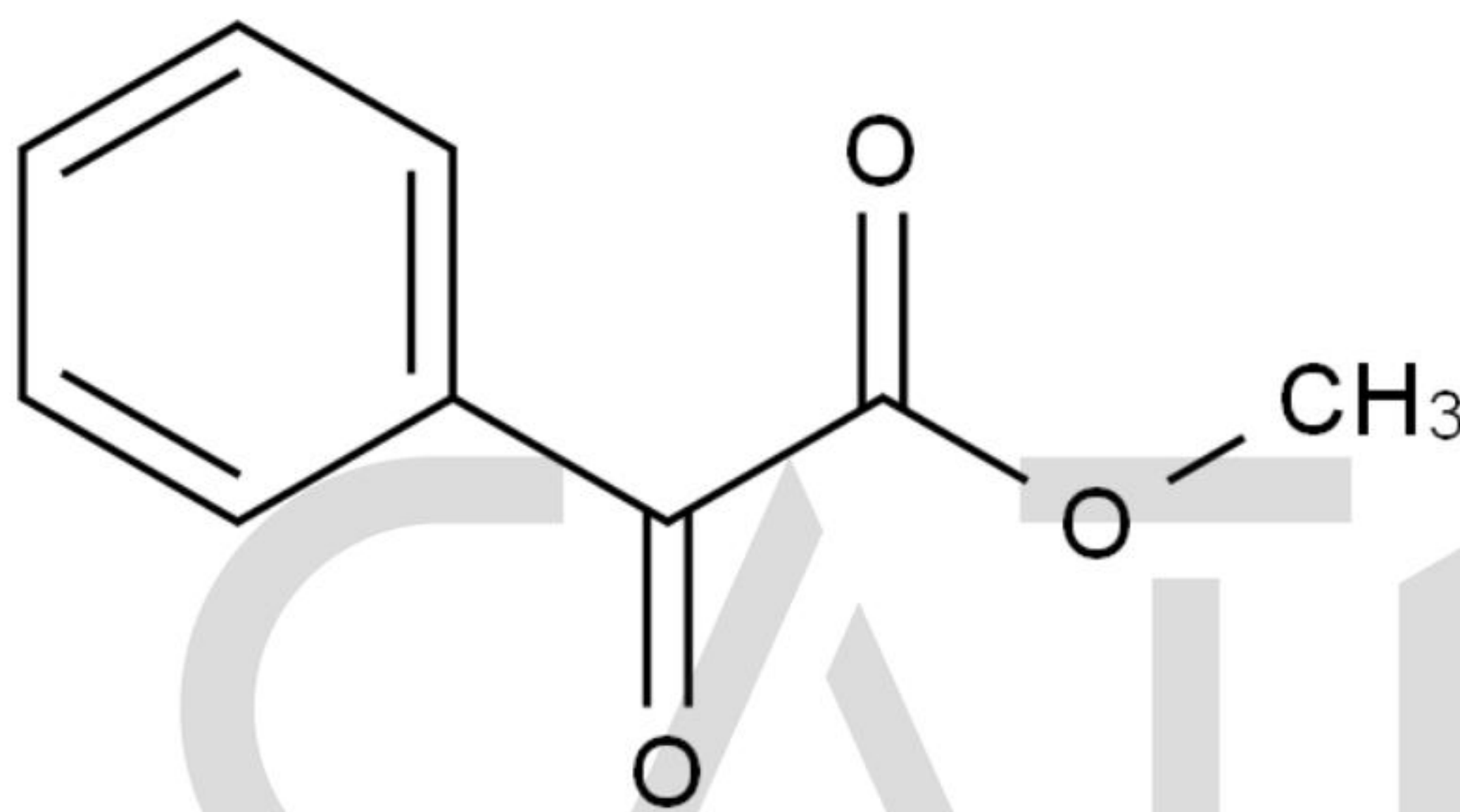


Certificate of Analysis

Reference Material & Standard

Product Name:	Glycopyrronium Bromide EP Impurity H	Catalogue Number:	C4X-15177
Synonyms:	N/A	Lot Number:	1213-RF-0023
CAS Number:	15206-55-0	Expiry Date:	Dec 12, 2027
Molecular Formula:	C ₉ H ₈ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	164.16	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Colourless Liquid
Identification	GCMS&HNMR	Confirmed
Purity	GC	98.115%
Water Content	Karl Fischer	0.1794%
Assay		97.9%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

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

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

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Dec 13, 2024

Date: Dec 16, 2024

Date: Dec 16, 2024

