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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ANALYSIS OF OXALIPLATIN IN PURE FORM AND MARKETED PHARMACEUTICAL DOSAGE FORMS BY USING RP-HPLC

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Abstract:

The present work includes a simple, economic, rapid, accurate and precise isocratic RP-HPLC method development for estimation of Oxaliplatin in bulk form and its marketed formulation. Estimation was done at 286nm which was found to be λmax of Oxaliplatin. The simple, selective, isocratic RP-HPLC method for Oxaliplatin was developed on Symmetry (C_{18}) RP Column; 250 mm x 4.6 mm, 5µm with a mobile phase of Phosphate Buffer (pH-4.6) and Methanol were taken in the ratio of 70:30% v/v at a flow rate of 1.0 ml/min and detection wavelength 286nm. The developed method was validated successfully according to ICH Q2 (R1) guidelines. The chromatographic methods showed a good linear response with r2 values of 0.9995. The percentage relative standard deviation for method was found to be less than two, indicating that the methods were precise. The mean percentage recovery was for RP-HPLC method was 100.437%. From the results it could be concluded that both the developed method was specific, selective and robust. The method could be successfully applied for analysis of Bulk form and Marketed formulation of Oxaliplatin.

Key Words: *Oxaliplatin, RP-HPLC, Method Development, Validation, ICH Guidelines.*

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INTRODUCTION:

Oxaliplatin is used for treatment of colorectal cancer, typically along with folinic acid (Leucovorin) and fluorouracil in a combination known as FOLFOX or along with Capecitabine in a combination known as CAPOX or XELOX. It also has uses in pancreatic cancer and stomach cancer or esophageal cancer[1]. It may also be effective against breast cancer, germ cell tumor, ovarian cancer and non-small-cell lung cancer. Oxaliplatin is an intravenously administered platinum containing alkylating agent which is used for the treatment of advanced colorectal cancer[2]. Oxaliplatin therapy is associated with a low rate of transient serum aminotransferase elevations, but is commonly associated with sinusoidal and vascular injury to the liver which can lead to sinusoidal obstruction syndrome and to nodular regenerative hyperplasia with noncirrhotic portal hypertension. Oxaliplatin, in combination with infusional fluorouracil and Leucovorin, is indicated for the treatment of advanced colorectal cancer and adjuvant treatment of stage III colon cancer in patients who have undergone complete resection of the primary tumor[3]. The IUPAC Name of Oxaliplatin is (1R, 2R)-cyclo hexane-1, 2-diamine; oxalate; platinum (2+). The Chemical Structure of Oxaliplatin is shown in following figure-1.

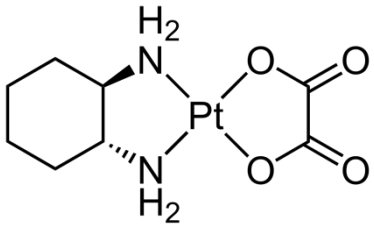

Fig-1: Chemical Structure of Oxaliplatin

EXPERIMENTAL

Instruments Used:

Table-1: Instruments Used

S.No.	Instruments and Glass wares	Model
1	HPLC	HPLC with Empower2 Software with Isocratic with UV-Visible Detector (Waters).
2	pH meter	Lab India
3	Weighing machine	Sartorius
4	Volumetric flasks	Borosil
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil
7	Digital Ultra Sonicator	Labman

Chemicals Used:

Table-2: Chemicals Used

S.No.	Chemical	Brand Names
1	Oxaliplatin	Synpharma Research Lab, Hyderabad
2	Water and Methanol for HPLC	LICHROSOLV (MERCK)
3	Acetonitrile for HPLC	Merck

Selection of Wavelength:
The Standard & Sample Stock Solutions were prepared separately by dissolving standard & sample in a solvent in mobile phase diluting with the same solvent. (After optimization of all conditions) for UV analysis[4-6]. It scanned in the UV spectrum in the range of 200 to 400nm. This has been performed to know the maxima of Oxaliplatin, so that the same wave number can be utilized in HPLC UV detector for estimating the Oxaliplatin. The scanned UV spectrum is attached in the following page,

Sample & Standard Preparation for the UV-Spectrophotometer Analysis: 25 mg of Oxaliplatin standard was transferred into 25 ml volumetric flask, dissolved & make up to volume with mobile phase. Further dilution was done by transferring 1ml of the above solution into a 10ml volumetric flask and make up to volume with mobile phase.

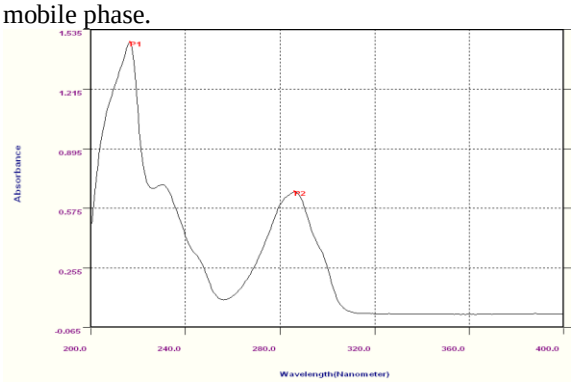

Fig-2: UV Spectrum for Oxaliplatin (286nm)

Observation: While scanning the Oxaliplatin solution we observed the maxima at 286nm[7]. The UV spectrum has been recorded on ELICO SL-159 make UV – Vis spectrophotometer model UV-2450.

HPLC Method Development:
Preparation of Standard Solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Methanol and sonicate to dissolve and removal of air completely and make volume up to the mark with the same Methanol.

Further pipette 0.1ml of the above Oxaliplatin stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Procedure:
Inject the samples by changing the chromatographic conditions and record the chromatograms, note the conditions of proper peak elution for performing validation parameters as per ICH guidelines[32].

Mobile Phase Optimization:
Initially the mobile phase tried was Methanol and Methanol: Water with varying proportions. Finally, the mobile phase was optimized to Phosphate Buffer (pH-4.6) and Methanol in proportion 70:30% v/v.

Optimization of Column:
The method was performed with various C18 columns like, X- bridge column, Xterra, and C18 column. Symmetry (C18) RP Column, 250 mm x 4.6 mm, 5µm was found to be ideal as it gave good peak shape and resolution at 1.0ml/min flow.

Preparation of Buffer and Mobile Phase:
Preparation of Potassium dihydrogen Phosphate (KH2PO4) buffer (pH-4.6):
Dissolve 6.8043 of potassium dihydrogen phosphate in 1000 ml HPLC water and adjust the pH 4.6 with diluted orthophosphoric acid[8]. Filter and sonicate the solution by vacuum filtration and ultra-sonication.

Preparation of Mobile Phase:
Accurately measured 300 ml (30%) of Methanol, 700 ml of Phosphate buffer (70%) were mixed and degassed in digital ultra sonicater for 15 minutes and then filtered through 0.45 µ filter under vacuum filtration.

Diluent Preparation:
The Mobile phase was used as the diluent.
Method Validation Parameters
System Suitability
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 0.1ml of the above Oxaliplatin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure:
The standard solution was injected for five times and measured the area for all five injections in HPLC. The %RSD for the area of five replicate injections was found to be within the specified limits[9].

Specificity:
Preparation of Standard Solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 0.1ml of the above Oxaliplatin stock solutions into a 10ml volumetric flask and dilute up to the mark with diluents.

Preparation of Sample Solution:
Weight 10 mg equivalent weight of Oxaliplatin sample into a 10mL clean dry volumetric flask and add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent.

Further pipette 0.1ml of Oxaliplatin above stock solution into a 10ml volumetric flask and dilute up to the mark with diluent.

Procedure:
Inject the three replicate injections of standard and sample solutions and calculate the assay by using formula[10-12]:
%ASSAY =

$$\frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Weight of standard}}{\text{Dilution of standard}} \times \frac{\text{Dilution of sample}}{\text{Weight of sample}} \times \frac{\text{Purity}}{100} \times \frac{\text{Weight of tablet}}{\text{Label claim}} \times 100$$

Linearity and Range:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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)

Preparation of Level – I (60ppm of Oxaliplatin):
Take 0.6ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – II (80ppm of Oxaliplatin):
Take 0.8ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – III (100ppm of Oxaliplatin):
Take 1.0ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator [13].

Preparation of Level – IV (120ppm of Oxaliplatin):
Take 1.2ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

Preparation of Level – V (140ppm of Oxaliplatin):
Take 1.4ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluents and sonicate the solution for bubble entrapment using ultrasonicator.

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[14].

Precision
Repeatability
Preparation of Oxaliplatin Product Solution for Precision:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 0.1ml of the above Oxaliplatin stock solutions 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:
To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different days by maintaining same conditions[15].

Procedure:
Analyst 1:
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.

Analyst 2:
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 Preparation of 80% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 0.8ml of the above Oxaliplatin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

For Preparation of 100% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 1.0ml of the above Oxaliplatin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents[16].

For Preparation of 120% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 1.2ml of the above Oxaliplatin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure:
Inject the Three replicate injections of individual concentrations (80%, 100%, 120%) were made under the optimized conditions. Recorded the chromatograms and measured the peak responses[17-19]. Calculate the Amount found and Amount added for Oxaliplatin and calculate the individual recovery and mean recovery values.

Robustness:
The analysis was performed in different conditions to find the variability of test results. The following conditions are checked for variation of results. .

For preparation of Standard solution:
Accurately weigh and transfer 10 mg of Oxaliplatin working standard into a 10ml of 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 0.1ml of the above Oxaliplatin stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Effect of Variation of Flow Conditions:
The sample was analyzed at 0.9 ml/min and 1.1 ml/min instead of 1ml/min, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded[20].

Effect of Variation of Mobile Phase Organic Composition:
The sample was analyzed by variation of mobile phase i.e. Methanol: Phosphate Buffer was taken in the ratio and 35:65, 25:65 instead (30:70), remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded.

RESULTS AND DISCUSSION:

Development of a New Analytical Method:
Optimized Chromatographic Conditions:

Mobile phase ratio	: Phosphate Buffer (pH-4.6): Methanol = 70:30% v/v
Column	: Symmetry (C18) RP Column, 250 mm x 4.6 mm, 5µm
Column temperature	: Ambient
Wavelength	: 286nm
Flow rate	: 1.0ml/min
Injection volume	: 20µl
Run time	: 10.0min

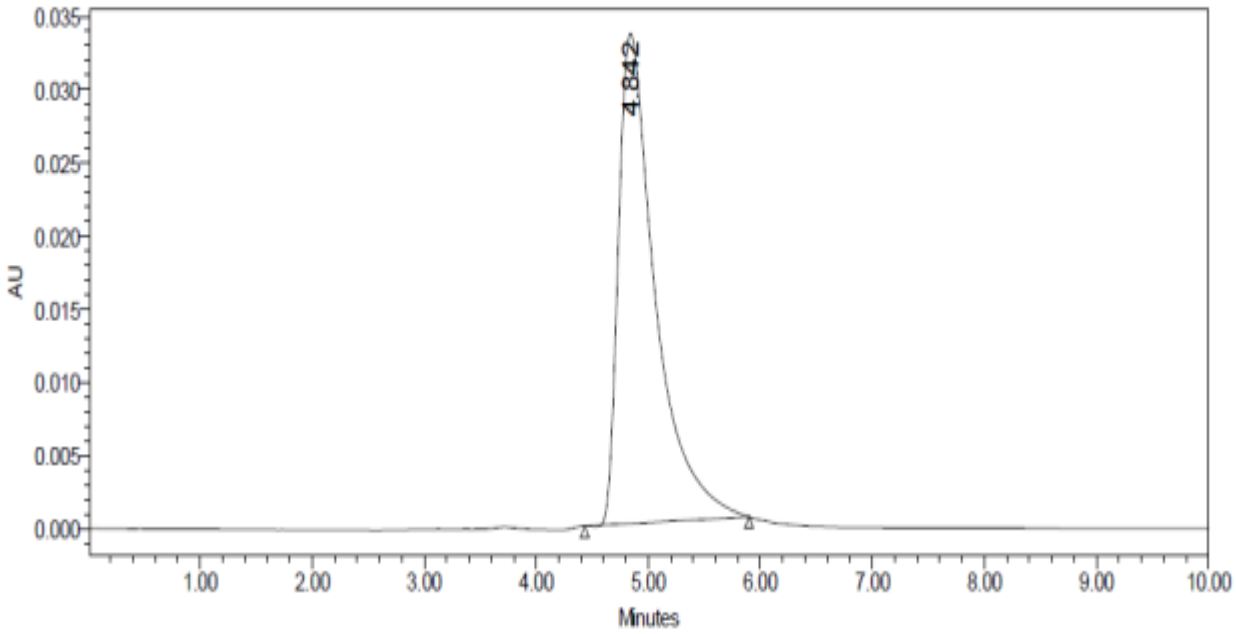

Fig-3: Optimized Chromatographic Condition

Validation of Analytical Method:

The developed chromatographic method was validated for Specificity, Linearity, Precision, Accuracy, Sensitivity, Robustness and System suitability[21-23].

System Suitability: System suitability testing is an integral part of many analytical procedures. The tests are based on the concept that the equipment, electronics, analytical operations and samples to be analysed constitute an integral system that can be evaluated as such. Following system suitability test parameters were established[24]. The data are shown in Table-3 & 4.

Table-3: Data of System Suitability Test

S.No.	Injection No.	RT	Area	USP Plate Count	USP Tailing
1	Injection 1	4.817	745236	6986	1.39
2	Injection 2	4.783	743652	6857	1.37
3	Injection 3	4.840	742587	6856	1.36
4	Injection 4	4.783	742946	6847	1.39
5	Injection 5	4.817	743654	6896	1.38
6	Injection 6	4.778	741698	6874	1.37
Mean			**743295.5**	**6886**	**1.37666**
S.D			**1199.773604**		
%RSD			**0.161412736**		

Table-4: Data of System Suitability Parameter

S.No.	Parameter	Limit	Result
1	Retention Time	RT > 2	Oxaliplatin= 4.778
2	Asymmetry	T ≤ 2	Oxaliplatin= 1.35
3	Theoretical plate	N > 2000	Oxaliplatin= 6859
4	Tailing Factor	T<2	Oxaliplatin= 1.37

2. Linearity: To evaluate the linearity, serial dilution of analyte were prepared from the stock solution was diluted with mobile phase to get a series of concentration ranging from 60-140µg/ml. The prepared solutions were sonicated. From these solutions, 10µl injections of each concentration were injected into the HPLC system and chromatographed under the optimized conditions. Calibration curve was constructed by plotting the mean peak area (Y-axis) against the concentration (X-axis)[25].

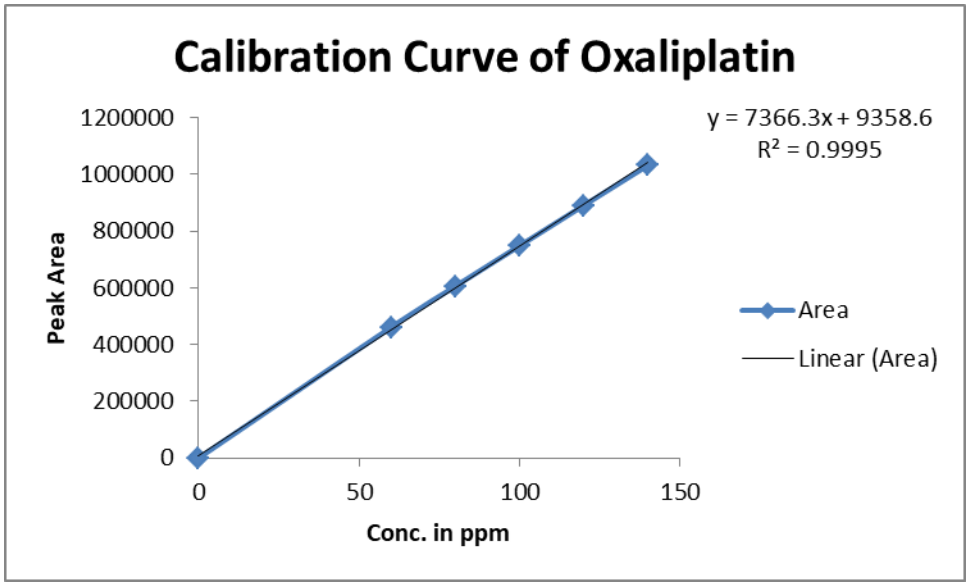

Fig-4: Calibration Curve of Oxaliplatin

Table-5: Linearity Data for Oxaliplatin

Conc. (µg/ml)	Peak Area
0	0
60	461404
80	606157
100	748506
120	891041
140	1032196

3. Accuracy: The accuracy of the method was determined by recovery studies and the percentage recovery was calculated. The recoveries of Oxaliplatin were found to be in the range of 99-102%. The proposed Liquid Chromatographic method was applied to the determination of Oxaliplatin. The results for Oxaliplatin comparable with the corresponding labeled amounts[26].

Table-6: Shown Accuracy Observation of Oxaliplatin

Accuracy	Amount Added	Amount Recovered	Peak Area	% Recovery	Mean Recovery
80%	80	80.798	604517	100.997	100.437%
	80	80.673	603598	100.841	
	80	80.756	604213	100.945	
100%	100	99.933	745471	99.933	
	100	100.083	746574	100.083	
	100	100.365	748652	100.365	
120%	120	120.290	895415	100.241	
	120	120.201	894762	100.167	
	120	120.442	896541	100.368	

4. Precision:

Repeatability: The precision of each method was ascertained separately from the peak areas & retention times obtained by actual determination of six replicates of a fixed amount of drug. Oxaliplatin (API)[27]. The percent relative standard deviation was calculated for Oxaliplatin are presented in the table-7.

Table-7: Repeatability Data for Oxaliplatin

S. No.	INJECTION	PEAK AREA
1	Injection 1	743826
2	Injection 2	745277
3	Injection 3	742506
4	Injection 4	747576
5	Injection 5	746715
6	Injection 6	741278
7	**Average**	**744529.6667**
8	**SD**	**2440.4116**
9	**% RSD**	**0.32777**

Intermediate Precision:

The Intermediate Precision consists of two methods:-

Intra Day: In Intra Day process, the 80%, 100% and 120% concentration are injected at different intervals of time in same day.

Inter Day: In Inter Day process, the 80%, 100% and 120% concentration are injected at same intervals of time in different days.

Table-8: Results of Intra-Assay & Inter-Assay

Conc. of Oxaliplatin (API) (µg/ml)	Observed Conc. of Oxaliplatin (µg/ml) by the Proposed Method			
	Intra-Day		Inter-Day	
	Mean (n=6)	% RSD	Mean (n=6)	% RSD
80	80.096	0.487	79.685	0.688
100	100.074	0.968	100.057	0.789
120	120.056	0.847	120.016	0.698

Observations: The intra & inter day variation of the method was carried out for standard deviation & % RSD (% RSD < 2%) within a day & day to day variations for Oxaliplatin revealed that the proposed method is precise.

5. Specificity:

Specificity can be determined by comparing the chromatograms obtained from the drugs with the chromatogram obtained from the blank solution. Blank solution was prepared by mixing the excipients in the mobile phase without drug. Drug solutions were prepared individually and the sample containing one drug was also prepared. Now these mixtures were filtered by passing through 0.45 µ membrane filter before the analysis. In this observation no excipient peaks were obtained near the drug in the study run time[28]. This indicates that the proposed method was specific.

The chromatograms representing the peaks of blank, Oxaliplatin and the sample containing the one drug was shown in following figures respectively.

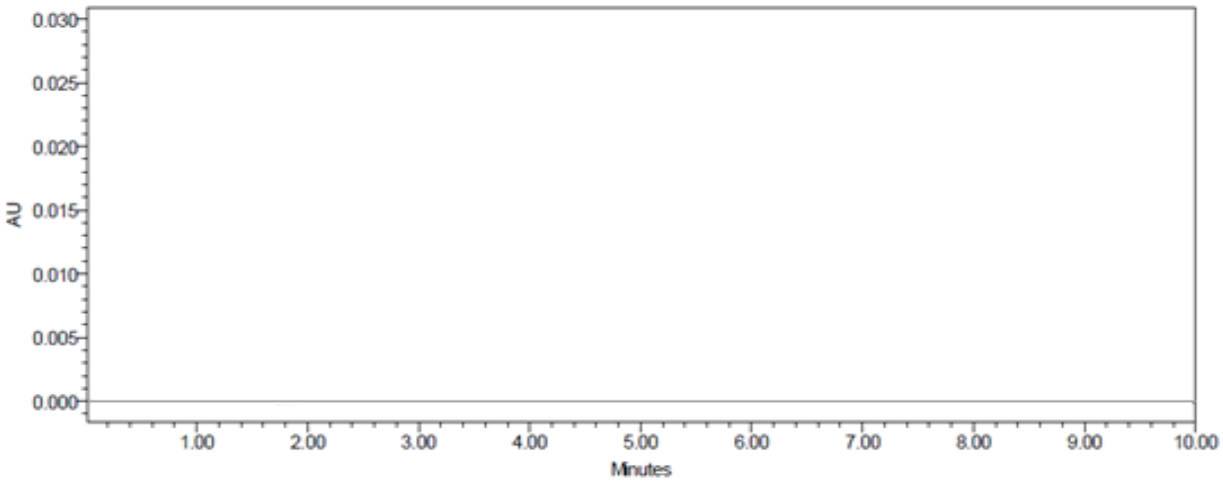

Fig-5: Chromatogram for Blank Solution

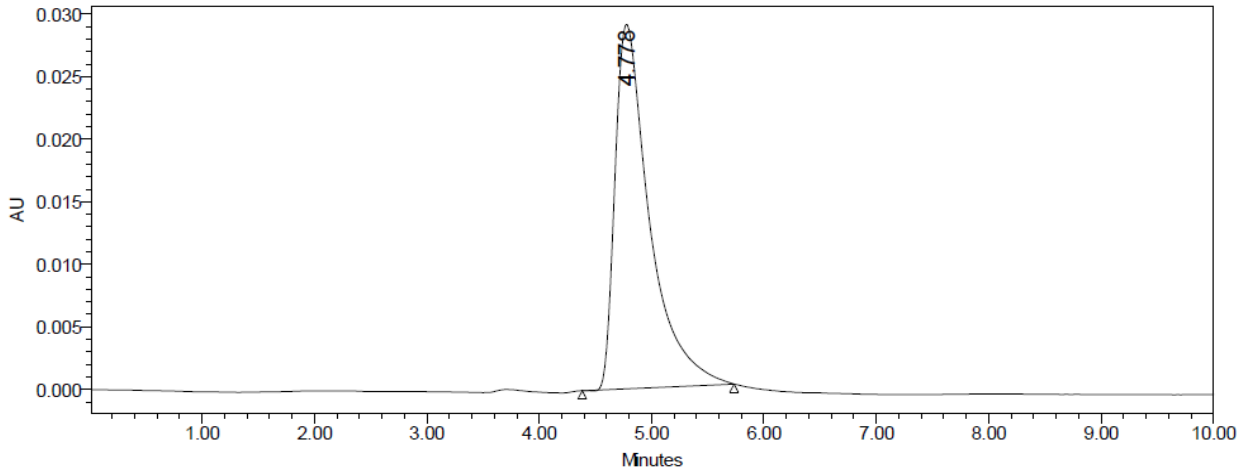

Fig-6: Chromatogram of Oxaliplatin Standard Solution

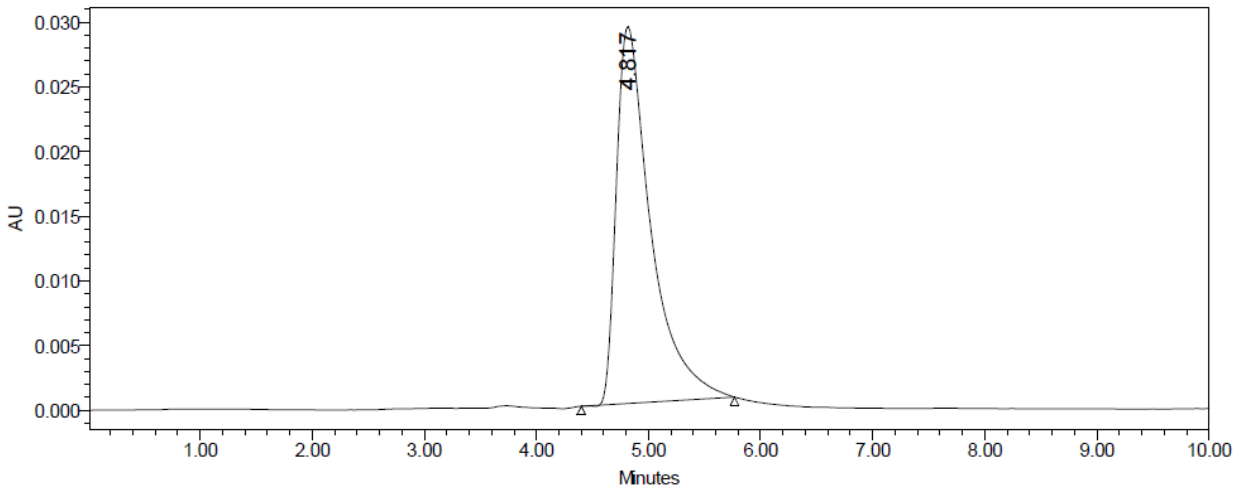

Fig-7: Chromatogram of Oxaliplatin Sample Solution

Observation: In this test method blank, standard solutions were analyzed individually to examine the interference. The above chromatograms show that the active ingredient was well separated from blank and their excipients and there was no interference of blank with the principal peak. Hence the method is specific.

6. Limit of Detection (LOD) and Limit of Quantification (LOQ):

The LOD and LOQ parameter was evaluated by mistreatment the slope of line and variance obtained from accuracy studies.

The detection limit (LOD) and quantization limit (LOQ) may be expressed as:

L.O.D. = 3.3(SD/S).

L.O.Q. = 10(SD/S)

Where, SD = Standard deviation of the response

S = Slope of the calibration curve

The slope S may be estimated from the calibration curve of the analyte.

The Minimum concentration level at which the analyte can be reliable detected (LOD) & quantified (LOQ) were found to be 1.469 & 4.454µg/ml respectively.

7. Method Robustness: Influence of small changes in chromatographic conditions such as change in flow rate 1.0 ml (± 0.1ml/min), Wavelength of detection 286 (± 2nm) & organic phase content in mobile phase (± 5%) studied to determine the robustness of the method are also in favour of (Table-9, % RSD < 2%) the developed RP-HPLC method for the analysis of Oxaliplatin (API)[29].

Effect of Variation of Flow Conditions:

The sample was analyzed at 0.9ml/min and 1.1ml/min instead of 1ml/min, remaining conditions are same. 10µl of the above sample was injected and chromatograms were recorded.

Effect of Variation of Mobile Phase Organic Composition:

The sample was analyzed by variation of mobile phase i.e. Methanol: Phosphate Buffer was taken in the ratio and 40:60, 30:70 instead of 35:65, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded.

Table-9: Results for Robustness

Parameter Used for Sample Analysis	Peak Area	Retention Time	Theoretical Plates	Tailing Factor
Actual Flow rate of 1.0 mL/min	742946	4.778	1.37	2896
Less Flow rate of 0.9 mL/min	698965	4.783	1.39	2986
More Flow rate of 1.1 mL/min	786598	4.817	1.42	2985
Less organic phase	732642	4.842	1.29	3102
More organic phase	702546	4.773	1.37	3247

8. Estimation of Oxaliplatin in Pharmaceutical Dosage Form

Twenty Pharmaceutical Dosage forms were taken and the I.P. method was followed to determine the average weight. Above weighed tablets were finally powdered and triturated well. A quantity of powder equivalent to 25 mg of drugs were transferred to 25 ml volumetric flask, make and solution was sonicated for 15 minutes, there after volume was made up to 25 ml with same solvent. Then 10 ml of the above solution was diluted to 100 ml with mobile phase. The solution was filtered through a membrane filter (0.45 µm) and sonicated to degas[30]. The solution prepared was injected in five replicates into the HPLC system and the observations were recorded[31]. The data are shown in Table-10.

ASSAY:

Assay % =

$$\frac{AT}{AS} \times \frac{WS}{DS} \times \frac{DT}{WT} \times \frac{P}{100} \times \text{Avg Wt.} = \text{mg}$$

Where:

AT = Peak Area of drug obtained with test preparation
AS = Peak Area of drug obtained with standard preparation
WS = Weight of working standard taken in mg
WT = Weight of sample taken in mg
DS = Dilution of Standard solution
DT = Dilution of sample solution
P = Percentage purity of working standard

Table-10: Recovery Data for Estimation Oxaliplatin in Oxitoz-100 Injection

Brand name of Oxaliplatin	Labelled amount of Drug (mg)	Mean (± SD) amount (mg) found by the proposed method (n=6)	Assay % (± SD)
Oxitoz-100 Injection (Intas Pharmaceutical Ltd.)	100mg	99.258 (± 0.426)	99.528 (± 0.698)

SUMMARY AND CONCLUSION:

To develop a precise, linear, specific & suitable stability indicating RP-HPLC method for analysis of Oxaliplatin, different chromatographic conditions were applied & the results observed are presented in previous chapters. Isocratic elution is simple, requires only one pump & flat baseline separation for easy and reproducible results. So, it was preferred for the current study over gradient elution. In case of RP-HPLC various columns are available, but here Symmetry (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm Column was preferred because using this column peak shape, resolution and absorbance were good. Detection wavelength was selected after scanning the standard solution of drug over 200 to 400nm. From the U.V spectrum of Oxaliplatin it is evident that most of the HPLC work can be accomplished in the wavelength range of 286 nm conveniently. Further, a flow rate of 1.0 ml/min & an injection volume of 20µl were found to be the best analysis. The result shows the developed method is yet another suitable method for assay and stability related impurity studies which can help in the analysis of Oxaliplatin in different formulations.

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