

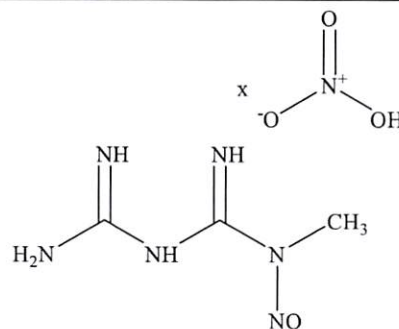
## Certificate of Analysis

Certificate No.: 20260528503



Date: May 28, 2026

Retest date: May 26, 2027

<b>Compound Name:</b> N-Nitroso Metformin EP Impurity E Nitrate (N-Nitroso Metformin USP Related Compound B Nitrate)	
<b>Synonyms:</b>	3-(azanylazanylidene)methyl-1-methyl-1-nitrosoguanidine, nitric acid (1:x)
<b>TLC Catalogue Number:</b>	M-4248
<b>CAS Number:</b>	N/A
<b>Alternate CAS Number:</b>	N/A
<b>Molecular Weight:</b>	144.14 x*63.01
<b>Molecular Formula:</b>	C <sub>3</sub> H <sub>8</sub> N <sub>6</sub> O. x HNO <sub>3</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	C0268-089A1
<b>Storage Conditions:</b>	Store at -20 °C
<b>Solubility:</b>	Water



Test Description	Specifications	Results
<b>Visual Description</b>	Pale yellow solid	<b>Conforms</b>
<b>Identification</b>		
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>98.3%</b>
<b>Impurity (HPLC)</b>	RT 3.30, 0.13%; RT 3.97, 0.65%; RT 17.76, 0.62%	
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (qNMR, free form)</b>	Not less than 55.0%	<b>60.3%</b>
<b>Recommendation:</b>	<b>Release.</b> The compound is an N-Nitroso product. Avoid using metal spatula and applying pressure. Wear proper personal protective equipment when handling.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/28/2026
Approved by:	Quality Assurance		05/28/2026

**Attachments:** Peak Attribution Table, Assay Calculation, HPLC, MS and NMR spectra.