

# CERTIFICATE OF ANALYSIS

(Certificate No. SZ-A043024-1043)

Analysis Date: 03/12/2022

Re-test Date: 02/12/2024

## N-Nitroso Desmethyl Azelastine

### Identification

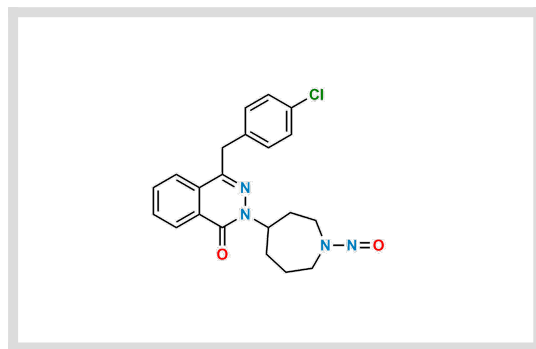
Chemical Name : 4-(4-Chlorobenzyl)-2-(1-nitrosoazepan-4-yl)phthalazin-1(2H)-one

CAT No. : SZ-A043024

CAS No. : NA

Molecular Formula : C<sub>21</sub>H<sub>21</sub>ClN<sub>4</sub>O<sub>2</sub>

Molecular Weight : 396.9



### Analytical Information

Batch Code : SRL-1012-132

HPLC Purity : 99.38 %

Solubility : ACN:Water (1:1)

Mass : Confirm

Appearance of product : Off White Solid

IR Analysis : Confirm

Long Term Storage : 2-8 °C for long term storage

<sup>1</sup>H NMR : Confirm

Weight Loss By TGA : 0.31 %

<sup>13</sup>C NMR : Confirm

Residue On Ignition : 0.20 %

DEPT Analysis : Confirm

### Additional Information

% Potency = [100 - 0.31 ( Wt loss by TGA ) - 0.20(ROI) ] X [99.38 (HPLC Purity) ] / 100 = 98.87 %

-Mixture of E/Z Isomers.

Elemental Analysis (Theoretical) : %C: 63.55 %H: 5.33 %N: 14.12 %S: 0.00

Elemental Analysis (Practical) : %C: 63.08 %H: 5.11 %N: 13.75 %S: 0.00

Recommendation : Released

Department

Signature

Date

Prepared and Reviewed by	Analytical		
Approved By	Quality Control		

Attachments : HPLC, Mass, <sup>1</sup>H NMR, IR, TGA, <sup>13</sup>C NMR, DEPT, ROI, CHNS

Shipping Condition : All Products are stable to be shipped at room temperature, unless otherwise specified.

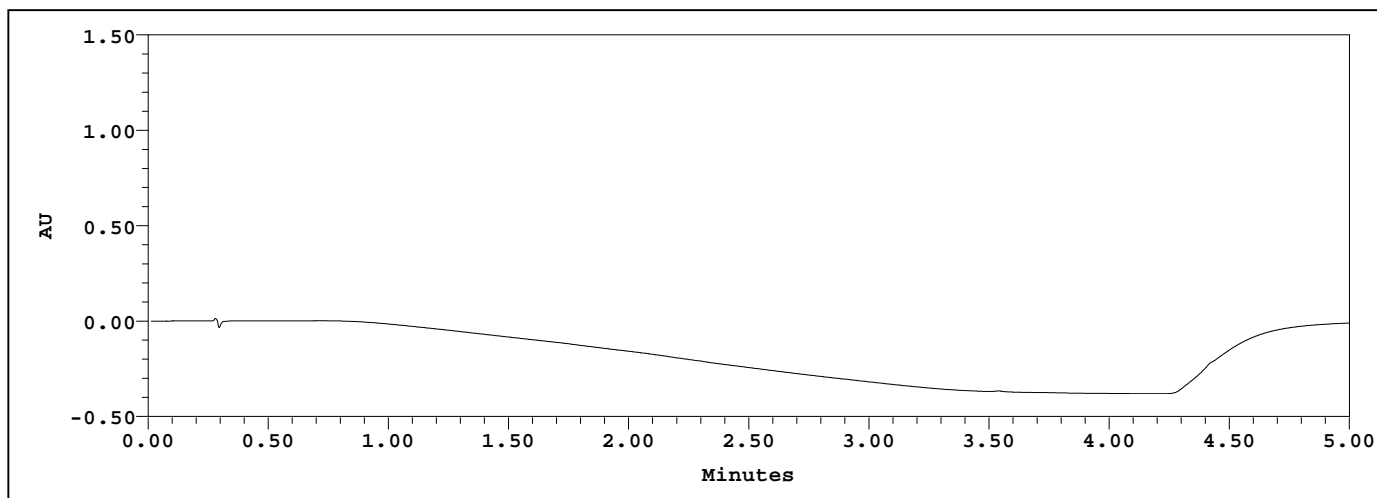


## === SynZeal HPLC Report ===

Sample Name : Blank Program : Gradient  
Sample ID : Diluent Column Temp : 40 °C  
Column Name : Acquity UPLC BEH Vial : 1:A,1  
Column ID : SRL/C18/2022/219 Injection Volume : 0.20 ul  
Column Desc. : 50 mm \* 2.1 mm; 1.7µ Sample Conc. : -  
Diluent : ACN:H2O (8:2) Flow Rate : 0.5 mL/min  
Mobile Phase\_A : 0.1 % TFA in water  
Mobile Phase\_B : ACN:H2O (90:10)  
Method Name : SZ\_UPLC\_RA\_AKIRA\_01  
Gradient :  
=> T(min)/%B 0.01-2.5/10-100 -> 2.5-3.5/100 -> 3.5-3.6/100-10 -> 3.6-5.0/10  
Sample Set Name : 2022\_11\_30\_UPLC\_02  
Date Acquired : 30-11-2022 13:44:29 IST  
Date Processed : 01-12-2022 11:30:48 IST  
Acquired By : Preeti\_Pal

## Chromatogram

Blank



Channel Name 210.0nm

## Results

	Retention Time (min)	Area (µV*sec)	Height (µV)	% Area
1				
Sum				

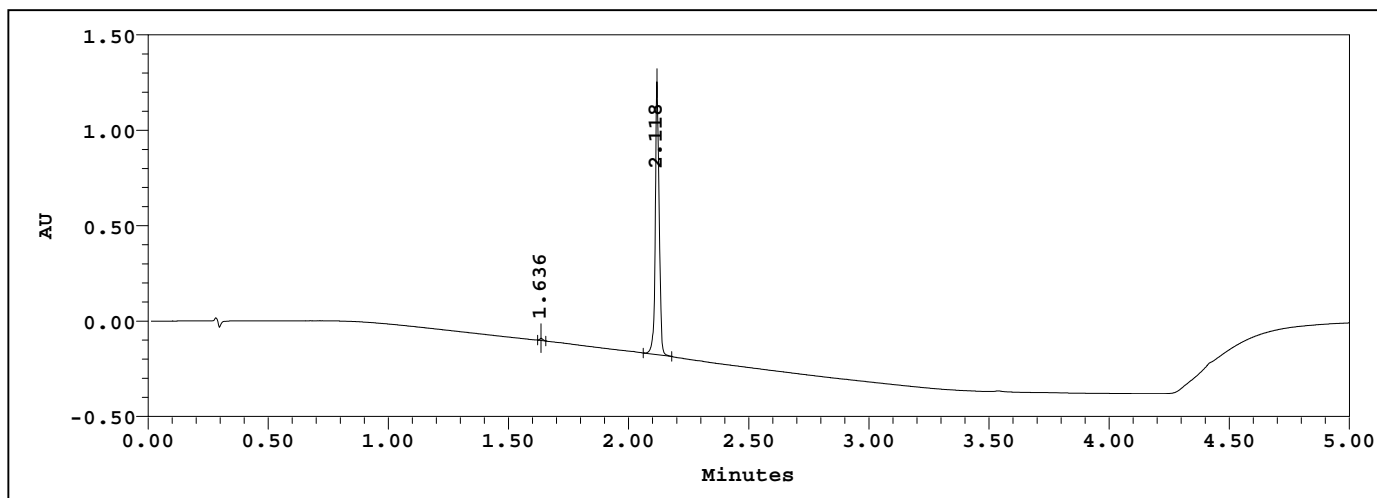


## === SynZeal HPLC Report ===

Sample Name : SRL-1012-132 Program : Gradient  
Sample ID : Azelastine Column Temp : 40 °C  
Column Name : Acquity UPLC BEH Vial : 2:A,8  
Column ID : SRL/C18/2022/219 Injection Volume : 0.20 ul  
Column Desc. : 50 mm \* 2.1 mm; 1.7µ Sample Conc. : 500 ppm  
Diluent : ACN:H2O (8:2) Flow Rate : 0.5 mL/min  
Mobile Phase\_A : 0.1 % TFA in water  
Mobile Phase\_B : ACN:H2O (90:10)  
Method Name : SZ\_UPLC\_RA\_AKIRA\_01  
Gradient :  
=> T(min)/%B 0.01-2.5/10-100 -> 2.5-3.5/100 -> 3.5-3.6/100-10 -> 3.6-5.0/10  
Sample Set Name : 2022\_11\_30\_UPLC\_02  
Date Acquired : 30-11-2022 14:37:42 IST  
Date Processed : 01-12-2022 11:31:12 IST  
Acquired By : Preeti\_Pal

## Chromatogram

SRL-1012-132



Channel Name 210.0nm

## Results

	Retention Time (min)	Area (µV*sec)	Height (µV)	% Area
1	1.636	9796	11522	0.61
2	2.118	1593991	1434233	99.39
Sum				100.0