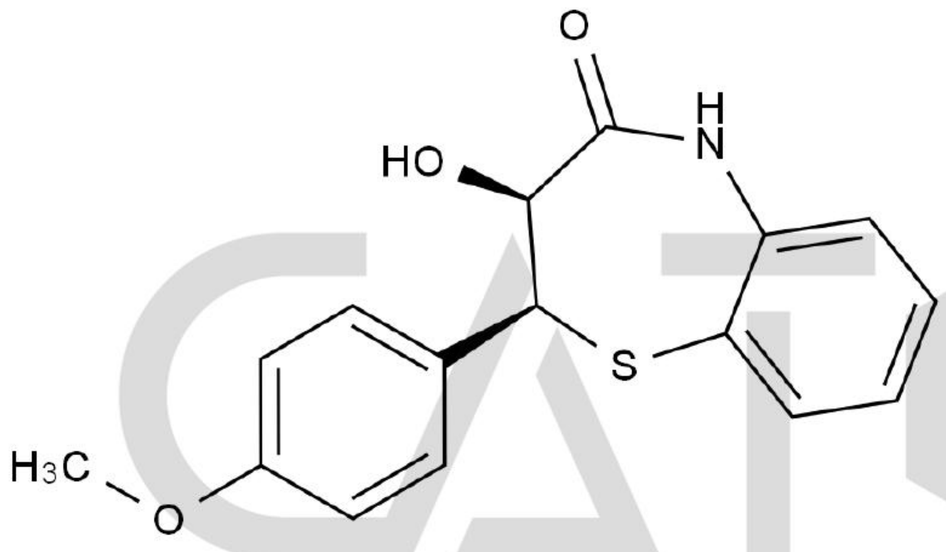
Certificate of Analysis

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:**	Oct 12, 2030
Molecular Formula:	$C_{16}H_{15}NO_3S$	**Storage:**	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	301.36	**Shipping Condition:**	Shipping at Room Temperature
		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	Mass Balance	99.9%

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Comment:

The calculation of the mass balance 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: Koji Date: Oct 13, 2026

Reviewed by: Lisa Date: Oct 13, 2026

Approved by General Manager: David Date: Oct 13, 2026

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