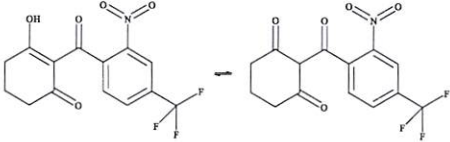


## Certificate of Analysis



Certificate No.: 20250616009-2

Date: June 16, 2025

Retest date: May 15, 2028

<b>Compound Name:</b>	<b>Nitisinone</b>	
<b>Synonyms:</b>	3-hydroxy-2-(2-nitro-4-(trifluoromethyl)benzoyl)cyclohex-2-en-1-one and 2-[2-nitro-4-(trifluoromethyl)benzoyl]-1,3-cyclohexanedione	
<b>TLC Catalogue Number:</b>	N-054001	
<b>CAS Number:</b>	486447-26-1 (enol form), 104206-65-7 (keto form)	
<b>Alternate CAS Number:</b>	N/A	
<b>Molecular Weight:</b>	329.23	
<b>Molecular Formula:</b>	C <sub>14</sub> H <sub>10</sub> F <sub>3</sub> NO <sub>5</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	6884-043A1	
<b>Storage Conditions:</b>	Store at 2-8 °C	
<b>Solubility:</b>	Methanol, DMSO, Acetonitrile	

Test Description	Specifications	Results
<b>Visual Description</b>	Off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</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>99.9%</b>
<b>Impurity (HPLC)</b>	N/A	
<b>Water Content (KF)</b>	N/A	<b>0.1%</b>
<b>Residue (TGA at 900 °C)</b>	N/A	<b>0.0%</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (%)</b>	Not less than 90.0%	<b>99.8%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		02/03/2026
Approved by:	Quality Assurance		02/03/2026

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