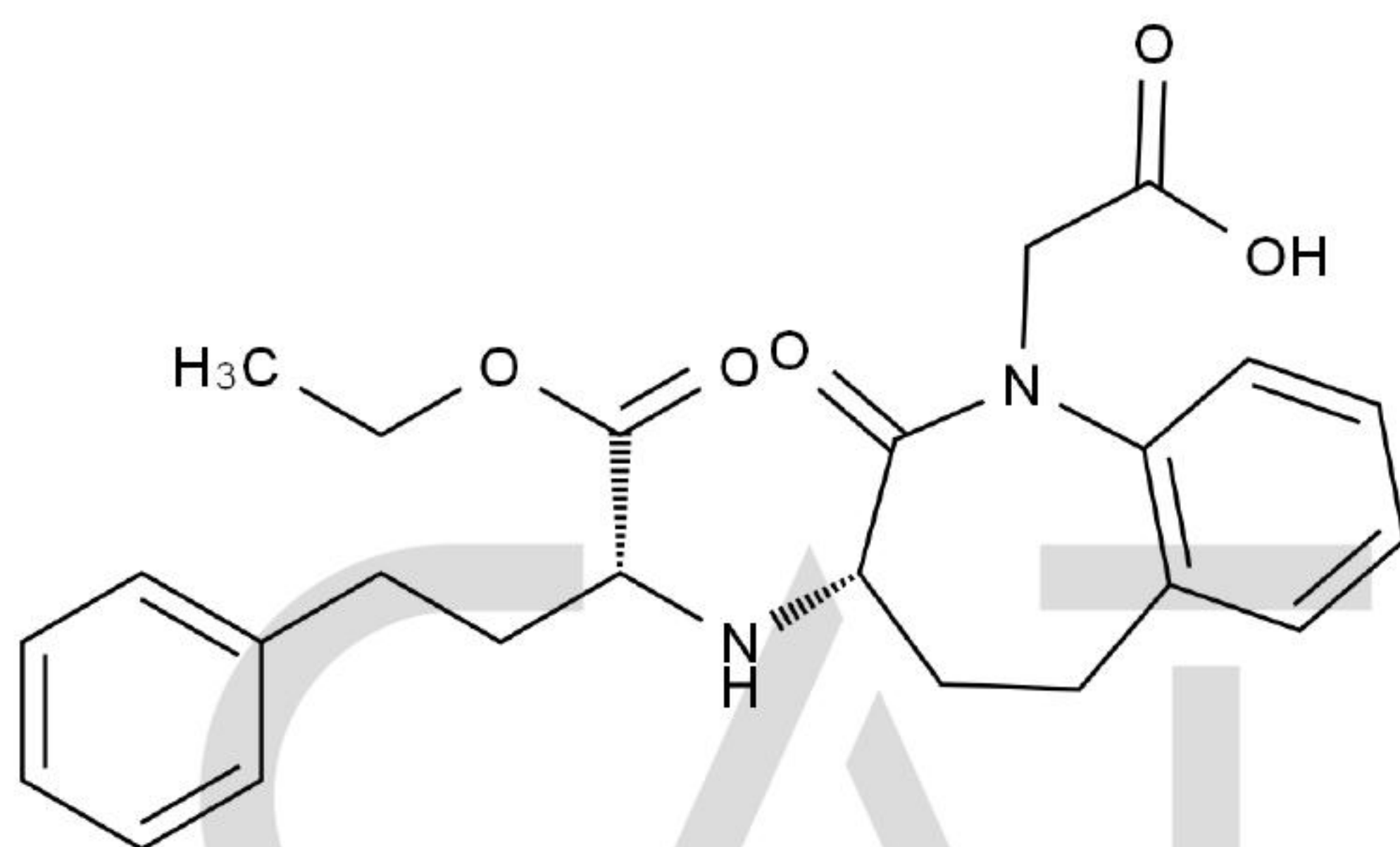


Certificate of Analysis

Reference Material & Standard

Product Name:	Benazepril EP Impurity B(1R,3S-Isomer)	Catalogue Number:	C4X-209611
Synonyms:	N/A	Lot Number:	0328-RF-0002
CAS Number:	86541-76-6	Expiry Date:	Aug 24, 2026
Molecular Formula:	C ₂₄ H ₂₈ N ₂ O ₅	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	424.49		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	98.5534%
Water Content	Karl Fischer	1.40%
Residual Solvents	NMR	0.7% ethyl acetate, 0.3% tetrahydrofuran and 0.3% acetic acid
Optical Rotation		[α] _D ²⁵ 0(c=0.30, ethanol): -176.1°
Assay		95.9%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Aproved by General Manager:

David

Date: Mar 28, 2024

Date: Mar 28, 2024

Date: Mar 28, 2024

