

Certificate of Analysis

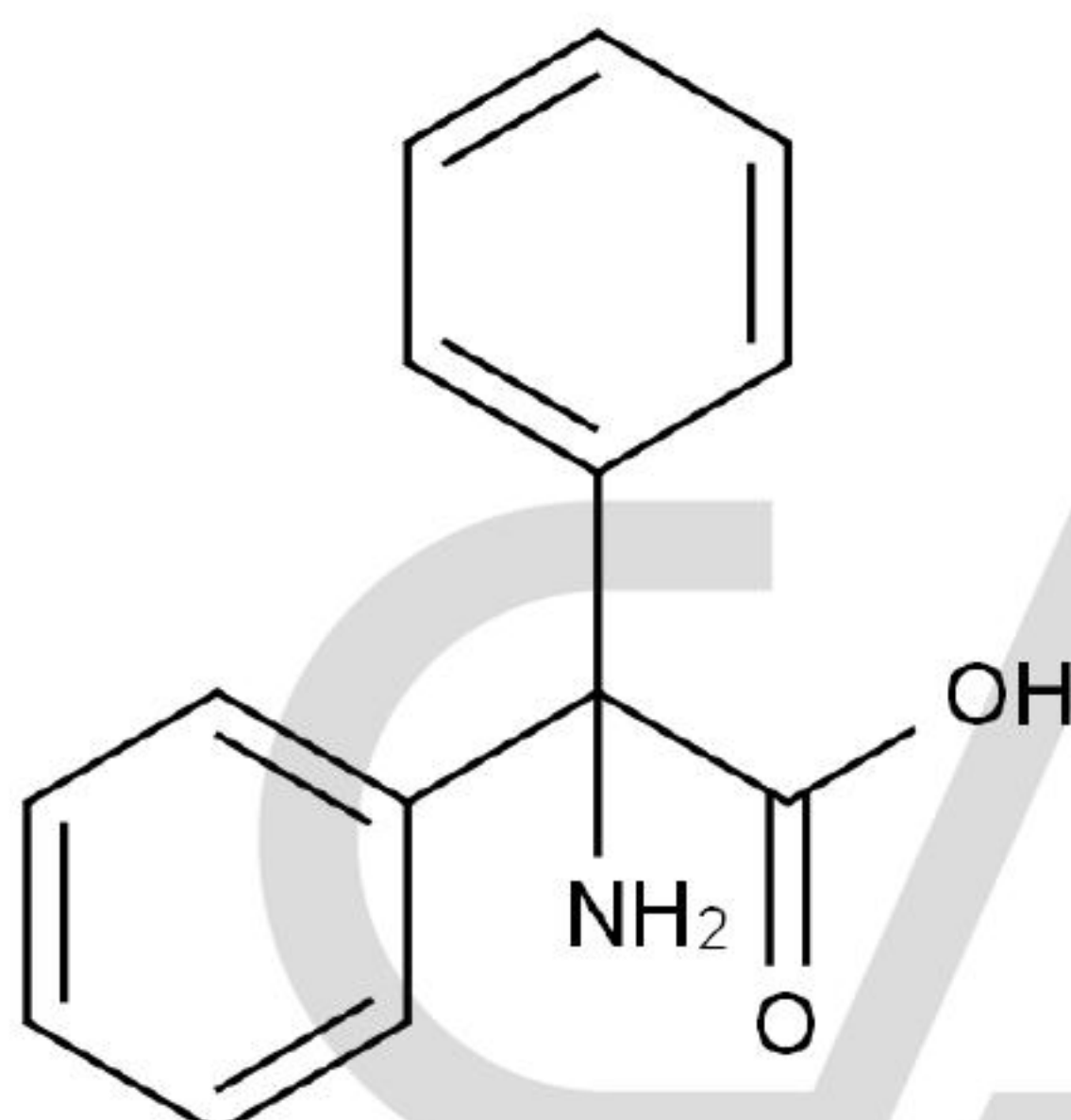
Reference Material & Standard

Product Name:	Phenytoin EP Impurity C	Catalogue Number:	C4X-18649
Synonyms:	2,2-Diphenylglycine	Lot Number:	0315-RD-0027
CAS Number:	3060-50-2	Expiry Date:	Apr 26, 2028
Molecular Formula:	C ₁₄ H ₁₃ NO ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	227.26	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	97.083%
Water Content	Karl Fischer	0.6944%
Assay		96.4%

Comment:

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

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

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

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Apr 27, 2025

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Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

Page 1 of 5



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