

Certificate of Analysis

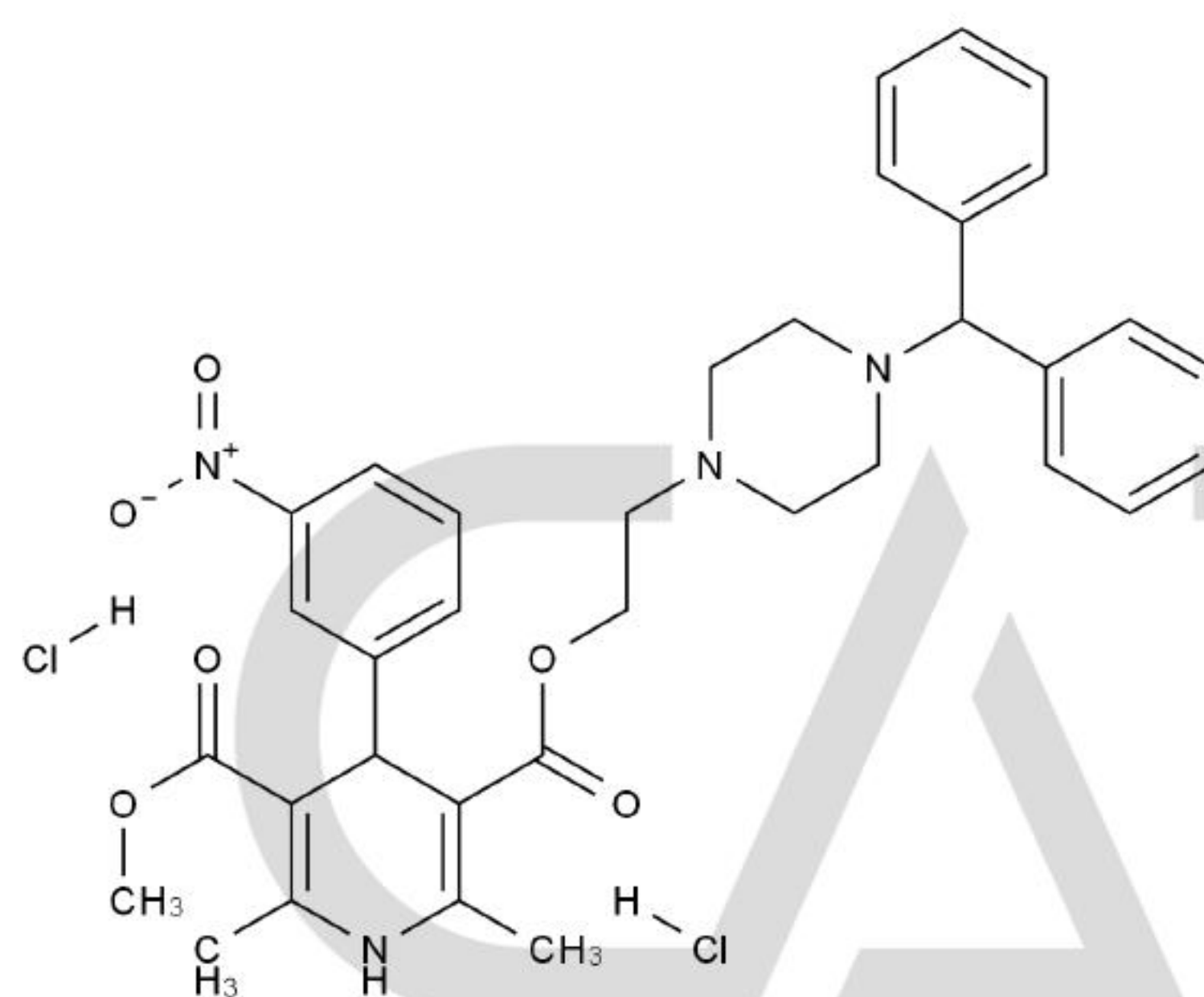
Reference Material & Standard

Product Name:	Manidipine Dihydrochloride	Catalogue Number:	CCAD301834
Synonyms:	N/A	Lot Number:	1122-RD-0008
CAS Number:	89226-75-5	Expiry Date:	Nov 24, 2026
Molecular Formula:	C ₃₅ H ₃₈ N ₄ O ₆ 2*HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	610.70 2*36.46	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Powder
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Water Content	Karl Fischer	0.9505%
Assay		99.0%
Uncertainty		±2.0%

Comment:

1. The calculation of the mass balance 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.

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:

Debia

Reviewed by:

Xenia

Approved by General Manager:

David

Date: Nov 25, 2022

Date: Nov 25, 2022

Date: Nov 25, 2022



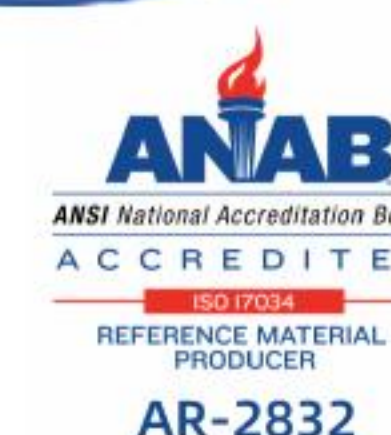
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