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Research Article

Development and Validation for Simultaneous Estimation of Pioiglitazone and Rosiglitazone in Bulk by RP-HPLC Method

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ABSTRACT

Pioglitazone and Rosiglitazone tablets contain two oral antihyperglycemic drugs used in the management of type 2 diabetes: Pioglitazone and Rosiglitazone hydrochloride. A simple, new, precise, economic, accurate, robust, rugged, specific and sensitive, isocratic RP- HPLC stability indicating method has been developed and subsequently validated for the determination of Pioglitazone and Rosiglitazone in API and pharmaceutical dosage forms as per ICH guidelines. A stability-indicating RP-HPLC method was developed and validated for simultaneous estimation of Pioglitazone and Rosiglitazone. Chromatographic separation was achieved on a Phenomenex Gemini C18 column (250 × 4.6 mm, 5 µm) using Methanol:Phosphate Buffer pH 4.2 (20:80 v/v), flow rate 1.0 mL/min, detection at 246 nm, and run time 7 min. Retention times were approximately 2.47 min (Pioglitazone) and 4.32 min (Rosiglitazone). The method was validated according to ICH guidelines and applied to assay, linearity, precision, accuracy, robustness, ruggedness and forced degradation studies.

INTRODUCTION

Type 2 diabetes mellitus is commonly treated with oral antihyperglycemic agents. Reliable analytical methods are required for quality control and stability assessment of combined dosage forms containing Pioglitazone and Rosiglitazone. Rosiglitazone and Pioglitazone work by helping to restore your body's proper response to the insulin you naturally produce. Pharmaceutical analysis is the branch of chemistry involved in separating, identifying and determining the relative amounts of the components making up a sample of matter. It is mainly involved in the qualitative identification or detection of compounds and quantitative measurements of the substances present in bulk drug and pharmaceutical preparations.

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Drug profile:

Name of the Drug: Pioglitazone

- IUPAC Name: 5-[[4-[2-(5-ethyl pyridin-2-yl) ethoxy] phenyl] methyl]-1, 3-thiazolidine-2, 4- dione
- Molecular Formula: C19H20N2O3S Molecular Weight: 356.439g/mol Pka Value: 5.19
- Log P: 3.17
- Melting Point: 193-1940C
- Structure:

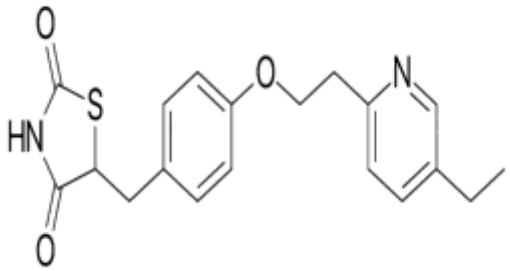

Fig. no.1

Name of the drug : Dulaglutie

- Molecular Weight: 357.436g/mol
- Chemical Formula: C18H19N3 o3S
- IUPAC Name: 3-(diamino methylidene)-1, 1-dimethylguanidine
- Structure:

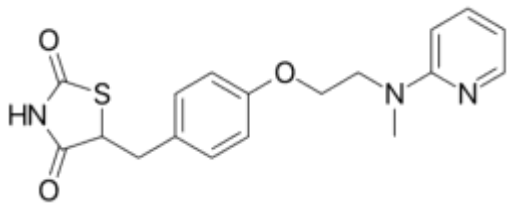

Fig. No.2

MATERIALS AND METHODS:

Column: Phenomenex Gemini C18 (250×4.6 mm, 5 µm). Mobile phase: Methanol : Phosphate Buffer pH 4.2 (20:80 v/v). Flow rate: 1.0 mL/min. Detection wavelength: 246 nm. Injection volume and validation studies were performed according to ICH guidelines.

Method Development

RP-HPLC Method Development and Validation for Pharmaceutical Analysis:

An RP-HPLC method was developed for the simultaneous estimation of Pioglitazone and Rosiglitazone. Various mobile phase compositions comprising methanol, acetonitrile, and water were evaluated during method optimization. Optimum chromatographic separation with satisfactory peak shape and resolution was achieved using a mobile phase consisting of Methanol: Phosphate Buffer (pH 4.2) in the ratio of 20:80 (% v/v).

Different stationary phases including C18, Symmetry, and X-Bridge columns were investigated. The Phenomenex Gemini C18 column (250 mm × 4.6 mm, 5 µm) was selected as the most suitable column due to its superior chromatographic performance.

The optimized chromatographic conditions were: Phenomenex Gemini C18 column (250 mm × 4.6 mm, 5 µm), mobile phase of Methanol: Phosphate Buffer (pH 4.2) (20:80 v/v), flow rate of 1.0 mL/min, detection wavelength of 246 nm, injection volume of 20 µL, column temperature of 32°C, and run time of 7 min. Analysis was performed using a Waters HPLC system equipped with an autosampler and PDA detector.

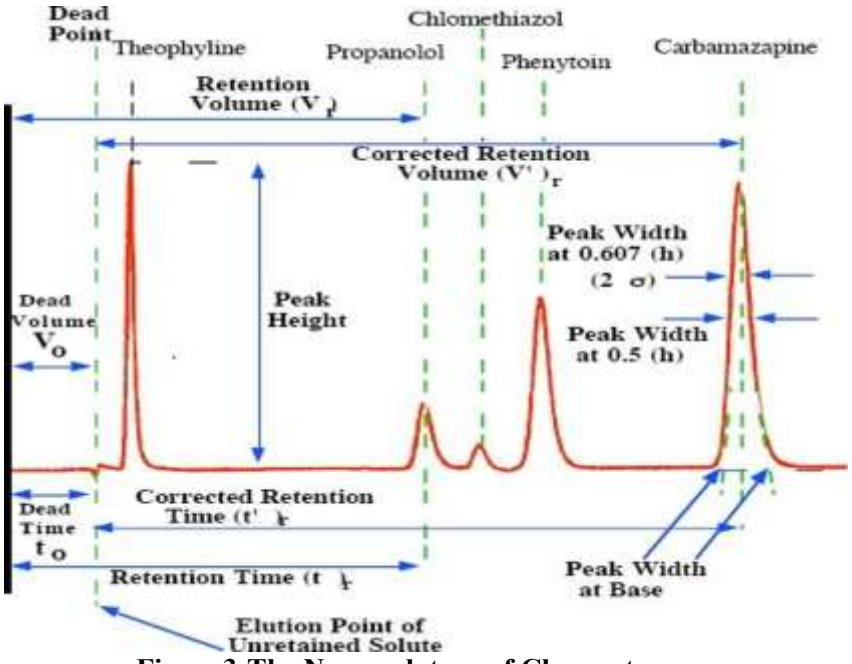

Fig.no.3-The Nomenclature of Chromatogram

Method Validation

The developed method was validated according to ICH guidelines for system suitability, specificity, linearity, and precision.

System Suitability: The standard solution containing Pioglitazone (60 µg/mL) and Rosiglitazone (80 µg/mL) was injected five times. The %RSD of peak areas was found to be within acceptable limits, indicating good system performance.

Specificity: The method demonstrated adequate specificity with no interference from tablet excipients at the retention times of Pioglitazone and Rosiglitazone. Assay analysis confirmed accurate quantification of both analytes in the pharmaceutical formulation.

Linearity: Linearity was evaluated over the concentration ranges of 20–100 µg/mL for Pioglitazone and 40–120 µg/mL for Rosiglitazone. Calibration curves were constructed by plotting peak area against concentration, and excellent linear relationships were obtained with correlation coefficients (r^2) close to 1.000.

Precision: Method precision was assessed by repeatability studies using six replicate injections of the standard solution. The %RSD values for peak areas were within the acceptable limit of less than 2%, demonstrating the precision and reproducibility of the method.

The validated RP-HPLC method was found to be simple, precise, specific, and suitable for routine quality control analysis of Pioglitazone and Rosiglitazone in pharmaceutical dosage forms.

Characterization of Pioglitazone and Rosiglitazone

Solubility Studies

The solubility of Pioglitazone and Rosiglitazone was evaluated in various solvents according to the Indian Pharmacopoeia (I.P., 1996) procedure. Accurately weighed drug samples were subjected to solubility testing using water, methanol, and DMSO under ambient conditions.

Pioglitazone exhibited good solubility in methanol, ethanol, DMF, and DMSO, while it was found to be practically insoluble in water and insoluble in ether. The drug showed slight solubility in acetone and acetonitrile.

Rosiglitazone was found to be freely soluble in water and exhibited slight solubility in alcohol. However, it was practically insoluble in acetone and methylene chloride.

The solubility profile of both drugs indicated that methanol was a suitable solvent for the preparation of standard and sample solutions during method development and validation studies.

UV Spectrophotometric Method :

A simple, accurate, and economical UV spectrophotometric method was developed for the simultaneous estimation of Pioglitazone and Rosiglitazone using methanol as the solvent. Standard stock solutions of both drugs were prepared by dissolving accurately weighed 10 mg of each drug in methanol and suitably diluting to obtain working standard solutions.The absorption spectra of Pioglitazone and Rosiglitazone were recorded in the wavelength range of 200–400 nm. The maximum absorbance (λmax) was observed at 223 nm for Pioglitazone and 264 nm for Rosiglitazone, while the isosbestic point was found at 254 nm.Calibration curves were constructed by measuring absorbance at the selected wavelengths over concentration ranges of 2–80 µg/mL for Pioglitazone and 5–70 µg/mL for Rosiglitazone. Beer–Lambert's law was obeyed within these concentration ranges. The regression equations obtained were:

Pioglitazone

At 223 nm: $y = 0.0303x + 0.0489$ ($R^2 = 0.9997$)

At 264 nm: $y = 0.0185x + 0.0408$ ($R^2 = 0.9998$)

Rosiglitazone

At 223 nm: $y = 0.0213x + 0.0242$ ($R^2 = 0.9997$)

At 264 nm: $y = 0.0307x + 0.0055$ ($R^2 = 0.9996$)

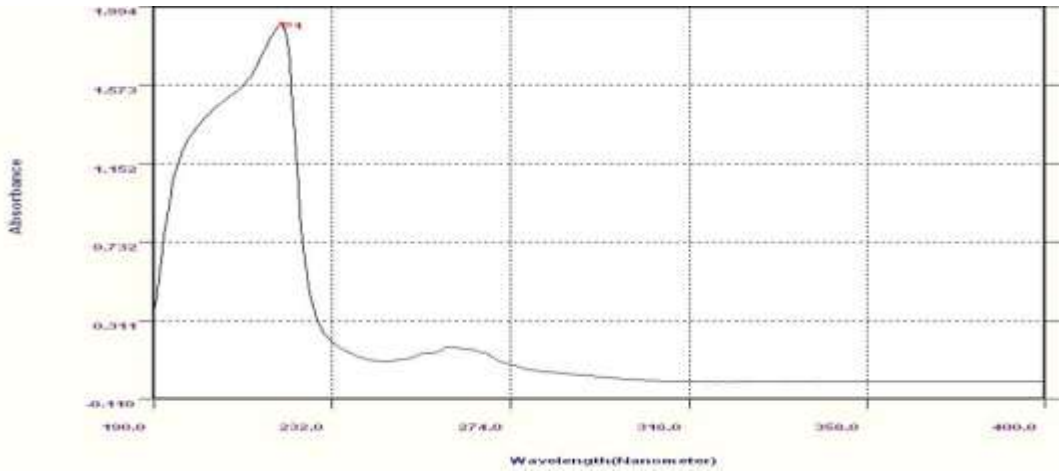

Fig.no.4 UV spectrum for Pioiglitazone

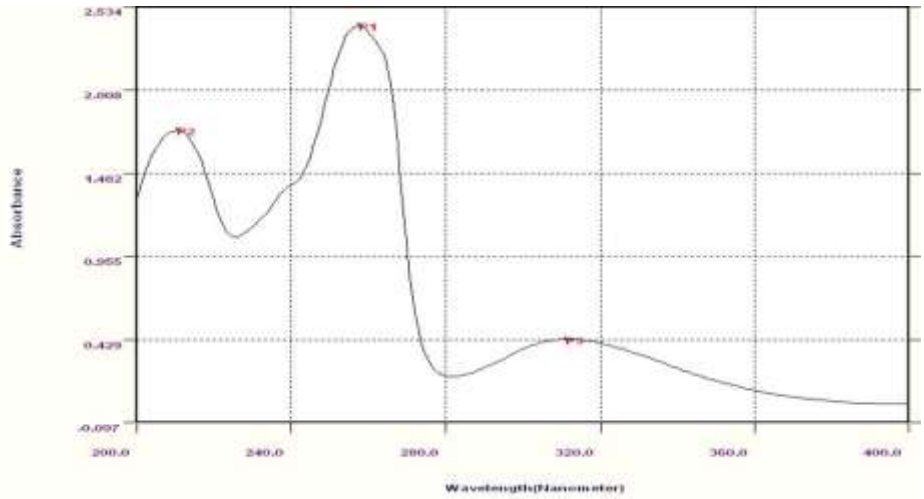

Fig.no.5:- UV Spectrum for Rosiglitazone (264nm)

Method Validation

The developed method was validated according to ICH guidelines with respect to linearity, accuracy, precision, sensitivity, and assay.

Linearity

Excellent linearity was observed over the concentration ranges of 2–80 µg/mL for Pioglitazone and 5–70 µg/mL for Rosiglitazone, with correlation coefficients greater than 0.999, indicating a strong linear relationship between concentration and absorbance.

Accuracy

Accuracy was evaluated using the recovery method at three concentration levels. The mean percentage recoveries were 99.38% for Pioglitazone and 99.78% for Rosiglitazone, with %RSD values below 1%, demonstrating the accuracy of the method.

Precision

Repeatability studies were performed at the target concentration level (n = 6). The %RSD values obtained were 0.437% for Pioglitazone and 0.096% for Rosiglitazone, confirming the excellent precision of the developed method.

Limit of Detection and Limit of Quantification

The sensitivity of the method was evaluated using LOD and LOQ values. The LOD values were found to be 0.3265 µg/mL for Pioglitazone and 0.9256 µg/mL for Rosiglitazone, while the LOQ values were 0.4265 µg/mL and 1.2154 µg/mL, respectively, indicating good sensitivity.

Assay of Pharmaceutical Formulation

The validated method was successfully applied to the analysis of tablet dosage forms. The assay results showed drug contents of 14.856 mg/tablet for Pioglitazone and 499.785 mg/tablet for Rosiglitazone, confirming the applicability of the method for routine quality control analysis.

Conclusion

The proposed UV spectrophotometric method was found to be simple, rapid, precise, accurate, and sensitive for the simultaneous estimation of Pioglitazone and Rosiglitazone in bulk drugs and pharmaceutical dosage forms. The method complies with ICH validation requirements and is suitable for routine analytical applications.

RESULT AND DISCUSSION:

TRAILS FOR METHOD DEVELOPMENT

Trail 1:

Mobile phase : Methanol: Water (80:20%v/v)

Column : X-Bridge (4.6 ×150mm, 5µm particle size)

Waters Flow rate : 1.0ml/min

Wavelength :246nm

Column temp : 32ºC

Injection Volume : 20µl

Run time : 5 minutes

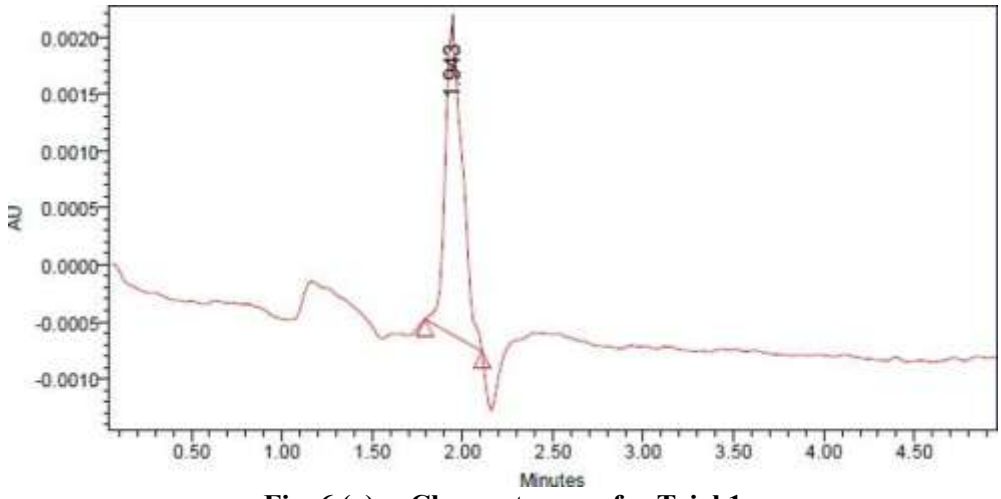

Fig. 6 (a) :- Chromatogram for Trial 1

Table 1 (a) :- Peak Results for Trail 1

S.No.	Peak Name	R_t	Area	Height	USP Resolution	USP Tailing	USP Plate count
1	Pioglitazone	1.834	569852	79346		1.61	2365
2	Rosiglitasone	3.564	647686	362789	1.18	1.12	3163

Observation: This trial shows improper separation of sample peaks and less plate count, improper baseline in the chromatogram. So more trials were required for obtaining good peaks.

Trail 2:

Mobile phase : Methanol: Acetonitrile (40:60 v/v)

Column : Hypersil C18 (4.6mm×250mm) 5µ Particle Size

Flow rate : 0.9 ml/min

Wavelength : 246nm

Ambient Injection Volume : 10µl

Run time : 10 minutes

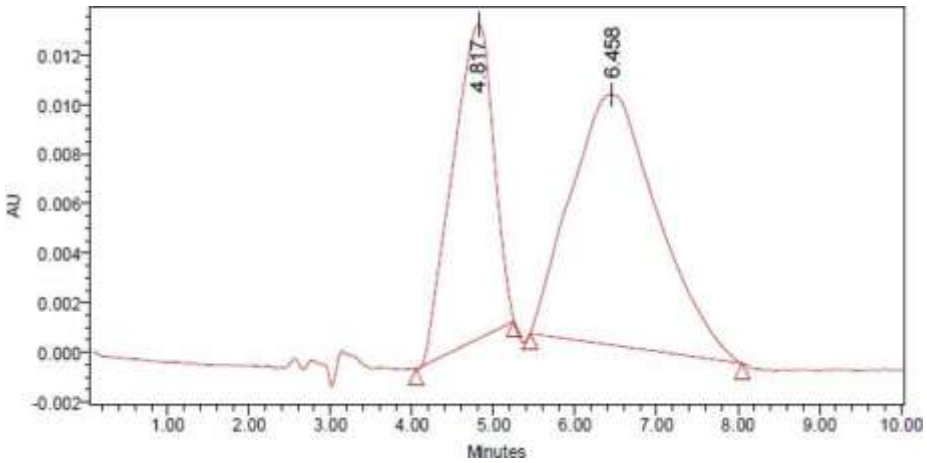

Fig. 6 (b) :- Chromatogram for Trail 2

Table2(b) :- Peak Results for Trail 2

S. No.	Peak name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Pioglitazone	4.156	8569885	685985		1.21	3021
2	Rosiglitazone	5.235	98569985	669584	1.23	1.16	3213

Observation: From the above chromatogram it was observed that the baseline is improper and sample peaks are not well separated. So it requires more trials to obtain well peaks.

Trail 3:

Mobile phase : Methanol: Water (60:40 % v/v)

Column : Symmetry C18 (4.6 × 250mm 5µm)

Flow rate : 0.9 ml/min

Wavelength : 255 nm

Column temp : 30ºC

Injection Volume : 15µl

Run time : 6 minutes

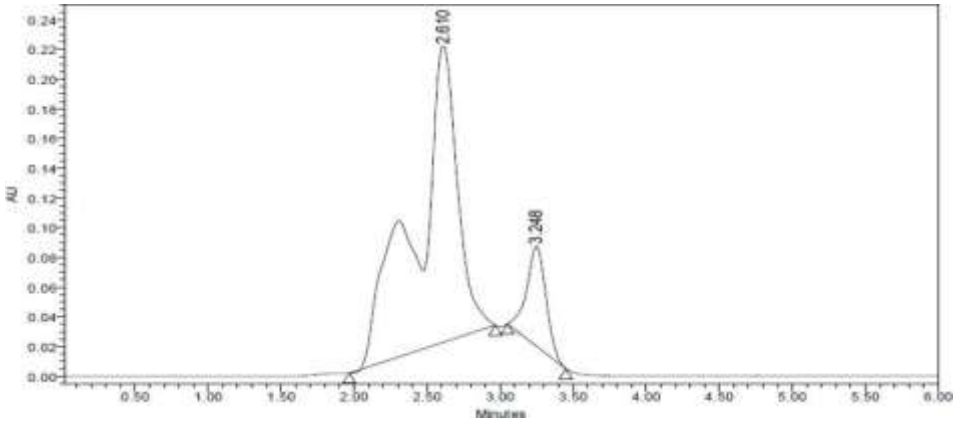

Fig. 6 © :- Chromatogram for Trail 3

Table 1© :- Peak Results for Trail 3

S. No	Peak Name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Pioglitazone	2.610	2865985	365845		1.07	3021
2	Rosiglitazone	3.248	548556	4256	0.59	1.34	2947

Observation: This trial show very less plate count and sample peaks are not well separated, so more trials were required for obtaining good peaks.

Trail 4:

Mobile phase : Acetonitrile: Acetate Buffer (30:70 % v/v)

Column : Symmetry C18 (4.6mm×150mm, 5µm)

Flow rate : 1.0 ml/min

Wavelength : 246 nm

Column temp : 34ºC

Injection Volume : 10µl

Run time : 10 minutes

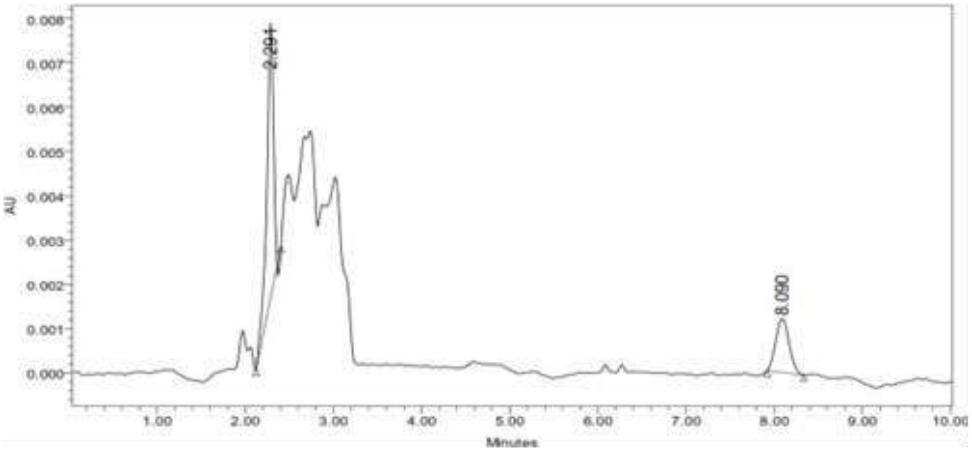

Fig.6 (d) :- Chromatogram for Trail 4

Table 1 (d) :- Peak Results for Trail 4

S. No	Peak Name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Pioglitazone	2.291	565842	468548		0.98	4652
2	Rosiglitazone	8.090	8598	3658	3.86	1.29	3854

Observation: This trial show very narrow peak and also retention time was more, so more trials were required for obtaining good peaks.

Trail 5:

Mobile phase : Methanol: Phosphate Buffer pH-3.6 (45:55v/v)

Column : Phenomenex Gemini (250mmx4.6mm) 5µm Particle size

Column Flow rate : 0.9 ml/min

Wavelength : 246 nm

Column temp : 38ºC

Injection Volume : 15µl

Run time : 10 minutes

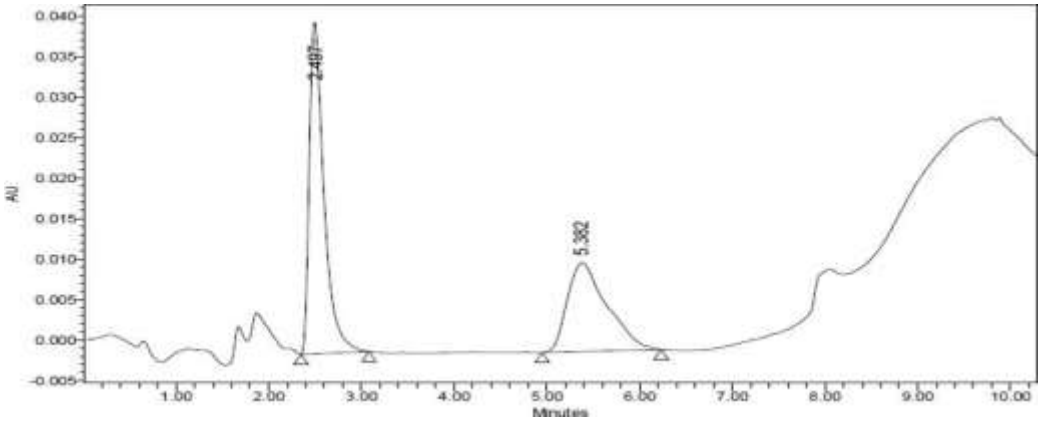

Fig. 6(e):- Chromatogram for Trail 5

Table 1 E :- Peak Results for Trail 5

S. No	Peak Name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Pioglitazone	2.497	7585486	865987		1.21	5869
2	Rosiglitazone	5.382	653264	35628	4.65	1.19	8547

Observation: Stabilization was not good and more tailing peaks were observed, theoretical plates were less and tailing was more than limit.

Optimized Chromatogram (Sample)

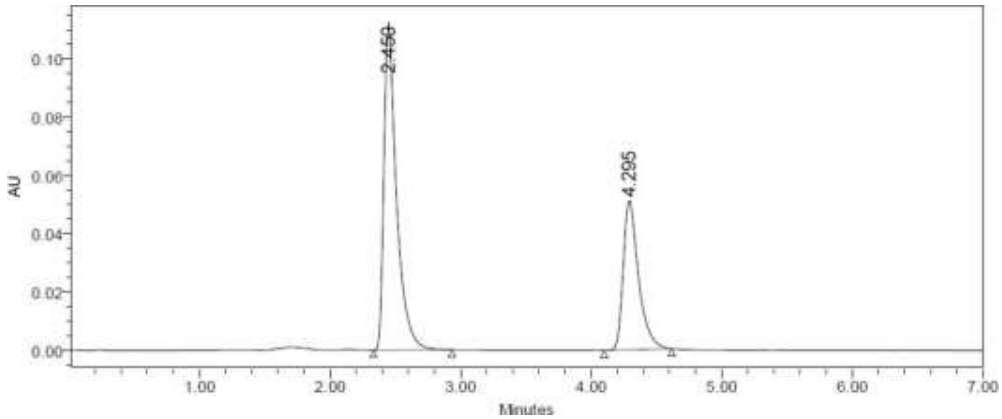

Fig. 7:- Optimized Chromatogram (Sample)

Table 2:- Optimized Chromatogram (Sample)

S. No.	Peak Name	R_t	Area	Height	USP Resolution	USP Tailing	USP plate count
1	Pioglitazone	2.450	8758646	136584		1.35	6428
2	Rosiglitazone	4.295	548562	47565	5.29	1.29	8569

Acceptance Criteria:

- Resolution between two drugs must be not less than 2.
- Theoretical plates must be not less than 2000.
- Tailing factor must be not less than 0.9 and not more than 2.
- It was found from above data that all the system suitability parameters for developed method were within the limit.

Optimized chromatographic conditions produced well resolved peaks with retention times near 2.466 min and 4.323 min for Pioglitazone and Rosiglitazone, respectively. Validation studies demonstrated acceptable system suitability, precision, accuracy, linearity, robustness, ruggedness and specificity. Forced degradation studies under acidic, basic, oxidative, thermal, photolytic and neutral conditions confirmed the stability-indicating nature of the method. RP-HPLC Method Development and Validation for Simultaneous Estimation of Pioglitazone and Rosiglitazone

Method Development

Several chromatographic conditions were investigated to achieve satisfactory separation of Pioglitazone and Rosiglitazone. Different mobile phase compositions, columns, flow rates, and chromatographic parameters were evaluated. Initial trials using methanol-water, methanol-acetonitrile, and acetonitrile-buffer systems resulted in inadequate peak separation, poor baseline resolution, low theoretical plate counts, and peak tailing.

An optimized chromatographic condition was achieved using a Phenomenex Gemini C18 column (250 mm × 4.6 mm, 5 µm particle size) with a mobile phase consisting of Methanol: Phosphate Buffer (pH 4.2) in the ratio of 20:80 (%v/v). The flow rate was maintained at 1.0 mL/min, the column temperature at 32°C, and detection was carried out at 246 nm with an injection volume of 20 µL.Under the optimized conditions, Pioglitazone and Rosiglitazone were eluted at retention times of 2.466 min and 4.323 min, respectively. The chromatographic peaks were well resolved with a resolution value of 5.28. The tailing factors were 1.34 and 1.28, while theoretical plate counts were 6358 and 8476 for Pioglitazone and Rosiglitazone, respectively, indicating excellent chromatographic performance.

Method Validation

System Suitability

System suitability studies were performed by injecting standard solutions five times. The %RSD of peak areas was found to be 0.042% for Pioglitazone and 0.17% for Rosiglitazone, demonstrating adequate system performance. All chromatographic parameters met the predefined

acceptance criteria, including resolution (>2), theoretical plate count (>2000), and tailing factor (<2).

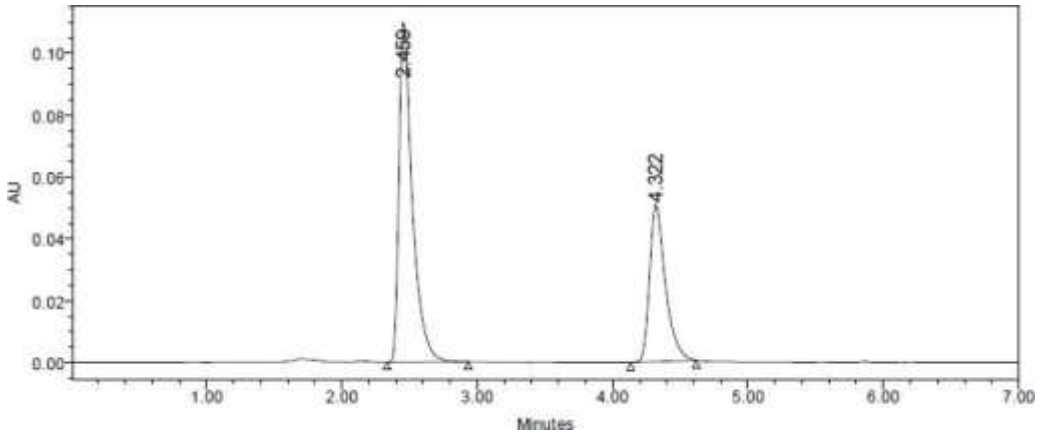

Fig. 8 (a) :- Chromatogram showing injection – 1

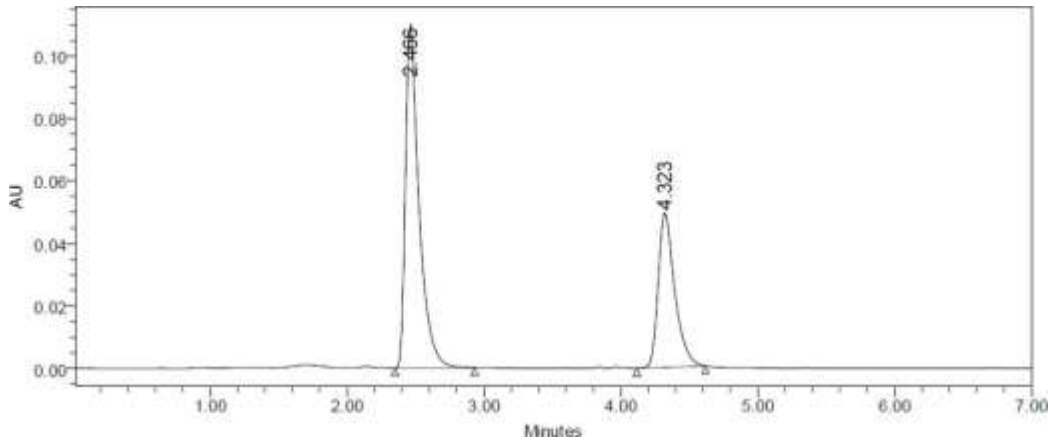

Fig. 8 (b) :- Chromatogram showing injection – 2

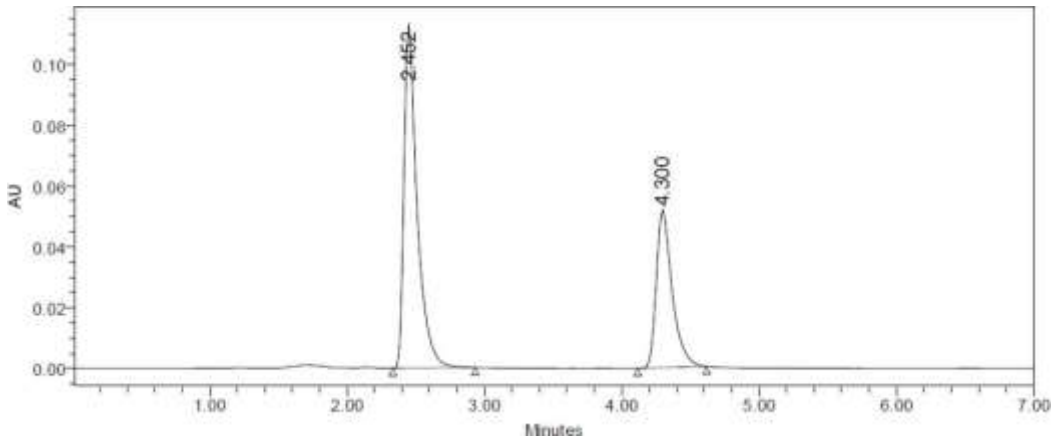

Fig. 8© :- Chromatogram showing injection – 3

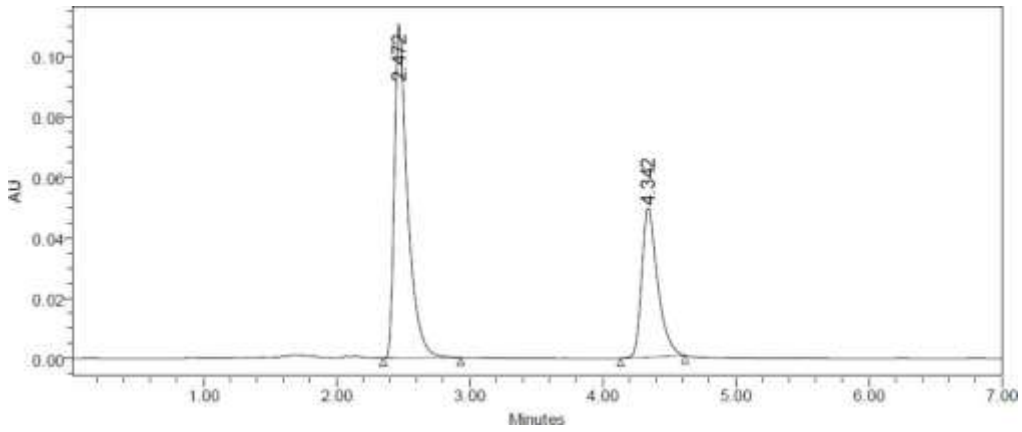

Fig. 8 (d) :- Chromatogram showing injection – 4

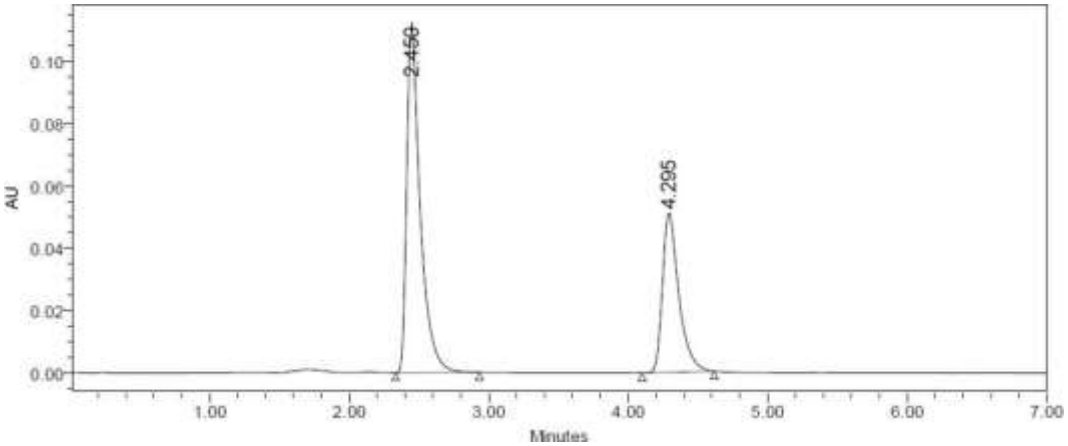

Fig. 8 E:- Chromatogram showing injection – 5

Specificity

The method exhibited excellent specificity, as no interference from excipients, mobile phase components, or other matrix constituents was observed at the retention times of the analytes. Well-resolved and symmetrical peaks were obtained for both drugs in standard and sample chromatograms.

Table no. 3

S.No.	Name	Rt	Area	Height	USP Resolution	USP Tailing	USP plate count	Injection
1	Pioglitazone	2.465	8756895	126585		1.35	6358	1
2	Rosiglitazone	4.337		46859	5.30	1.28	8566	1
3	Pioglitazone	2.474	8754258	126985		1.34	6397	2
4	Rosiglitazone	4.356		46258	5.31	1.29	8534	2
5	Pioglitazone	2.465	8725642	126859		1.35	6324	3
6	Rosiglitazone	4.337		46256	5.30	1.28	8695	3

Conclusion :The % purity of Pioglitazone and Rosiglitazone in pharmaceutical dosage form was found to be 99.98%.

Linearity

Linearity was established over the concentration range of 20–100 µg/mL for Pioglitazone and 40–120 µg/mL for Rosiglitazone. Calibration plots of peak area versus concentration showed excellent linearity with correlation coefficients (r^2) of 0.999 for both analytes.

Regression equations obtained were:

Pioglitazone: $y = 137797x + 160071$ ($r^2 = 0.999$)

Rosiglitazone: $y = 6966.9x + 13995$ ($r^2 = 0.999$)

Table no.4 Chromatographic data for linearity study

Concentration µg/ml	Average Peak Area
20	2869587
40	5685225
60	8459858
80	11265886
100	13858985

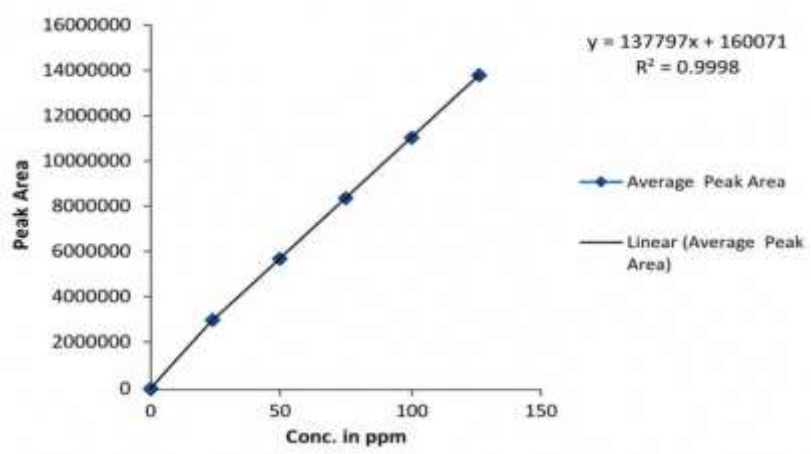

Fig. No.9 Calibration graph for pioglitazone

Conclusion: Correlation Coefficient ® is 0.99, and the intercept is 160071. These values meet the validation criteria.

Rosiglitasone:

Table no.5 Chromatographic data for linearity study

Concentration µg/ml	Average Peak Area
40	265867
60	405698
80	536985
100	685685
120	822568

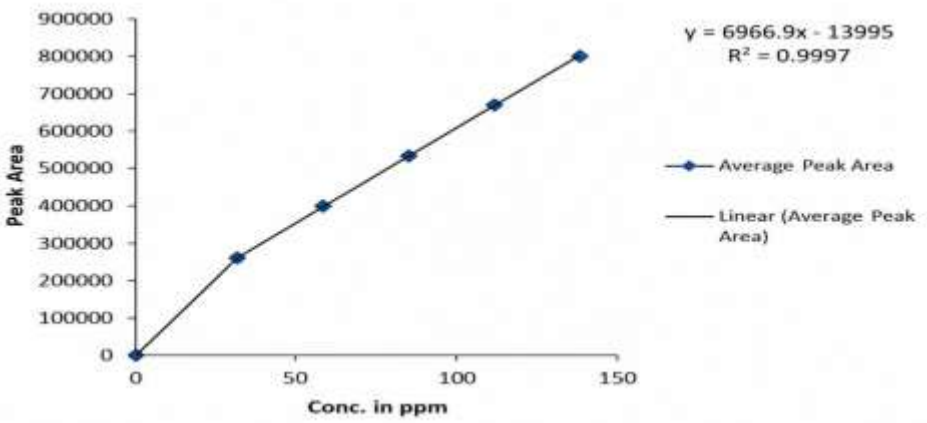

Fig no.10 Calibration graph for Rosiglitazone

Conclusion: Correlation Coefficient is 0.99, and the intercept is 13995. These values meet the validation criteria.

Precision:

Repeatability studies demonstrated excellent precision with %RSD values of 0.035% for Pioglitazone and 0.350% for Rosiglitazone. Intermediate precision studies conducted on two different days also showed %RSD values below 2%, confirming the reproducibility and ruggedness of the method.

Table no.6 Results of Method Precision for Pioglitazone :

S.No.	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Pioglitazone	2.453	8658785	125698	6359	1.36
2	Pioglitazone	2.455	8652474	126985	6485	1.35
3	Pioglitazone	2.453	8659865	126587	6459	1.36
4	Pioglitazone	2.452	8659328	125498	6359	1.35
5	Pioglitazone	2.450	8657487	126525	6375	1.36
Mean			8657588			
Std. Dev			2992.003			
% RSD			0.034559			

Table no.7 Results of Method Precision for Rosiglitazone

S.No.	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Rosiglitazone	4.289	536985	46985	1.29	8548	5.38
2	Rosiglitazone	4.309	534887	46536	1.28	8498	5.39
3	Rosiglitazone	4.306	536588	46365	1.29	8426	5.38
4	Rosiglitazone	4.300	532642	46359	1.28	8425	5.36
5	Rosiglitazone	4.295	536985	46825	1.29	8457	5.38
Mean			535617.4				
Std. Dev			1875.447				
% RSD			0.350147				

Accuracy

Accuracy was evaluated by recovery studies at 50%, 100%, and 150% concentration levels. The mean percentage recoveries were found to be 100.20% for Pioglitazone and 100.25% for Rosiglitazone. These results indicate that the method is accurate and free from interference by formulation excipients.

Table no 8 :- The accuracy results for Pioglitazone

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	493113.3	30	30.004	100.013%	100.20%
100%	912300.3	60	60.175	100.291%	
150%	1330473	90	90.272	100.302%	

Table no 9 :- The accuracy results for Rosiglitazone

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	281726	40	40.298	100.745%	100.25%
100%	554209.7	80	79.978	99.972%	
150%	829292	120	120.036	100.030%	

Limit of Detection:

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

$$LOD = 3.3 \times \sigma / s$$

Where

Σ = Standard deviation of the response, S = Slope of the calibration curve

Result:

Pioglitazone: 0.98µg/ml

Rosiglitazone: 1.27µg/ml

Limit of quantification:

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined.

$$LOQ = 10 \times \sigma / S$$

Where

Σ = Standard deviation of the response S = Slope of the calibration curve Result:

Pioglitazone: 2.94µg/ml

Rosiglitazone: 3.81µg/ml

Robustness:

Robustness was evaluated by deliberately varying chromatographic conditions, including flow rate (0.9–1.1 mL/min) and mobile phase composition (±5% organic phase). No significant changes were observed in retention time, resolution, tailing factor, or theoretical plate count. The method remained unaffected by these minor variations, confirming its robustness.

Table no 10:- Results for Robustness Pioglitazone

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	8658972	2.466	6358	1.34
Less Flow rate of 0.9 mL/min	9122485	2.741	6587	1.39
More Flow rate of 1.1 mL/min	8587852	2.270	6152	1.35
Less organic phase	8326585	3.266	6258	1.36
More organic phase	8256854	2.147	6354	1.37

Table no11:- Results for Robustness Rosiglitasone

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	536584	4.323	8476	1.28
Less Flow rate of 0.9 mL/min	612548	4.830	8859	1.30
More Flow rate of 1.1 mL/min	546584	3.979	8622	1.29
Less organic phase	526587	3.266	8854	1.31
More organic phase	512586	2.147	8726	1.28

Acceptance Criteria: The trailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

CONCLUSION:

A simple, precise, accurate, robust, and sensitive RP-HPLC method was successfully developed and validated for the simultaneous estimation of Pioglitazone and Rosiglitazone. The method complied with ICH validation requirements and demonstrated excellent specificity, linearity, precision, accuracy, and robustness. Therefore, it is suitable for routine quality control analysis of Pioglitazone and Rosiglitazone in pharmaceutical dosage forms.

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