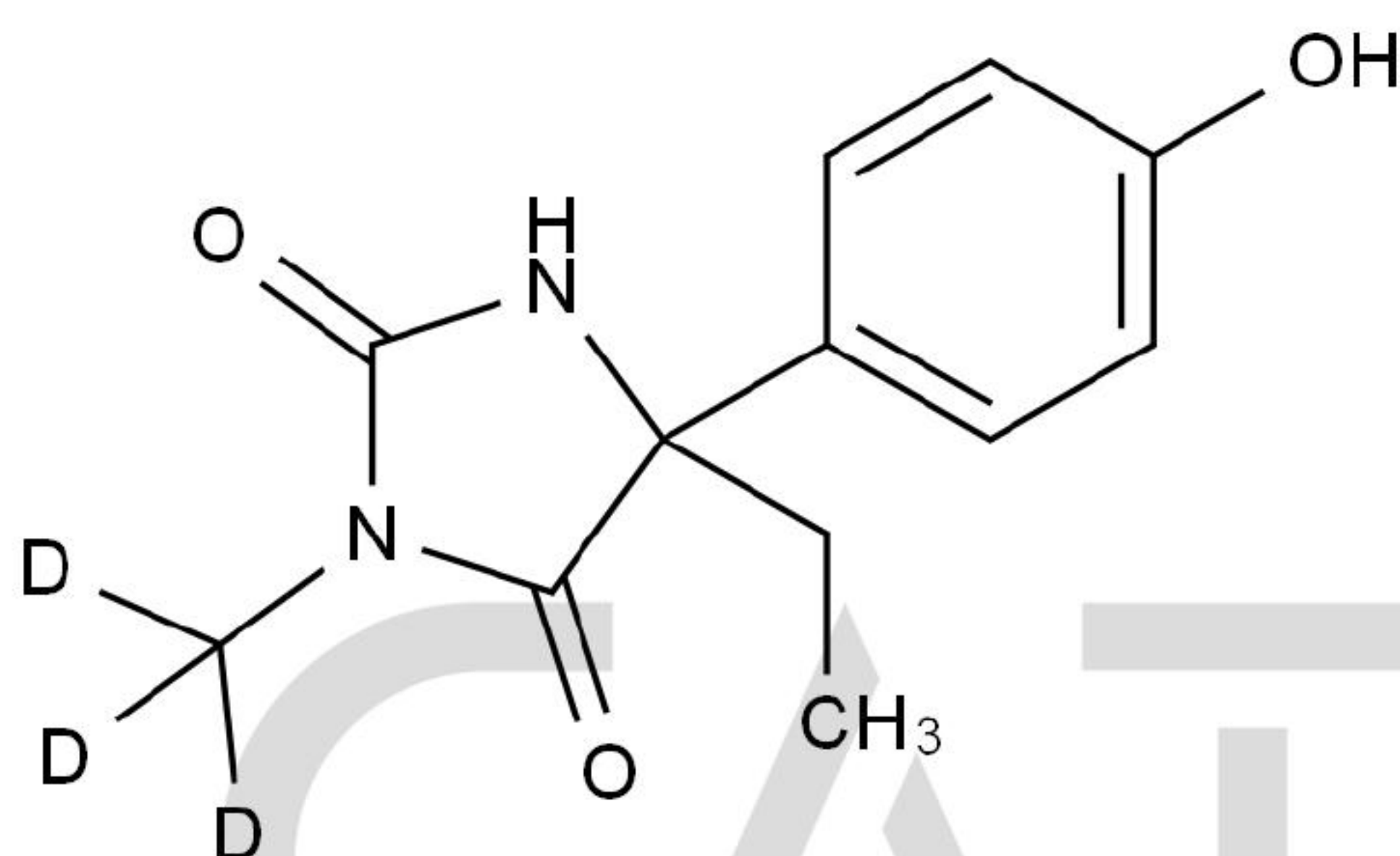


Certificate of Analysis

Reference Material

Product Name:	Mephenytoin Impurity 1	Catalogue Number:	C4X-24591
Chemical Name:	N/A	Lot Number:	1101-RD-0009
CAS Number:	1173022-56-4	Expiry Date:	Aug 01, 2025
Molecular Formula:	C ₁₂ H ₁₁ D ₃ N ₂ O ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	237.27		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Chemical Purity	HPLC	98.3654%
Isotopic Purity		99.5%
Water Content	Karl Fischer	0.3%
Residual Solvents	NMR	0.4% ethyl acetate
Assay		97.7%

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:

Hinlam

Reviewed by:

Xenia

Aproved by General manager:

David

Date: Aug 03, 2022

Date: Nov 03, 2022

Date: Nov 03, 2022

