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Original Article

Development And Validation Of Stability Indicating HPLC Method For The Simultaneous Quantification Of Meloxicam And Rizatriptan In Its Pure & Dosage Forms

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ABSTRACT

A simple, precise, and reliable reverse-phase high-performance liquid chromatography (RP-HPLC) method was successfully developed and optimized for the simultaneous estimation of Meloxicam and Rizatriptan in bulk and pharmaceutical dosage forms. Chromatographic separation was achieved using a Spurcil C18 column with a mobile phase of acetonitrile and phosphate buffer (60:40, pH 4.0), resulting in well-resolved peaks with good symmetry and acceptable retention times. System suitability parameters, including theoretical plate count, tailing factor, and resolution, were within prescribed limits, confirming the efficiency of the method. Validation studies demonstrated excellent linearity ($R^2 > 0.999$), high precision (%RSD < 2), and satisfactory accuracy with recovery values close to 100%. Sensitivity was established through low LOD and LOQ values, while robustness studies confirmed the reliability of the method under slight variations in chromatographic conditions. Forced degradation studies under acidic, basic, thermal, oxidative, and photolytic conditions revealed degradation of both drugs, but the method effectively separated degradation products from the main peaks, proving its stability-indicating capability. Overall, the validated RP-HPLC method is accurate, precise, sensitive, robust, and stability-indicating, making it suitable for routine quality control analysis of Meloxicam and Rizatriptan in pharmaceutical formulations.

Keywords: Meloxicam; Rizatriptan; RP-HPLC; Method development; Validation; ICH guidelines; Simultaneous estimation; Stability-indicating method; Quality control.

INTRODUCTION

Pharmaceutical analysis is a critical branch of pharmaceutical sciences that focuses on the identification, quantification, and characterization of drug substances and formulations. It ensures that pharmaceutical products meet the required standards of quality, safety, and efficacy. Analytical methods are essential throughout the drug development process, from raw material testing to finished product evaluation and stability studies. (1–5).Among the various analytical techniques available, High-Performance Liquid Chromatography (HPLC) has emerged as one of the most reliable and widely used methods due to its high sensitivity, specificity, accuracy, and reproducibility. It is particularly useful in the analysis of complex mixtures, impurities, degradation products, and multi-component dosage forms.

MATERIALS AND METHODS:

The experimental work was carried out using various analytical instruments and high quality glassware to ensure accuracy and precision. A waters 2690 HPLC System separation module and empower 2 software was employed for chromatographic analysis. Additional instruments included a Thermoscientific pH Meter, Dwaraka scientific Thermal Oven, Labman scientific india Ultra-Sonicator, Scaletec Electronic Balance.All volumetric flasks,Pippets and Buretts,Beakers used were of Borosil make.The chemicals used in the study were of analytical grade including Meloxicam and Rizatriptan procured from Qualigens,, Phosphate buffer, Acetic acid, Water,

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Acetonitrile for HPLC is provided by Qualigens, Methanol for HPLC from Rankem.

METHOD DEVELOPMET

Preparation of Standard Solution.

Accurately weigh and transfer 25mg of Meloxicam, Rizatriptan 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 0.5ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Optimization of Column:

SpurcilC18 Column, (250×4.6mm, 5µm) was found to be ideal as it gave good peak shape and resolution at 1.0 ml/min flow.

METHOD VALIDATION

preparation of buffer and mobile phase:

preparation of nah2po4 buffer ph 4.0:

To prepare NAH2PO4 Buffer solution, by adding 6.4Grams of Potassium dihydrogen orthophosphate in 1000ml water. Adjust this solution to pH 4.0 by using sodium hydroxide.

Preparation of mobile phase:

Mix a mixture of above ACN 600ml (60%), 400 ml NAH2PO4 (40%) and degas in ultrasonic water bath for 5 minutes. Filter through 0.45 µ filter under vacuum filtration.

Diluent Preparation:

ACN: NAH2PO4 PH 4 (600:400ml) ratio.

METHOD VALIDATION PARAMETERS:

System Suitability:

Procedure:

Inject 20 µL of the standard, sample into the chromatographic system and measure the areas for the Meloxicam and Rizatriptan peaks and calculate the % Assay by using the formulae.

LINEARITY:

Preparation of stock solution:

Preparation of Level – I-0.2ml Meloxicam and 0.1ml Rizatriptan

Preparation of Level – II-0.4ml Meloxicam and 0.2ml Rizatriptan

Preparation of Level – III-0.6ml Meloxicam and 0.3ml Rizatriptan

Preparation of Level – IV-0.8ml Meloxicam and 0.4ml Rizatriptan

Preparation of Level – V-0.10ml Meloxicam and 0.5ml Rizatriptan

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:

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:

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:

preparation of 50-150% Sample solution

Accurately weigh and transfer 10 mg of Meloxicam and 5mg Rizatriptan (50%), 20 mg of Meloxicam and 10 mg Rizatriptan (100%), 30 mg of Meloxicam and 15mg Rizatriptane (150%), working standard into a 20ml 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 0.6ml 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 Meloxicam and Rizatriptan and calculate the individual recovery and mean recovery values.

RESULTS AND DISCUSSION

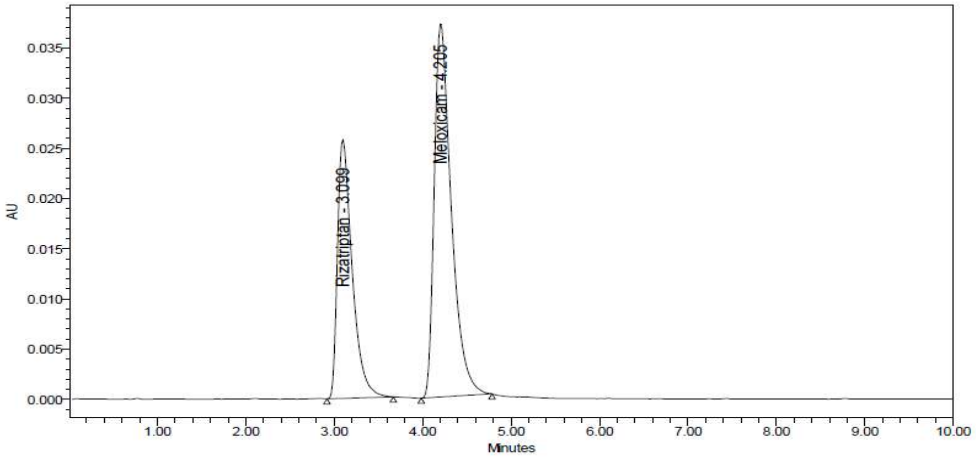

Figure:1 Optimized chromatogram(sample)

SYSTEM SUITABILITY:

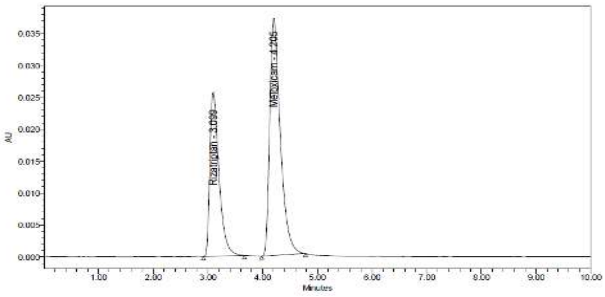

Figure 2: Chromatogram for system suitability

S.No	Name	RT(min)	Area (µV sec)	Height (µV)	Resolution	USP tailing	USP plate count
1	Rizatriptan	3.099	256214	241189	4.23	1.15	5989
2	Meloxicam	4.205	3654786	3834602		1.32	3998

Table 1: Results of system suitability parameters

VALIDATION PARAMETERS:

ASSAY:

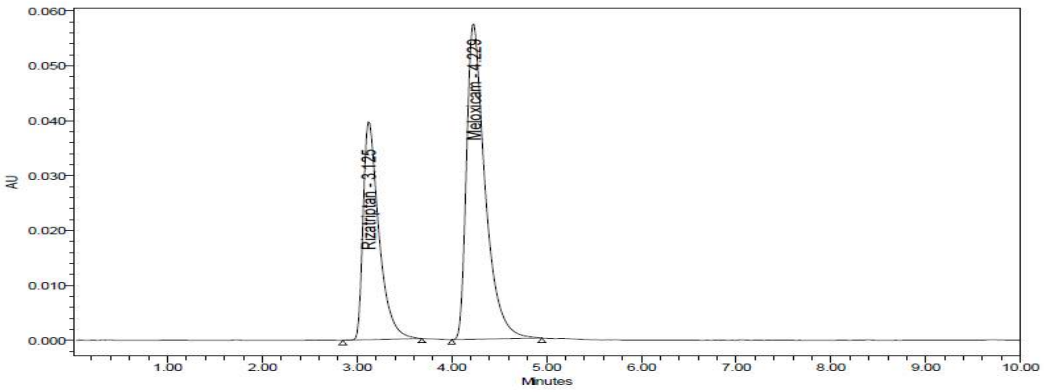

Figure 3: Chromatogram for Standard

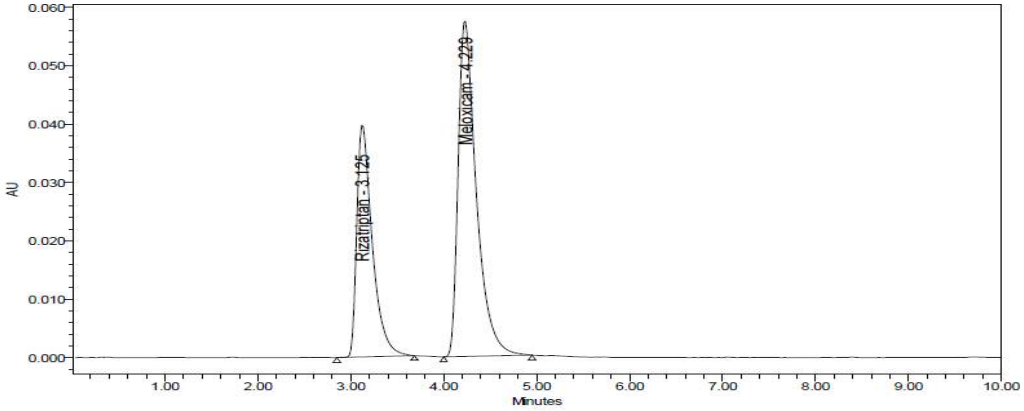

Figure 4: Chromatogram for Sample

Drug Name	Label Claim(mg)	% Assay
Rizatriptan	10mg	99.4%
Meloxican	20mg	99.5%

Table 2: Results of Assay for Rizatriptan and Meloxican

LINEARITY:

S. No	Rizatriptan	
	Concentration (µg/ml)	Area
1	10	85438
2	20	170528
3	30	247841
4	40	341085
5	50	427851

S. No	Meloxican	
	Concentration (µg/ml)	Area
1	20	1282684
2	40	2436854
3	60	3657423
4	80	4873968
5	100	6092543

Table 3: Area of different concentration of Rizatriptan and Meloxican

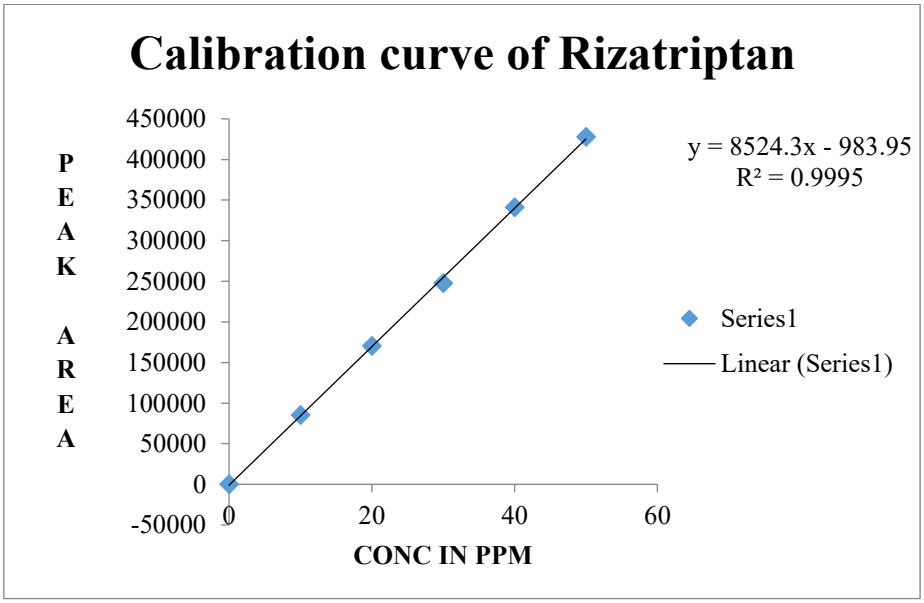

Figure 5: Calibration graph for Rizatriptan

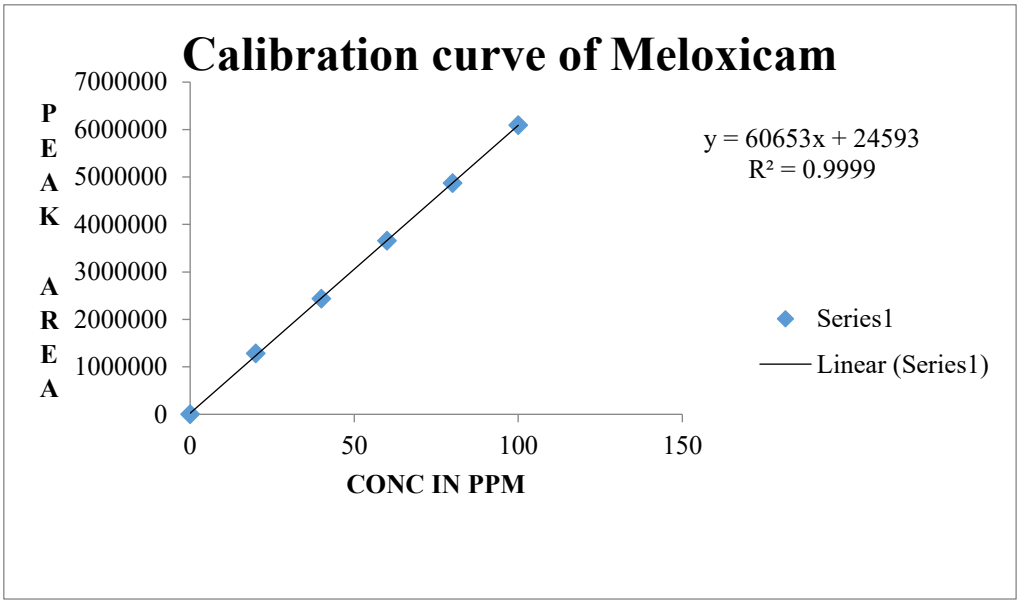

Figure 6: Calibration graph for Meloxican

Parameters	Rizatriptan	Meloxican
Slope (m)	8524.3	60653
Intercept (c)	983.95	24593
Correlation coefficient (R^2)	0.9995	0.9999

Table 4: Analytical performance parameters of Rizatriptan and Meloxican

Acceptance criteria:

- Correlation coefficient (R^2) should not be less than 0.999.
- The correlation coefficient obtained was 0.999 which is in the acceptance limit.

PRECISION:

Injection	Rizatriptan Area	Meloxican Area
Injection-1	2478358	3758753
Injection-2	2461069	3763210
Injection-3	2464136	3787521
Injection-4	2461386	3710258
Injection-5	2466583	3769821
Injection-6	2474139	3730214
Average	2467612	3753296
Standard Deviation	7110.465	28133.75
%RSD	0.3	0.7

Table 5: Results of Precision for Rizatriptan and Meloxican

Acceptance criteria:

- %RSD for sample should be NMT 2.
- The %RSD for the standard solution is below 2, which is within the limits hence method is precise.

INTERMEDIATE PRECISION (ruggedness)

Injection	Rizatriptan Area	Meloxican Area
Injection-1	2464380	3887269
Injection-2	2452096	3832589
Injection-3	2466274	3841296
Injection-4	2459384	3878263
Injection-5	2454296	3850214

Injection-6	2453904	3830269
Average	2458389	3853317
Standard Deviation	5408.713	24041.77
%RSD	0.2	0.6

Table 6: Results of Intermediate precision for Rizatriptan and Meloxican

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2.
- The %RSD obtained is within the limit, hence the method is rugged.

ACCURACY:

Drug Name	%Concentration (at specification Level)	Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
Rizatriptan	50%	125305	5	5.0	100.9	Rizatriptan 100.3
Meloxican	50%	1911423	10	9.99	99.9	
Rizatriptan	100%	247721	10	10.0	99.7	
Meloxican	100%	3804656	20	19.89	99.4	Meloxican 100.1
Rizatriptan	150%	373085	15	15.0	100.2	
Meloxican	150%	5793856	30	30.3	101.0	

Table 7: Accuracy (recovery) data for Rizatriptan and Meloxican.

LIMIT OF DETECTION FOR RIZATRIPTAN AND MELOXICAN

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio	Conc.
Rizatriptan	60	179	2.98	0.02µg/ml
Meloxican	60	173	2.88	0.003µg/ml

Table 8: Results of LOD

Acceptance criteria:

- Signal to noise ratio shall be 3 for LOD solution.
- The result obtained is within the limit.

LIMIT OF QUANTIFICATION FOR MELOXICAN AND RIZATRIPTAN

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio	Conc.
Meloxican	60	587	9.78	0.01µg/ml
Rizatriptan	60	595	9.92	0.07µg/ml

Table 9: Results of LOQ

ROBUSTNESS:

Drug name	Flow Rate (ml/min)	System Suitability Results of Rizatriptan	
		USP Plate Count	USP Tailing
Rizatriptan	0.9	5874	1.01
Meloxican	0.9	3964	1.44
Rizatriptan	1.0	5989	1.21
Meloxican	1.0	3991	1.17
Rizatriptan	1.1	5947	1.18
Meloxican	1.1	3854	1.31

Table 10: Results for variation in flow for Rizatriptan and Meloxican

S. No	Drug name	Change in Organic Composition in the Mobile Phase	System Suitability Results of Rizatriptan Meloxican	
			USP Plate Count	USP Tailing
1	Rizatriptan	10% less(54ml)	5974	1.01
	Meloxican	10% less(54ml)	3897	1.41
2	Rizatriptan	*Actual(60ml)	5874	1.12
	Meloxican	*Actual(60ml)	3947	1.34
3	Rizatriptan	10% more(66ml)	5748	1.21
	Meloxican	10% more(66ml)	3947	1.54

Table 11: Results for variation in mobile phase composition for Rizatriptan and Meloxican

Acceptance criteria:

- The Retention time, USP plate count, USP tailing factor obtained for change of flow rate, variation in mobile phase was found to be within the acceptance criteria. Hence the method is robust.

DEGRADATION STUDIES

Parameters	Rizatriptan		Meloxicam	
	Area	%Degraded	Area	% Degraded
Standard	247853	-----	3818543	-----
Acid	231478	6.61	3457891	9.44
Base	241457	2.58	3741256	2.02
Peroxide	241057	2.74	3700100	3.10
Thermal	228987	7.61	3547891	7.09
Photo	239614	3.32	3714789	2.72

Table 12: Results of Degradation studies

CONCLUSION

The present study successfully developed and optimized a simple, precise, and reliable RP-HPLC method for the simultaneous estimation of Meloxicam and Rizatriptan in bulk and pharmaceutical dosage forms. The optimized chromatographic conditions, employing a Spurcil C18 column with a mobile phase of acetonitrile and phosphate buffer (60:40, pH 4.0), provided well-resolved peaks with good symmetry and acceptable retention times. System suitability parameters such as theoretical plate count, tailing factor, and resolution were found to be within the prescribed limits, indicating the efficiency of the method. The method validation results demonstrated excellent linearity ($R^2 > 0.999$), high precision (%RSD < 2), and satisfactory accuracy with recovery values close to 100%, confirming the reliability of the method for quantitative analysis.

Furthermore, the developed method exhibited good sensitivity with low limits of detection (LOD) and quantification (LOQ), enabling accurate estimation even at trace levels. Robustness studies confirmed that small deliberate variations in chromatographic conditions did not significantly affect the method performance, highlighting its ruggedness for routine use. Forced degradation studies under various stress conditions (acidic, basic, thermal, oxidative, and photolytic) indicated that both drugs undergo degradation to some extent, but the method effectively separated the degradation products from the main peaks, proving its stability-indicating capability. Overall, the developed RP-HPLC method is simple, accurate, precise, robust, and suitable for routine quality control analysis of Meloxicam and Rizatriptan in pharmaceutical formulations.

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