

CERTIFICATE OF ANALYSIS

(Certificate No. SZ-A043024-1043)

Analysis Date: 03/12/2022

Re-test Date: 02/12/2024

N-Nitroso Desmethyl Azelastine

Identification

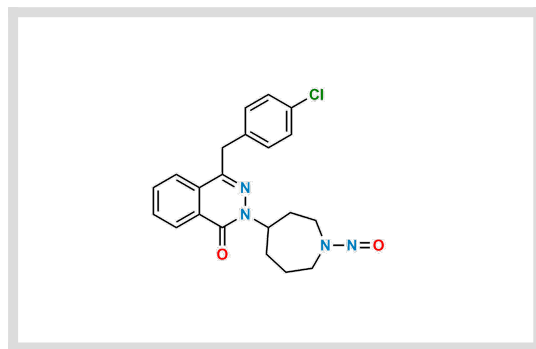
Chemical Name : 4-(4-Chlorobenzyl)-2-(1-nitrosoazepan-4-yl)phthalazin-1(2H)-one

CAT No. : SZ-A043024

CAS No. : NA

Molecular Formula : C₂₁H₂₁ClN₄O₂

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

¹H NMR : Confirm

Weight Loss By TGA : 0.31 %

¹³C 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, ¹H NMR, IR, TGA, ¹³C NMR, DEPT, ROI, CHNS

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

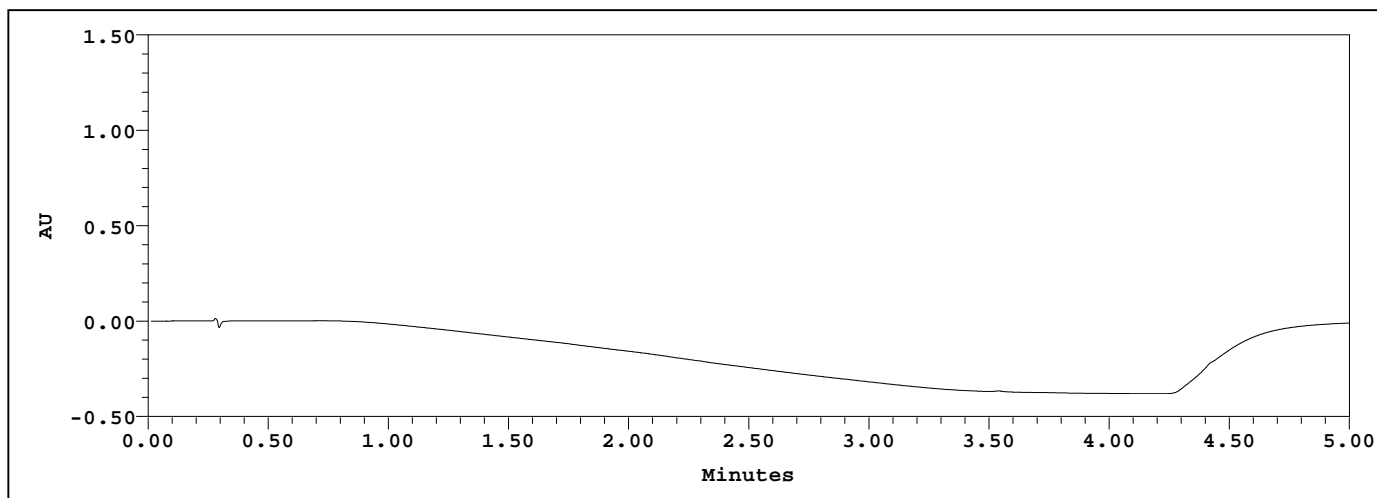


=== SynZeal HPLC Report ===

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 | | | | |

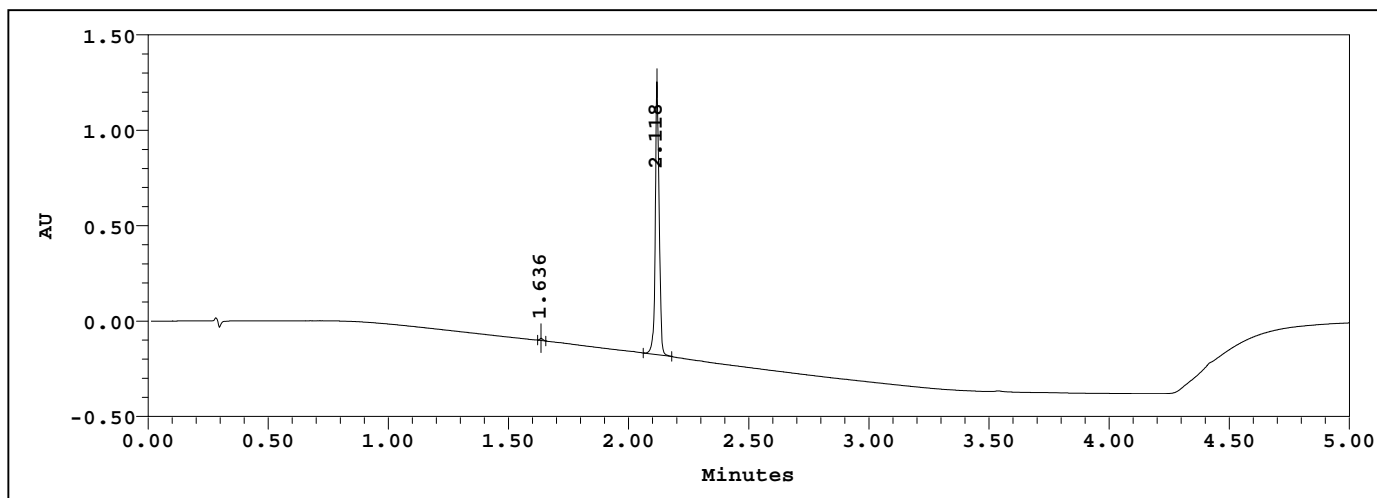


=== SynZeal HPLC Report ===

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 |