purity	HPLC	99.916%
Loss On Drying	TGA	0.0432%
Assay		99.9%

Comment:

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

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

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

Signature:

Prepared by:

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Reviewed by:

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Approved by General Manager:

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Date: Feb 11, 2025

Date: Feb 12, 2025

Date: Feb 12, 2025

