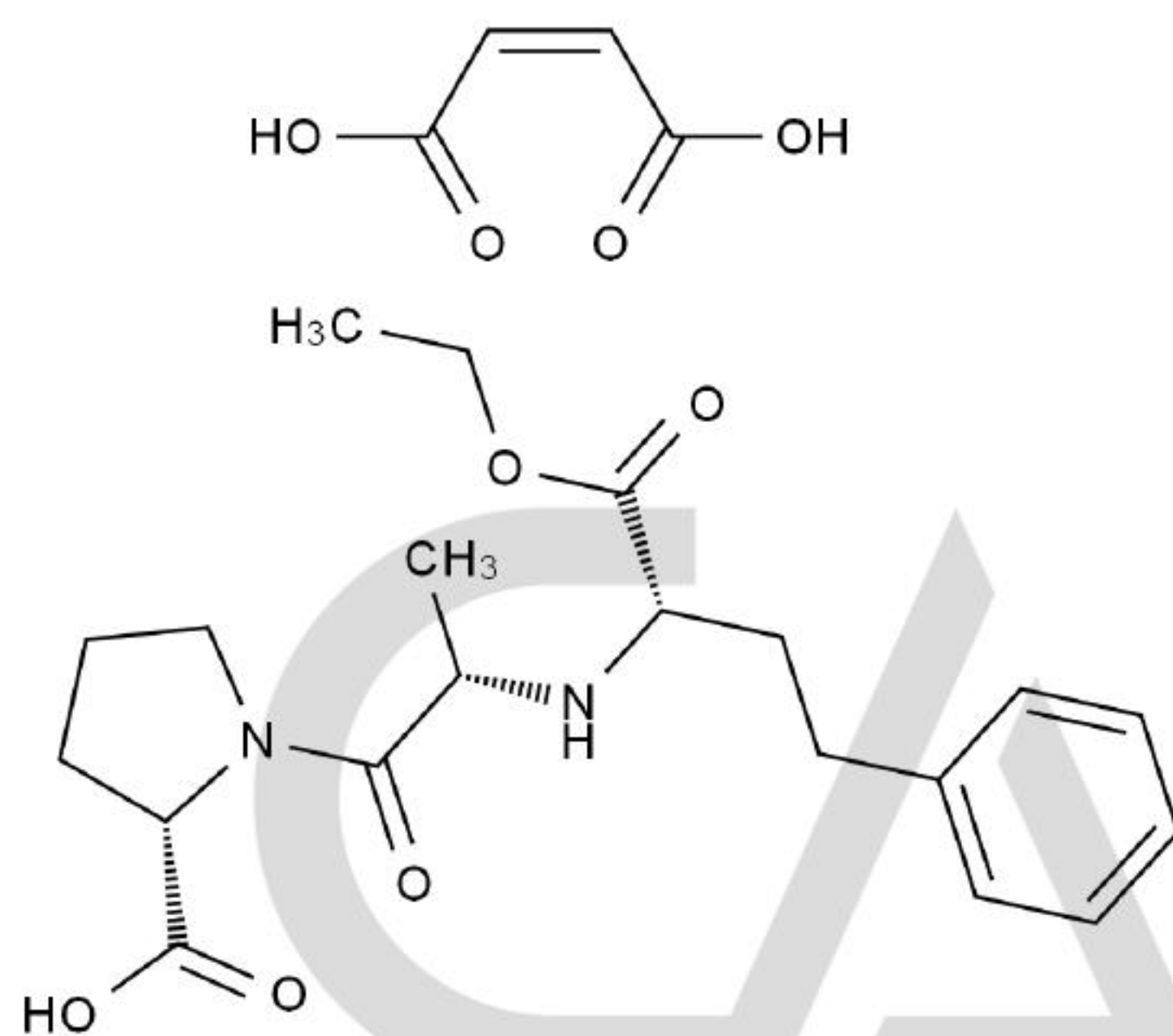


Certificate of Analysis

Reference Material & Standard

Product Name:	Enalapril Maleate	Catalogue Number:	CCAD300210
Synonyms:	N/A	Lot Number:	0702-RC-0006
CAS Number:	76095-16-4	Expiry Date:	Aug 12, 2028
Molecular Formula:	C ₂₀ H ₂₈ N ₂ O ₅ C ₄ H ₄ O ₄	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	376.45 116.07	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.9391%
Water Content	Karl Fischer	0.7682%
Assay		99.2%
Uncertainty		±2.0%

Comment:

- The peak of Maleic Acid was from 2.491min to 2.628min.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.
- 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:

Nice

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Aug 13, 2024

Date: Aug 14, 2024

Date: Aug 14, 2024

