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RP-HPLC METHOD DEVELOPMENT FOR THE SIMULTANEOUS ESTIMATION OF NIRAPARIB AND ABIRATERONE ACETATE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A new RP-HPLC method was established for simultaneous estimation of Niraparib and abiraterone acetate. The chromatographic conditions were successfully developed for the separation of Niraparib and abiraterone acetate. The analytical method was developed by studying different parameters. First of all, maximum absorbance was found to be at 250nm and the peak purity was excellent. Injection volume was selected to be 10µl which gave a good peak area. The column used for study was C_{18}, ambient temperature was found to be suitable for the nature of drug solution. The flow rate was fixed at 1.0 ml/min because of good peak area and satisfactory retention time. Mobile phase Acetonitrile: Water (70:30% v/v) was fixed due to good symmetrical peak. So this mobile phase was used for the proposed study. Run time was selected to be 10min because analyze gave peak around 2.073, 5.052 ±0.02min respectively and also to reduce the total run time. The percent recovery was found to be 98.0-102 was linear and precise over the same range. Both system and method precision were found to be accurate and well within range. The analytical method was found linearity over the range 5-50µg/ml of Niraparib and 30-230 µg/ml of Abiraterone of the target concentration. Relative standard deviation was well satisfactory. Hence the suggested RP-HPLC method can be used for routine analysis of Niraparib and abiraterone acetate in API and Pharmaceutical dosage form.

KEYWORDS: Niraparib, abiraterone acetate, simultaneous estimation, linearity, SD, RSD.

INTRODUCTION

Niraparib is a poly-ADP ribose polymerase inhibitor used to treat recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer responding to platinum based chemotherapy. Niraparib is an orally active poly (ADP-ribose) polymerase (PARP) inhibitor.[1] By blocking the enzymes responsible for DNA repair, niraparib induces cytotoxicity in cancer cells. Niraparib is selective towards PARP-1 and PARP-2. First approved by the FDA on March 27, 2017, niraparib is used to treat epithelial ovarian, fallopian tube, or primary peritoneal cancer. Niraparib was approved by the European Commission on November 16, 2017 and by Health Canada on June 27, 2019.[2] Venu GopalKamani and M. Sujatha, developed a novel and sensitive HPLC method and subsequently validated for the analysis of Niraparib, its impurity 1, and impurity 2 in formulations. The separation of Niraparib and its impurities was achieved on Inertsil 3V ODS (250mm×4.6mm, 5µm) as stationary phase, methanol, 20mM ammonium formate and 0.05% of triethylamine in 80:15:5 (V/V) at pH 5.5 (adjusted with formic acid) at 1.0 mL/min isocratic flow and 246 nm wavelength. In the optimized conditions, the retention time was observed at 8.10, 11.01, 13.50, and 5.18 min respectively for Niraparib, impurity 1, Impurity 1 Acyl Glucuronide, and impurity 2. The method was confirmed to be sensitive with a detection limit of 0.015, 0.045, and 0.024 µg/mL for impurity 1, Impurity 1 Acyl Glucuronide, and impurity 2 respectively.[3]

Abiraterone is used to treat metastatic castration-resistant prostate cancer and hormone-sensitive high-risk

metastatic prostate cancer. inhibits CYP17 to block androgen production. Inhibition of CYP17 can also result in increased mineralocorticoid production by the adrenals.[4] Sarwar Beg et al, developed a reversed-phase liquid chromatographic method for the estimation of abiraterone acetate by Quality by Design (QbD) approach. Using an isocratic solvent system for the mobile phase, the chromatographic estimation of analyte was performed on a Hypersil BDS C18 column using mobile phase mixture containing acetonitrile and water with pH adjusted with 0.1% v/v orthophosphoric acid (15:85%v/v ratio), flow rate 1.0 mL.min-1 and detection at 250 nm using photodiode array detector.[5]

Methods are available for the estimation of drugs individually but not simultaneously, so effort has been done for estimation of drugs simultaneously and validated according to ICH guidelines.[6-18]

HPLC METHOD DEVELOPMENT

Accurately weigh and transfer 10 mg of Niraparib and 50 mg of Abiraterone working standards 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 0.3 ml of the above Niraparib and Abiraterone stock solution into a 10ml volumetric flask and dilute up to the mark with Methanol. 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.

OPTIMIZED CHROMATOGRAPHIC CONDITIONS

Instrument used	:	Waters HPLC with auto sampler and PDA Detector 996 model.
Temperature	:	35˚C
Column	:	X-Terra C18 (4.6×150mm,5µ)
Mobile phase	:	Acetonitrile: Water (70:30% v/v)pH 3.5
Flow rate	:	1ml/min
Wavelength	:	250nm
Injection volume	:	10 µl
Run time	:	10 min

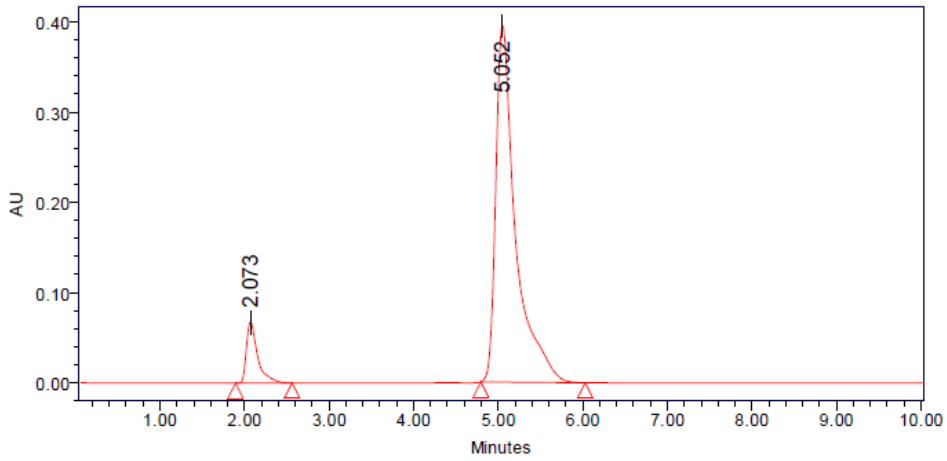

Fig. 1: Optimized Chromatogram.

Preparation of mobile phase

Accurately measured 700 ml (70%) of Acetonitrile, 300 ml (30%) of Water were mixed and degassed in digital ultrasonicater for 10 minutes and then filtered through 0.45 µ filter under vacuum filtration. The Mobile phase was used as the diluent.

VALIDATION PARAMETERS

SYSTEM SUITABILITY

Accurately weigh and transfer 10 mg of Niraparib and 50 mg of Abiraterone working standards into a 10ml of clean dry volumetric flasks add about 7ml of Methanol and make volume up to the mark with the same Methanol. Further pipette 0.3 ml of the above Niraparib and Abiraterone stock solution into a 10ml volumetric flask and dilute up to the mark with Diluent. 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.

Linearity: Linearity was evaluated over the concentration range of 5–50 µg/mL for Niraparib and 30–230 µg/mL for Abiraterone Acetate. The calibration curves were linear with correlation coefficients (r^2) of 0.999 for both drugs.

PRECISION

- Precision was demonstrated through intra-day (repeatability) and inter-day studies. The %RSD for the standard solution is below 1, which is within the limits hence method is precise.

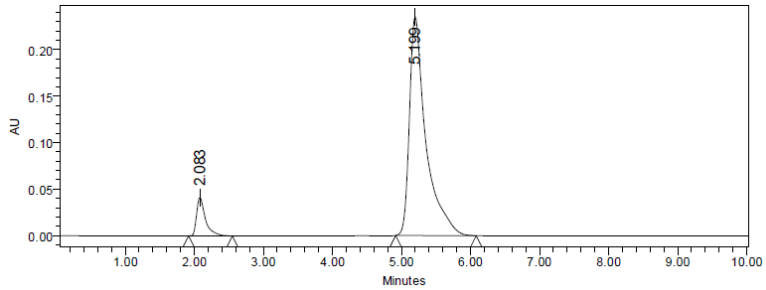

Fig. 2: Chromatogram showing precision.

Table 1: Results of repeatability for Niraparib.

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Niraparib	2.086	362266	41697	5081.3	1.8
2	Niraparib	2.083	364902	41402	5144.1	1.8
3	Niraparib	2.083	366870	41540	5118.1	1.8
4	Niraparib	2.081	367273	42256	5147.3	1.8
5	Niraparib	2.081	368101	42143	5101.8	1.8
6	Niraparib	2.081	367102	42152	5102.3	1.6
Mean			366085.6667			
Std. D			2149.9			
% RSD			0.59			

Table 2: Results of method preision for Abiraterone.

S no	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Abiraterone	5.178	3903548	240181	5988.3	2.0	9.8
2	Abiraterone	5.199	3905819	235523	5856.3	2.0	9.7
3	Abiraterone	5.235	3916120	238578	5930.2	2.0	9.9
4	Abiraterone	5.202	3916542	238814	5936.9	2.0	9.8
5	Abiraterone	5.206	3920943	241006	5040.0	2.0	9.5
6	Abiraterone	5.204	3920922	241012	5044.2	1.9	9.5
Mean			**3913982.3**				
Std. D			**7526.6**				
%RSD			**0.2**				

Table 3: Results of Intermediate precision for Niraparib.

S no	Name	Rt	Area	Height	USP plate count	USP Tailing
1	Niraparib	2.083	369246	42277	5537.8	1.6
2	Niraparib	2.083	370766	42708	5561.8	1.6
3	Niraparib	2.089	370840	42065	5489.3	1.6
4	Niraparib	2.083	370840	42065	5489.3	1.6
5	Niraparib	2.082	371041	42568	5583.2	1.8
6	Niraparib	2.080	371386	42211	5533.2	1.8
Mean			370686.5			
Std. D			740.7369			
% RSD			0.19			

Table 4: Results of Intermediate precision for Abiraterone.

S no	Name	Rt	Area	Height	USP plate count	USP Tailing	USP Resolution
1	Abiraterone	5.077	3841404	246818	5208.0	2.1	10.1
2	Abiraterone	5.151	3885014	242854	5127.6	2.1	10.0
3	Abiraterone	5.112	3743003	242955	5269.7	2.2	10.2
4	Abiraterone	5.133	3743003	242955	5269.7	2.2	10.2
5	Abiraterone	5.203	3885014	242854	5127.6	2.1	10.0
6	Abiraterone	5.133	3743003	242955	5269.7	2.2	10.2
Mean			3806740				
Std. D			71613.47				
% RSD			1.8				

Accuracy

Inject the Three replicate injections of individual concentrations (50%,100%,150%) were made under the optimized conditions. Recorded the chromatograms and measured the peak responses. Calculate the Amount found and Amount added for Niraparib and Abiraterone and calculate the individual recovery and mean recovery values.

Table 5: The accuracy results for Niraparib.

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	192446.6	10.5	10.49	99.9	99.8%
100%	374222	21	21	100	
150%	555891.3	31.5	31.4	99.6	

Table 6: The accuracy results for Abiraterone.

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	2001752	27.3	27.28	99.9	99.8%
100%	3927797	54.6	54.59	99.9	
150%	5858665	81.9	81.7	99.7	

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.

$$\mathbf{LOD = 3.3 \times \sigma / s}$$

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

RESULT

Niraparib

=3.3 × 5088.67/17628

=0.95µg/ml

Abiraterone

=3.3 × 143236.4/71839

=6.5µg/ml

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 Niraparib and 50 mg of Abiraterone working standards 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 0.3 ml of the above Niraparib and Abiraterone stock solution into a 10ml volumetric flask and dilute up to the mark with Diluent.

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. 10µl of the above sample was injected and chromatograms were recorded.

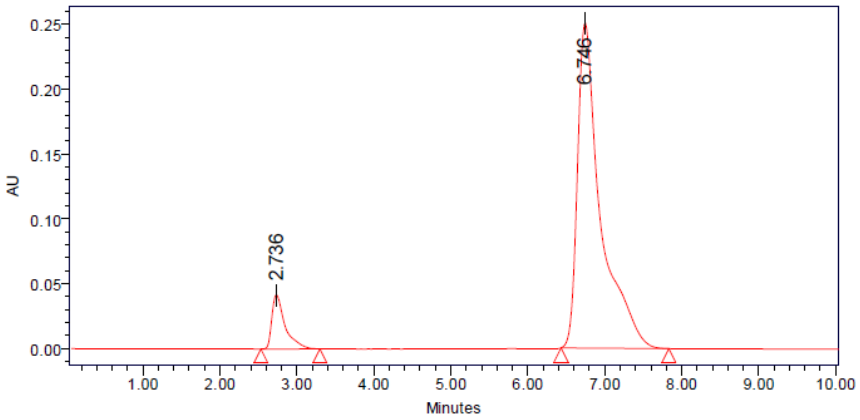

Figure: chromatogram showing less flow of 0.9ml/min.

Abiraterone

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	3864998	5.289	5698	1.77
Less Flow rate of 0.9 mL/min	3546737	6.746	5546	1.88
More Flow rate of 1.1 mL/min	3857216	4.032	5124	1.91
Less organic phase	3810347	6.746	5034	1.88
More organic phase	3875642	4.032	5612	1.91

The sample was analyzed by variation of mobile phase i.e. Acetonitrile: Water pH 3.5was taken in the ratio and 75:25, 65:35 instead (70:30% v/v), remaining conditions are same. 10µl of the above sample was injected and chromatograms were recorded.

CONCLUSION

A new RP-HPLC method was established for simultaneous estimation of Niraparib and abiraterone acetate. The analytical method was developed by studying different parameters. First of all, maximum absorbance was found to be at 250nm and the peak purity was excellent. Injection volume was selected to be 10µl which gave a good peak area. The column used for study was X-Terra C_{18} ambient temperature was found to be suitable for the nature of drug solution. The flow rate was fixed at 1.0ml/min because of good peak area and satisfactory retention time. Mobile phase is Acetonitrile: Water(70:30% v/v) was fixed due to good symmetrical peak. So this mobile phase was used for the proposed study. Run time was selected to be 10min because analyze gave peak around 2.090, 5.289 ±0.02min respectively and also to reduce the total run time.

The percent recovery was found to be 98.0-102, was linear and precise over the same range. Both system and method precision were found to be accurate and well within range.The analytical method was found linearity over the range5-50µg/ml of Niraparibband 30-230 µg/ml of Abiraterone of the target concentration. The analytical passed both robustness and ruggedness tests. On both cases, relative standard deviation was well satisfactory.

Hence the suggested RP-HPLC method can be used for routine analysis of Niraparib and abiraterone acetate in API and Pharmaceutical dosage form.

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