

Certificate of Analysis

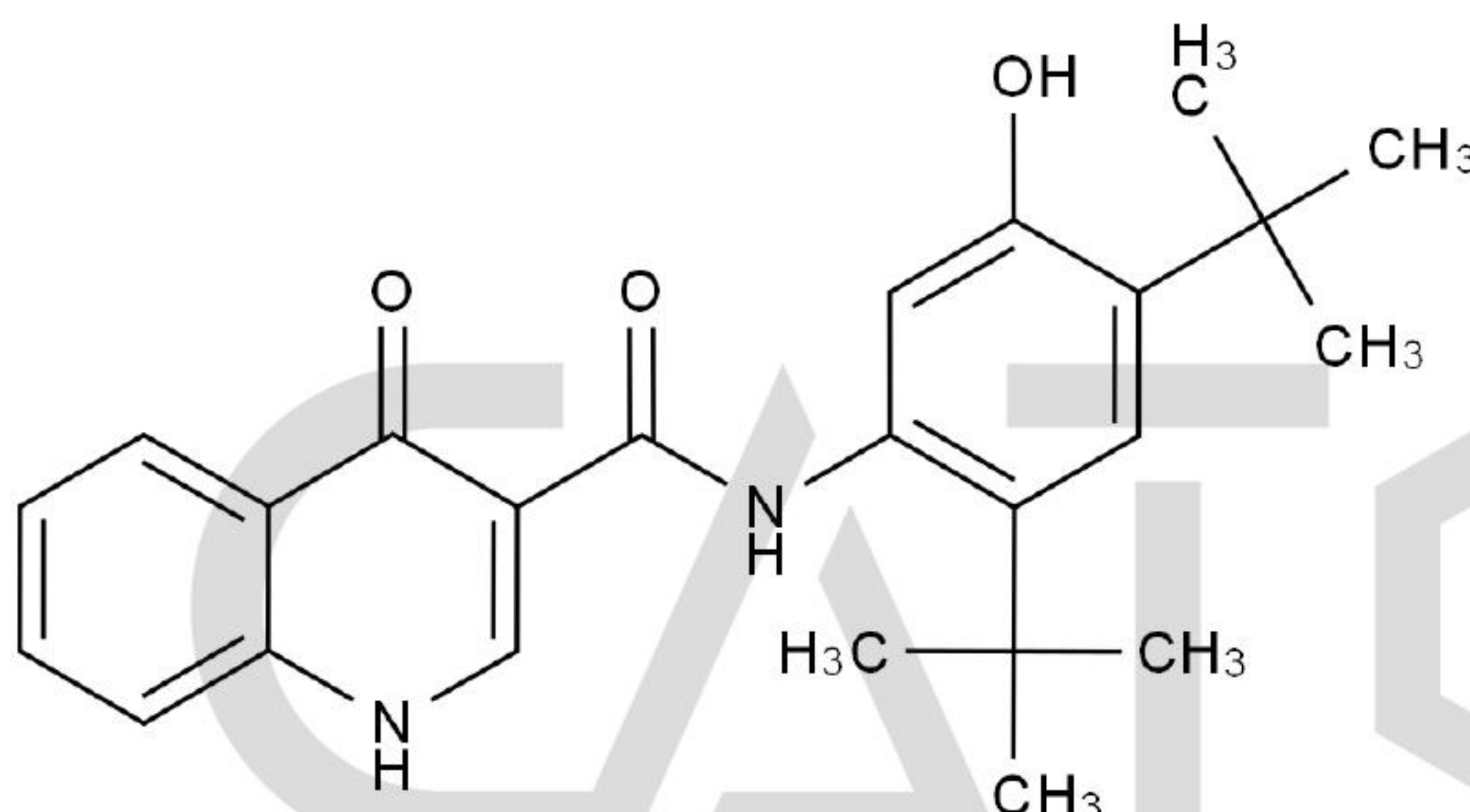
Reference Material & Standard

Product Name:	Ivacaftor	Catalogue Number:	CCAD302725
Synonyms:	N/A	Lot Number:	0918-RH-0069
CAS Number:	873054-44-5	Expiry Date:	Sep 28, 2030
Molecular Formula:	C ₂₄ H ₂₈ N ₂ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	392.49	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.963%
Residue on Ignition	TGA	0.6308%
Loss on Drying	TGA	0.1647%
Assay		99.2%
Uncertainty		±0.1%

Comment:

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

$$\text{Assay (\%)} = (100\% - \text{Residue on Ignition} - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$
 Residue on Ignition and Loss on Drying are 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: Sep 29, 2026

Date: Sep 29, 2026

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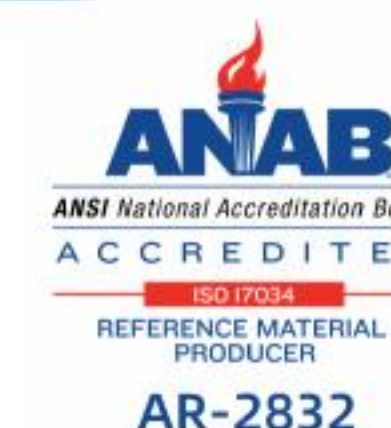
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