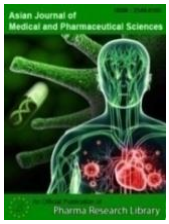

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QBD Driven Analytical Method Development and Validation for Ganaxolone in Bulk and Pharmaceutical Dosage Form by RP-HPLC

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A B S T R A C T

A robust and reliable Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the estimation of Ganaxolone in bulk and pharmaceutical dosage forms in accordance with ICH Q2(R1) guidelines. Method optimization was carried out using a Box–Behnken design to evaluate the influence of flow rate, mobile phase ratio, and buffer pH on key responses such as tailing factor and retention time. The optimized chromatographic conditions included a SPURSIL C18-EP column (3.0×150mm, 3µm), a mobile phase of 40% formic acid and 60% acetonitrile, a flow rate of 1.0 mL/min, and detection at 220 nm. The developed method yielded sharp, symmetrical peaks with satisfactory system suitability parameters. Validation results confirmed excellent performance with assay (100.6%), linearity (10–50 µg/mL, R^2 = 0.9998), precision (%RSD<1), accuracy (mean recovery ~100.2%), LOD (0.03 ppm), and LOQ (0.11 ppm). Robustness studies demonstrated the stability of the method under small deliberate variations in chromatographic conditions. The results establish that the proposed RP-HPLC method is simple, precise, accurate, sensitive, and reproducible, making it highly suitable for routine quality control of Ganaxolone in bulk and dosage forms. Its reliability, cost-effectiveness, and compliance with regulatory requirements further support its applicability in stability studies, batch release testing, and industrial pharmaceutical analysis.

Keywords: Ganaxolone, RP-HPLC, Method Development, Validation, ICH Q2(R1), Box–Behnken Design, Accuracy, Precision, Linearity, LOD, LOQ, Robustness, Stability-indicating Method, Quality Control, Pharmaceutical Analysis.

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C O N T E N T S

1. Introduction

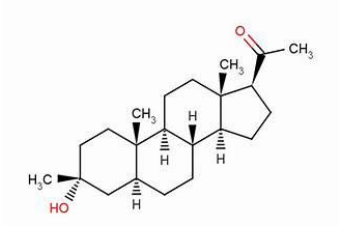

Fig.1: Ganaxolone

Table 1: Drug profile

Property	**Value**
Molecular Formula	C22H36O2
Molecular Weight	332.528 g/mol
IUPAC Name	1[(3R,5S,8R,9S,10S,13S,14S,17S)-3-Hydroxy-3,10,13-trimethyl-1,2,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydrocyclopenta[a]phenanth

	ren-17-yl]ethanone
Chem Spider ID	5293511
Density	1.15 g/cm³
Boiling Point	Approximately 504°C (at 760 mmHg)
Vapour Pressure	Very low, < 0.000001 mmHg at 25°C
Flash Point	220°C
Refractive Index	1.590 (at 20°C)
Polar Surface Area	37.92 Å²
LogP (Octanol /Water)	4.35
Generic Name	Ganaxolone
Brand Names	Ztalmy
Drug Category	Neuroactive Steroid, Anticonvulsant
Indications	Seizures associated with CDKL5 deficiency disorder (CDD)
Pharmacology	GABA-A receptor positive allosteric modulator
Potency	Not specified
Tolerability	Common side effects: drowsiness, fever, excessive saliva or drooling, seasonal allergy
Contraindications	Liver disease, depression, suicidal thoughts or behavior, alcohol or drug addiction
Adverse Effects	Mood changes, suicidal thoughts, drowsiness, fever, excessive saliva or drooling, seasonal allergy
Availability	Approved in the US and EU

2. Materials and Methods

Table 2: Instruments used

S.N	Instrument	Model
1	HPLC	WATERS, software: Empower, 2695separation module.2487 UV detector.
2	UV/VIS spectrophotometer	LABINDIA UV 3000^{+}
3	pH meter	Adwa – AD 1020
4	Weighing machine	Afcoset ER-200A
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil

Table 3: Chemicals used

S.N	Chemical	Brand
1	Ganaxolone	Supplied by MSN LAB
2	KH_2PO_4	FINAR chemical LTD
3	Water and Methanol for HPLC	Standard solutions Ltd
4	Acetonitrile for HPLC	Standard solutions Ltd
5	HCl, H_2O_2, NaOH	MERCK

Wave length selection:
UV spectrum of 10 µg / ml each drug of Ganaxolonein diluent (mobile phase composition) was recorded by scanning in the range of 200nm to 400nm. From the UV spectrum wavelength selected 260nm. At this wavelength both the drugs show good absorbance.

Optimization of Column:
DIKMA SPURSIL C18-EP (3.0 x 150mm, 3µm) was found to be ideal as it gave good peak shape and resolution at 1.0 ml/min flow.

Optimized chromatographic conditions:
Instrument used : High performance liquid chromatography equipped with Auto Sampler and PDA detector
Temperature : Ambient
Column : Spursil C18-EP(3.0 x 150mm, 3µm)
Mobile phase : 40% Formic acid :60% Acetonitrile
Flow rate : 1ml/min
Wavelength : 220 nm
Injection volume : 20µl
Run time : 10min.

Preparation of buffer and mobile phase:
Preparation of 0.1% Formic acid pH 4.0:
To prepare phosphate buffer solution, by adding 0.1ml of formic acid in 1000ml water. Adjust this solution to pH 4.0 by using sodium hydroxide.

Preparation of mobile phase:
Mix a mixture of above Formic acid buffer 400ml (40%), 600 ml Acetonitrile (60%) and degas in ultrasonic water bath for 5 minutes. Filter through 0.45 µ filter under vacuum filtration.

Diluent Preparation:
Formic acid buffer 40% : Acetonitrile 60%

System Suitability: Tailing factor for the peaks due to Ganaxolone in Standard solution should not be more than 2.0.Theoretical plates for the Ganaxolone peaks in Standard solution should not be less than 2000

Calculation: (For Ganaxolone)

$$\%\ Assay = \frac{AT}{AS} * \frac{WS}{DS} * \frac{DT}{WT} * \frac{Average\ weight}{Label\ Claim} * \frac{P}{100} * 100$$

Where:
AT = average area counts of sample preparation.
AS = average area counts of standard preparation.
WS= Weight of working standard taken in mg.
P= Percentage purity of working standard
LC= Label Claim mg/ml.

System Suitability Results:
Tailing factor Obtained from the standard injection is <2
Theoretical Plates Obtained from the standard injection is >2000.

Validation parameters:

Assay:

Standard Solution Preparation:
Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25ml clean dry volumetric flasks add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of each of the above stock solutions into a two 10ml volumetric flasks and dilute up to the mark with Diluents.

Sample Solution Preparation:
Accurately weigh and transfer equivalent to 25 mg of Ganaxolone equivalent weight of the sample into a two 25 ml clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up

to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of each of the above stock solution into a two 10ml volumetric flasks and dilute up to the mark with Diluents.

Procedure: Inject 10 µL of the standard, sample into the chromatographic system and measure the areas for the Ganaxolone peaks and calculate the % Assay by using the formulae.

Linearity:

Preparation of stock solution:

Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25 ml clean dry volumetric flasks add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Preparation of Level – I (10ppm of Ganaxolone):

0.1ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – II (20ppm of Ganaxolone):

0.2ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – III (30ppm of Ganaxolone):

0.3ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – IV (40ppm of Ganaxolone):

0.4ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – V (50ppm of Ganaxolone):

0.5ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Procedure: Inject each level into the chromatographic system and measure the peak area. Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient.

Precision:

Preparation of stock Solution:

Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Procedure: The standard solution was injected for Six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Intermediate precision/ruggedness:

To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different day within the laboratory.

Preparation of stock solution:

Accurately weigh and transfer 25mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents**.**

Procedure: The standard solution was injected for six times and measured the area for all Six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Accuracy:

For accuracy determination, three different concentrations were prepared separately i.e. 50%, 100% and 150% for the analyte and chromatograms are recorded for the same.

Preparation of Standard stock solution:

Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Preparation Sample solutions:

For preparation of 50% solution (With respect to target Assay concentration): Accurately weigh and transfer 12.5mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

For preparation of 100% solution (With respect to target Assay concentration): Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

For preparation of 150% solution (With respect to target Assay concentration):

Accurately weigh and transfer 37.5 mg of Ganaxolone working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Procedure: Inject the standard solution, Accuracy -50%, Accuracy -100% and Accuracy -150% solutions. Calculate the Amount found and Amount added for Ganaxolone and calculate the individual recovery and mean recovery values.

Limit of detection:

Preparation of Ganaxolone solution:

Preparation of 0.03µg/ml solution: Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25 ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Limit of quantification:

Preparation of Ganaxolone solution:

Preparation of 0.11µg/ml solution: Accurately weigh and transfer 25 mg of Ganaxolone working standard into a 25

ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.3ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 3.5ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Robustness:

As part of the Robustness, deliberate change in the Flow rate, Mobile Phase composition, Temperature Variation was made to evaluate the impact on the method.

- The flow rate was varied at 0.8 ml/min to 1.2 ml/min. Standard solution 30 µg/ml of Ganaxolone prepared and analyzed using the varied flow rates along with method flow rate.
- The Organic composition in the Mobile phase was varied from 54% to 66%

Standard solution 30 µg/ml of Ganaxolone was prepared and analyzed using the varied Mobile phase composition along with the actual mobile phase composition in the method.

3. Results and Discussion

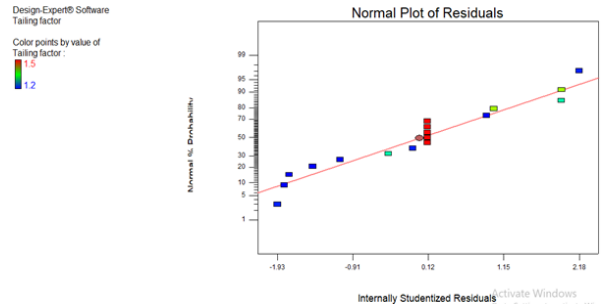

Fig.2: Normal plot of Residuals for Ganaxolone

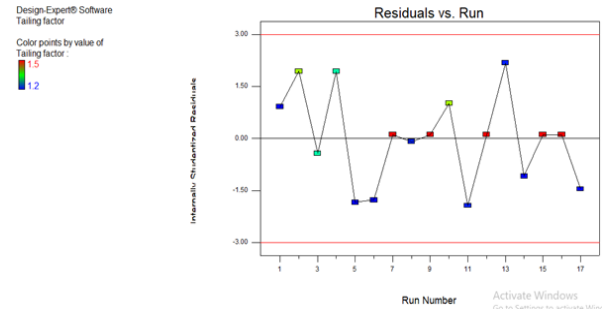

Fig.3: Residuals vs. Run for Ganaxolone

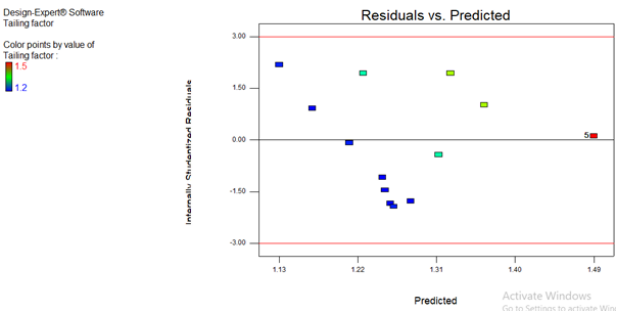

Fig.4: Predicted vs. Actual for Ganaxolone

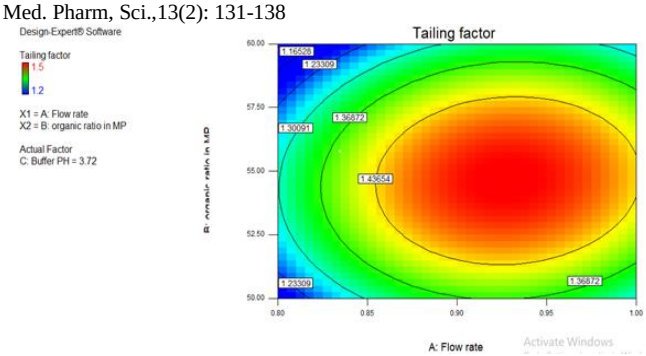

Fig.5: Tailing factor for Ganaxolone

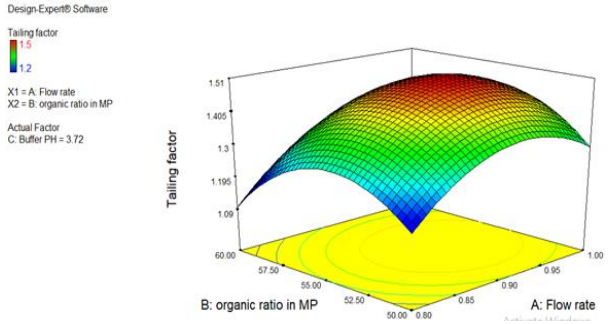

Fig.6: 3D Surface for Ganaxolone

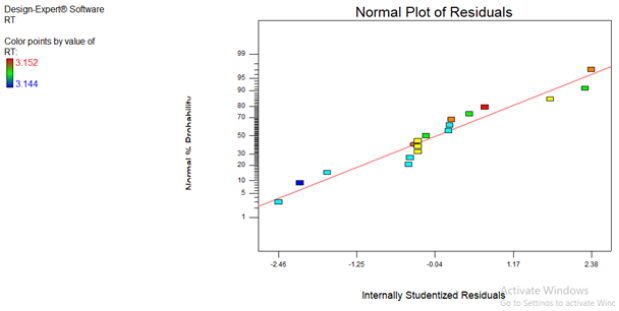

Fig.7: Normal plot of Residuals for Ganaxolone

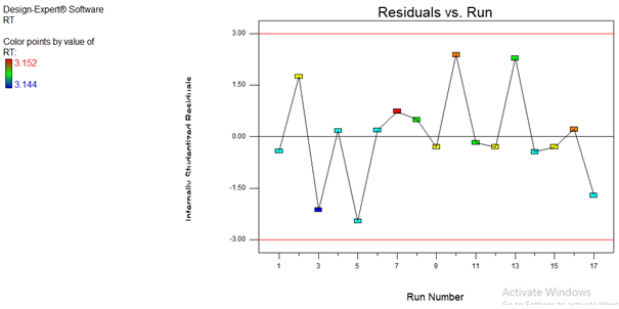

Fig.8: Residual's vs. Run for Ganaxolone

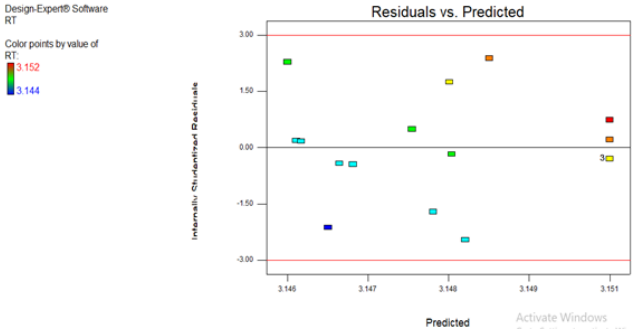

Fig.9: Predicted vs. Actual for Ganaxolone

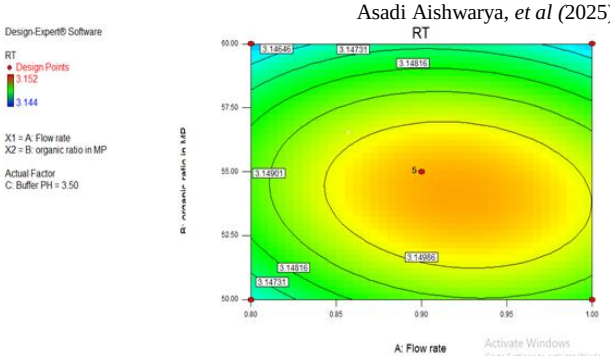

Fig.10: Resolution for Ganaxolone

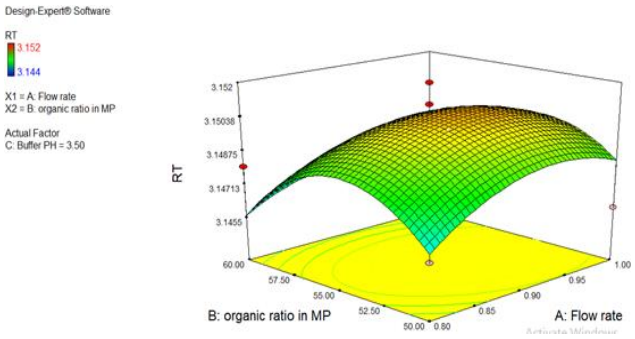

Fig.11: 3D Surface for Ganaxolone

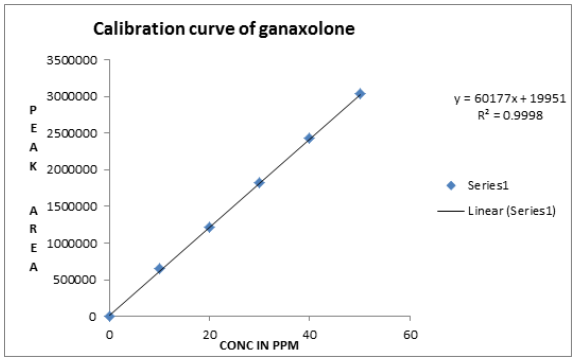

Fig.12: Calibration graph for Ganaxolone

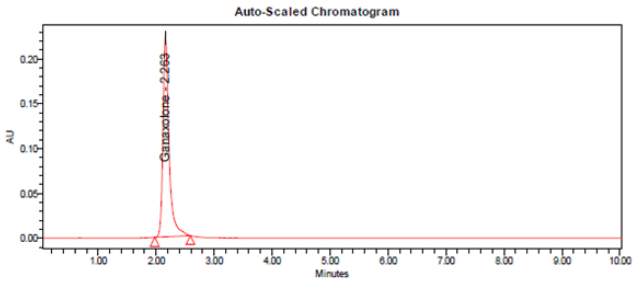

Fig.13: Chromatogram for Precision -6

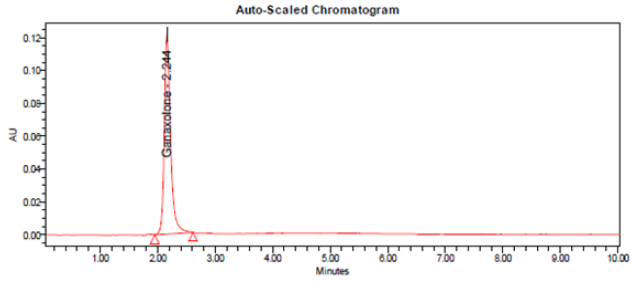

Fig.14: Chromatogram for ID Precision -6

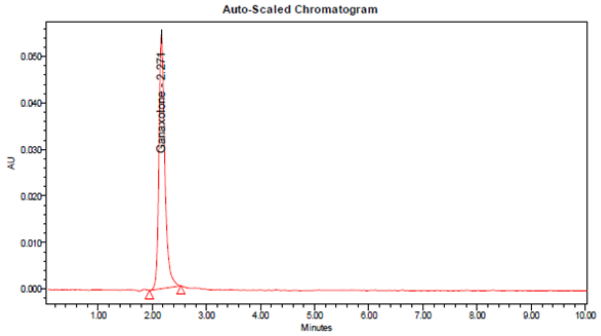

Fig.15: Chromatogram for Accuracy 50%-3

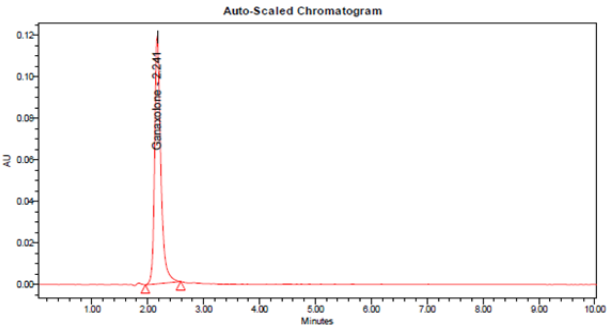

Fig.16: Chromatogram for Accuracy 100%-3

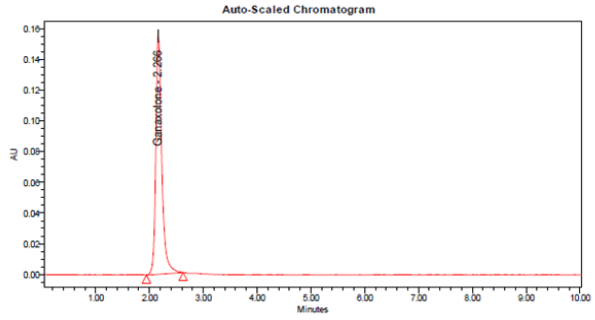

Fig.17: Chromatogram for Accuracy 150%-3

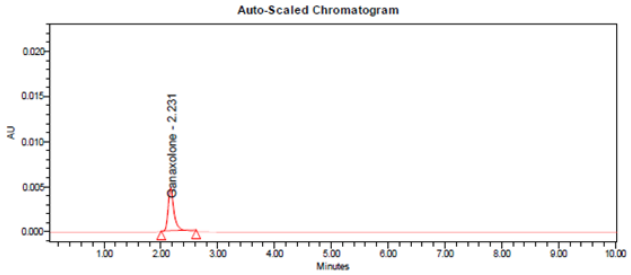

Fig.18: Chromatogram of Ganaxolone showing LOD

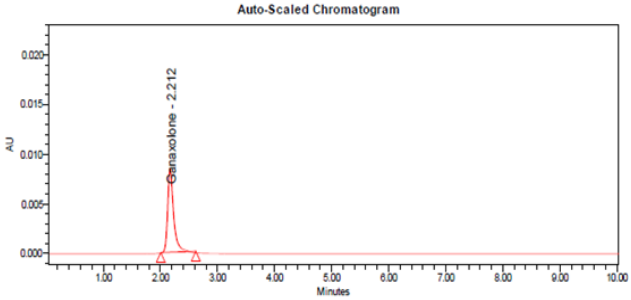

Fig.19: Chromatogram of Ganaxolone showing LOQ

Table 5: Model Table

Study Type	**Response Surface**	**Runs**	**17**
Initial Design	Box-Behnken	Blocks	No Blocks
Design Model	Quadratic		

Table 5: Run Table

STD	**Run**	**blocks**	**Factor 1:A. flow rate**	**Factor 2:B.organic ratio in MP**			
1	1	Block 1	0.80	50.00	3.50	1.2	3.146
6	2	Block 1	1.00	55.00	3.00	1.4	3.15
10	3	Block 1	0.90	60.00	3.00	1.3	3.144
8	4	Block 1	1.00	60.00	4.00	1.3	3.146
2	5	Block 1	1.00	50.00	3.50	1.2	3.146
4	6	Block 1	1.00	60.00	3.50	1.2	3.146
14	7	Block 1	0.90	55.00	3.50	1.5	3.152
9	8	Block 1	0.90	50.00	3.00	1.21	3.148
17	9	Block 1	0.90	55.00	3.50	1.5	3.15
11	10	Block 1	0.90	50.00	4.00	1.4	3.151
5	11	Block 1	0.80	55.00	3.00	1.21	3.148
15	12	Block 1	0.90	55.00	3.50	1.5	3.15
3	13	Block 1	0.80	60.00	3.50	1.21	3.148
12	14	Block 1	0.90	60.00	4.00	1.2	3.146
16	15	Block 1	0.90	55.00	3.50	1.5	3.15
13	16	Block 1	0.90	55.00	3.50	1.5	3.151
7	17	Block 1	0.80	55.00	4.00	1.2	3.146

Table 5: Factors

Factor	**Name**	**Units**	**Type**	**Low Actual**	**High Actual**	**Low Coded**	**High Coded**	**Mean**	**Std. Dev.**
A	Flow rate	ml/min	Numeric	0.80	1.00	-1.000	1.000	0.900	0.069
B	organic ratio in MP	ml	Numeric	50.00	60.00	-1.000	1.000	55.294	3.626
C	Buffer PH		Numeric	3.00	4.00	-1.000	1.000	3.500	0.343

Table 5: Responses

Response	**Name**	**Units**	**Obs**	**Analysis**	**Minimum**	**Maximum**	**Mean**	**Std.Dev**	**Ratio**	**Trans**	**Model**
Y1	Tailing factor		17	Polynomial	1.20	1.50	1.33	0.13	1.25	None	Quadratic
Y2	RT		17	Polynomial	3.14	3.15	3.15	2.298E-003	1.00	None	Quadratic

Table 7: FIT Summary

Source	**Sum of Squares**	**df**	**Square**	**F Value**	**p-value Prob > F**	
Mean vs Total	29.86	1	29.86			Suggested
Linear vs Mean	0.013	3	4.238E-003	0.20	0.8921	
2FI vs Linear	0.024	3	8.088E-003	0.33	0.8052	
Quadratic vs 2FI	0.21	3	0.070	13.04	0.0030	Suggested
Cubic vs Quadratic	0.037	3	0.012	6.366E+007	< 0.0001	Aliased
Residual	0.000	4	0.000			
Total	30.14	17	1.77			

Table 7: ANOVA for Quadratic model

Source	**Sum of Squares**	**df**	**Mean Square**	**F-Value**	**P-value Prob > F**	
Model	0.25	9	0.027	5.12	0.0213	significant
A-Flow rate	0.026	1	0.026	4.85	0.0635	
B-organic ratio in MP	1.061E-004	1	1.061E-004	0.020	0.8919	
C-Buffer PH	3.636E-003	1	3.636E-003	0.68	0.4366	

AB	1.005E-003	1	1.005E-003	0.19	0.6776	
AC	2.466E-003	1	2.466E-003	0.46	0.5187	
BC	0.013	1	0.013	2.39	0.1661	
A^2	0.061	1	0.061	11.46	0.0117	
B^2	0.085	1	0.085	15.87	0.0053	
C^2	9.718E-003	1	9.718E-003	1.82	0.2194	
Residual	0.037	7	5.343E-003			
Lack of Fit	0.037	3	0.012			
Pure Error	0.000	4	0.000			
Cor Total	0.28	16				

Table 11: Results of LOD

Drug name	Baseline noise(µV)	Signal obtained(µV)	S/N ratio	Conc. In ppm
Ganaxolone	75	220	2.93	0.03

Table 12: Results of LOQ

Drug name	Baseline noise(µV)	Signal obtained(µV)	S/N ratio	Conc. In ppm
Ganaxolone	75	745	9.93	0.11

4. Conclusion

In this study, a robust RP-HPLC method for the estimation of Ganaxolone was successfully developed and validated as per ICH Q2(R1) guidelines. A Box–Behnken design was employed to optimize critical chromatographic factors such as flow rate, mobile phase ratio, and buffer pH, with responses studied for tailing factor and retention time. The optimized chromatographic conditions SPURSIL C18-EP column (3.0 × 150 mm, 3 µm), mobile phase consisting of 40% formic acid and 60% acetonitrile, flow rate of 1.0 mL/min, and detection wavelength at 220nm produced sharp, symmetrical peaks with excellent system suitability parameters. All critical validation parameters, including assay (100.6%), linearity (10–50 µg/mL, R^2 = 0.9998), precision (%RSD < 1), accuracy (mean recovery ~100.2%), LOD (0.03 ppm), and LOQ (0.11 ppm), were found to be well within the acceptance limits. Robustness testing confirmed the method's reliability under slight variations in flow rate and mobile phase composition. The findings confirm that the developed RP-HPLC method is simple, precise, accurate, and reproducible, making it highly suitable for routine quality control analysis of Ganaxolone in bulk and pharmaceutical dosage forms. Its short run time, high sensitivity, and compliance with regulatory standards ensure applicability in stability testing, batch release, and industrial quality assurance. Overall, the method provides a reliable analytical tool that can be confidently adopted by pharmaceutical laboratories for the consistent evaluation of Ganaxolone formulations

5. References

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