

# RP-HPLC Method Development and Validation for Estimation of Niraparib and Abiraterone

Najma Banu H<sup>1</sup>, Sekar V<sup>1\*</sup>, Krishnan R<sup>1</sup>, Mohanapriya N<sup>1</sup>, Venkatesan M<sup>1</sup>

<sup>1</sup>Department of Pharmaceutical Analysis, J. K. K. Natraja College of Pharmacy, Kumarapalayam-638613, Tamil Nadu, India

DOI: <https://doi.org/10.36348/sijb.2025.v08i03.007>

| Received: 28.07.2025 | Accepted: 25.09.2025 | Published: 30.09.2025

\*Corresponding author: Sekar V

Department of Pharmaceutical Analysis, J. K. K. Natraja College of Pharmacy, Kumarapalayam-638613, Tamil Nadu, India

## Abstract

A simple, Accurate, precise method was developed for the simultaneous estimation of the Abiraterone and Niraparib in syrup dosage form. Chromatogram was run through AgilentC18150 x 4.6 mm, 5m. Mobile phase containing 0.01N Potassium dihydrogen ortho phosphate: Methanol taken in the ratio 60:40 was pumped through column at a flow rate of 1.0ml/min. Temperature was maintained at 30°C. Optimized wavelength selected was 260nm. A simple, Accurate, precise method was developed for the simultaneous estimation of the Abiraterone and Niraparib in tablet dosage form. Retention time of Abiraterone and Niraparib were found to be 2.185 min and 2.660 min. %RSD of the Abiraterone and Niraparib were and found to be 0.6 and 0.3 respectively. %Recovery was obtained as 99.09% and 99.60% for Abiraterone and Niraparib respectively. LOD, LOQ values obtained from regression equations of Abiraterone and Niraparib were 0.26, 0.80 and 0.03, 0.08 respectively. Regression equation of Niraparib is  $y = 90785x + 1183.6$  and  $y = 42063x + 50388$  of Abiraterone. Retention times were decreased and run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

**Keywords:** Niraparib, Abiraterone, RP-HPLC.

**Copyright © 2025 The Author(s):** This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International License (CC BY-NC 4.0) which permits unrestricted use, distribution, and reproduction in any medium for non-commercial use provided the original author and source are credited.

## INTRODUCTION

Drug quality is critical for ensuring safety and therapeutic efficacy. Quality assurance and control of pharmaceutical formulations help guarantee the availability of safe and effective medicines. Analytical evaluation of pure drugs and dosage forms is central to assessing their suitability for patient use. The reliability of analytical data depends on the robustness and precision of the employed methods, making method development vital for regulatory approval.

Drug quality is typically assured by monitoring both assay and impurities: assay reflects potency, while impurity profiling ensures safety. Analytical method development faces challenges due to the diverse chemical and physical properties of drugs. Therefore, methods must be selective, accurate, sensitive, reproducible, simple, rapid, and cost-effective to meet industry demands.

Various physico-chemical methods are employed, including optical (refractometry, polarimetry, fluorescence), photometric (UV-Vis, IR,

spectrophotometry), and chromatographic techniques (TLC, GC, HPLC). Advanced methods such as NMR, MS, and hyphenated techniques (e.g., GC-MS) have further strengthened pharmaceutical analysis. Classical chemical approaches like gravimetry, volumetry, titrations, and complexometry also remain relevant. Modern pharmaceutical analysis must therefore aim to be accurate, economical, precise, selective, and time-efficient.

### High Performance Liquid Chromatography (HPLC)

Liquid chromatography is a powerful analytical technique used to separate ions or molecules in solution based on differences in adsorption, ion exchange, partitioning, or size. Earlier methods such as paper chromatography, TLC, and open-column chromatography lacked sufficient resolution and quantification capabilities. In the 1970s, pressure liquid chromatography evolved into High Performance Liquid Chromatography (HPLC) with advancements in column packing materials, flow control, and on-line detectors, making it one of the most reliable and versatile separation methods today.

**Classification of HPLC**

- **By mode of chromatography:** Normal phase, Reverse phase
- **By principle of separation:** Adsorption, Partition, Ion exchange, Size exclusion, Affinity, Chiral phase
- **By elution technique:** Isocratic, Gradient
- **By scale of operation:** Analytical, Preparative

**Normal Phase HPLC (NP-HPLC):**

Uses a polar stationary phase (e.g., silica) and a non-polar mobile phase. Polar compounds are retained longer, making it suitable for separating hydrophilic molecules and positional isomers.

**Reversed Phase – High Performance Liquid Chromatography (RP-HPLC)**

As opposed to NP-HPLC, RP-HPLC employs mainly dispersive forces (hydrophobic or van der Waals interactions). The polarities of mobile and stationary phases are reversed, such that the surface of the stationary phase in RP-HPLC is hydrophobic and mobile phase is polar, where mainly water-based solutions are employed. RP-HPLC is by far the most popular mode of chromatography.

**MATERIALS AND METHODS****Materials:**

Niraparib and Abiraterone pure drugs (API), Combination tablets (Akeega), Distilled water, Acetonitrile, Methanol, Phosphate buffer,  $\text{KH}_2\text{PO}_4$ , and Orthophosphoric acid (Rankem grade).

**Instruments:**

- Electronic Balance (Denver)
- pH meter and Ultrasonicator (BVK Enterprises, India)
- WATERS HPLC 2695 with quaternary pump, PDA detector, Auto sampler, Empower 2 software

- UV-Vis Spectrophotometer (PG Instruments T60) with UV win 6 software

**Diluent:** Methanol: Water (50:50)

**Preparation of Solutions**

- **Standard Stock Solutions:** 2.5 mg Niraparib and 25 mg Abiraterone in 50 mL diluent → (100  $\mu\text{g}/\text{mL}$  Niraparib, 1000  $\mu\text{g}/\text{mL}$  Abiraterone).
- **Standard Working Solution (100%):** 1 mL from each stock diluted to 10 mL → (5  $\mu\text{g}/\text{mL}$  Niraparib, 50  $\mu\text{g}/\text{mL}$  Abiraterone).
- **Sample Stock Solution:** Equivalent to 50 mg Niraparib and 500 mg Abiraterone in 500 mL diluent, sonicated 25 min, filtered → (100  $\mu\text{g}/\text{mL}$ , 1000  $\mu\text{g}/\text{mL}$ ).
- **Sample Working Solution (100%):** 0.5 mL of sample stock diluted to 10 mL → (5  $\mu\text{g}/\text{mL}$  Niraparib, 50  $\mu\text{g}/\text{mL}$  Abiraterone).
- **Buffer:** 0.01N  $\text{KH}_2\text{PO}_4$  prepared (pH adjusted to 5.0 with dilute  $\text{H}_3\text{PO}_4$ ).

**Validation Parameters**

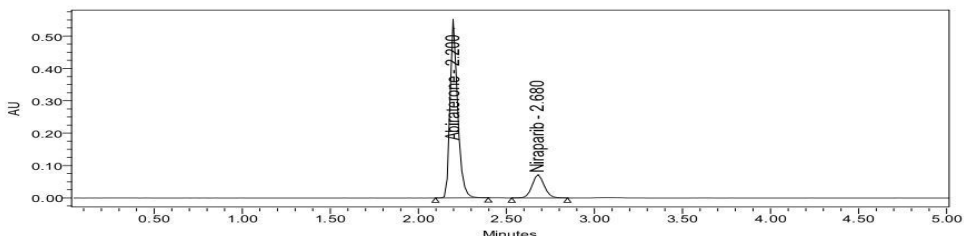
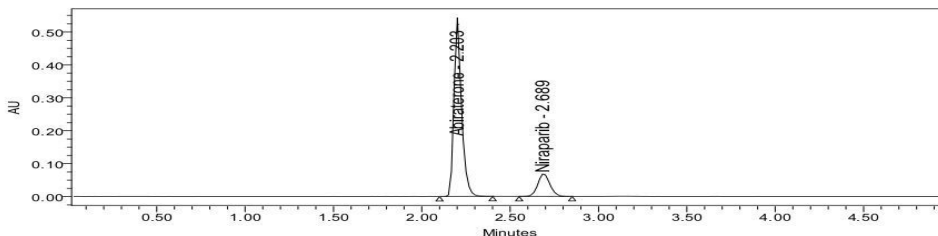
- **System Suitability:** Six replicate injections; evaluated for peak tailing, resolution, USP plate count (%RSD  $\leq$  2%).
- **Specificity:** No interference at retention times of Niraparib and Abiraterone in blank/placebo.
- **Precision:** Standard and sample solutions prepared at working concentration; %RSD checked.
- **Linearity:** 25–150% concentrations (1.25–7.5  $\mu\text{g}/\text{mL}$  Niraparib, 12.5–75  $\mu\text{g}/\text{mL}$  Abiraterone).
- **Accuracy (Recovery):** 50%, 100%, 150% spiked levels; acceptance 98–102%.
- **Robustness:** Deliberate variations (flow  $\pm$ 0.1 mL/min, mobile phase ratio, temp  $\pm$ 5°C); parameters within limits (%RSD < 2%).
- **LOD & LOQ:** Prepared by serial dilutions from stock solutions.



STD Report 1

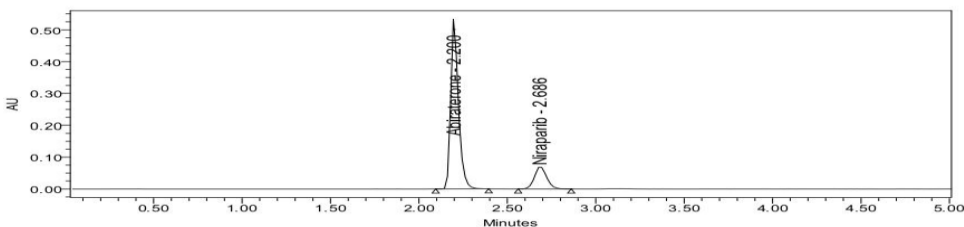
SAMPLE INFORMATION

Sample Name:	Accuracy_50%_2,	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	17, 18, 19	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	FDA 260.0 nm
Date Acquired:	13-08-2024 18:49:13 IST, 13-08-2024 18:55:00 IST, 13-08-2024 19:00:47 IST		
Date Processed:	15-08-2024 11:10:28 IST, 15-08-2024 11:10:29 IST, 15-08-2024 11:10:30 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420  
 Page: 1 of 2

Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:30:38 Asia/Calcutta



Peak Name: Abiraterone

Peak Name	RT	Area	USP Plate Count	USP Tailing
1 Abiraterone	2.200	3190278	11514	1.29
2 Abiraterone	2.200	3191813	10095	1.24
3 Abiraterone	2.203	3191511	10087	1.22

Peak Name: Niraparib

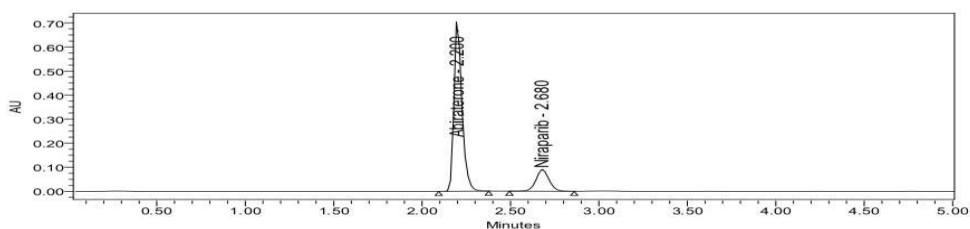
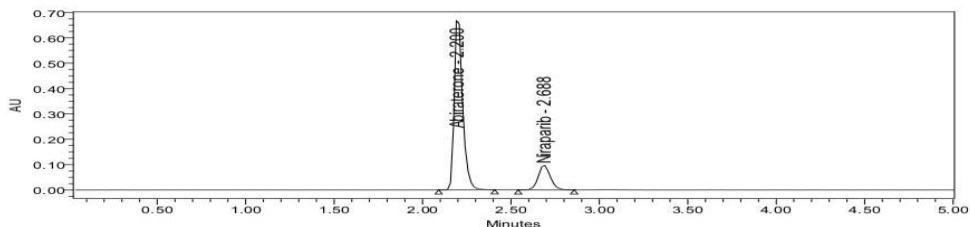
Peak Name	RT	Area	USP Plate Count	USP Tailing	USP Resolution
1 Niraparib	2.680	682772	7267	1.06	4.4
2 Niraparib	2.686	680917	7289	1.11	4.6
3 Niraparib	2.689	682986	7142	1.09	4.5



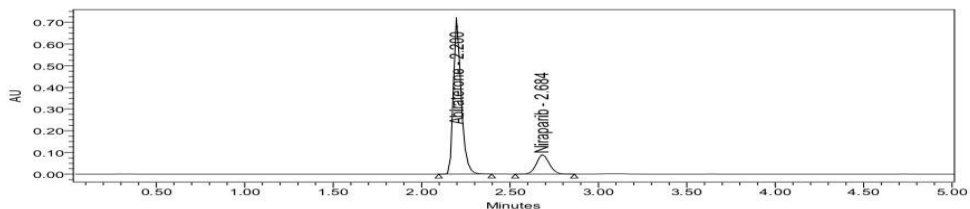
STD Report 1

SAMPLE INFORMATION

Sample Name:	Accuracy_100%_2,	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	21, 20, 22	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	13-08-2024 19:06:34 IST, 13-08-2024 19:12:21 IST, 13-08-2024 19:18:07 IST		
Date Processed:	15-08-2024 11:10:31 IST, 15-08-2024 11:10:38 IST, 15-08-2024 11:10:39 IST		



Reported by User: System Project Name: Abiraterone\_Niraparib  
 Report Method: STD\_Report\_1 Date Printed: 16-08-2024  
 Report Method ID: 1420 Page: 1 of 2 11:30:59 Asia/Calcutta



Peak Name: Abiraterone

Peak Name	RT	Area	USP Plate Count	USP Tailing
1 Abiraterone	2.200	4232949	12057	1.38
2 Abiraterone	2.200	4258247	11709	1.34
3 Abiraterone	2.200	4240384	10215	1.26

Peak Name: Niraparib

Peak Name	RT	Area	USP Plate Count	USP Tailing	USP Resolution
1 Niraparib	2.680	908912	6323	1.05	4.4
2 Niraparib	2.684	908942	6474	1.08	4.3
3 Niraparib	2.688	908574	7180	1.07	4.4

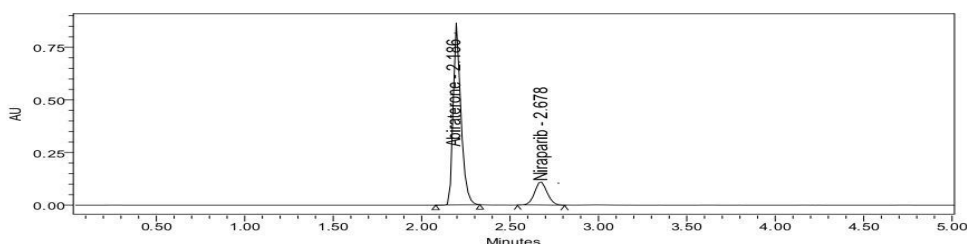
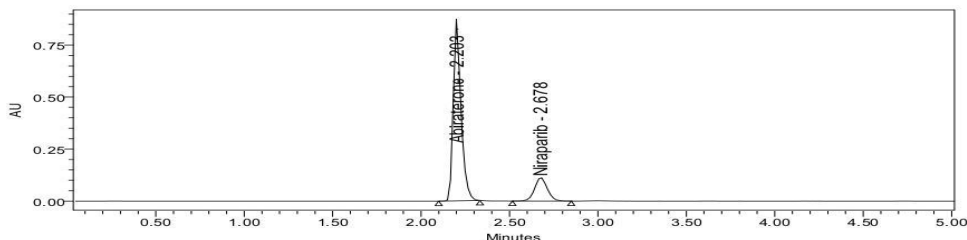
Reported by User: System Project Name: Abiraterone\_Niraparib  
 Report Method: STD\_Report\_1 Date Printed: 16-08-2024  
 Report Method ID: 1420 Page: 2 of 2 11:30:59 Asia/Calcutta



STD Report 1

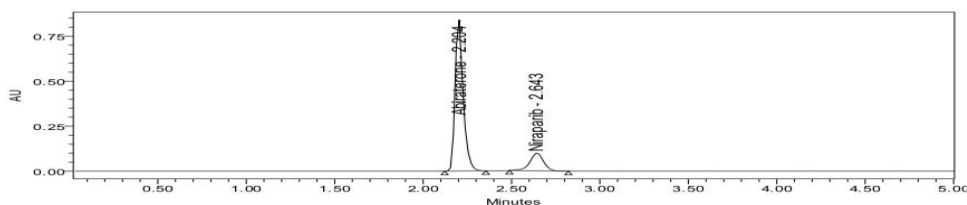
SAMPLE INFORMATION

Sample Name:	Accuracy_150%_1,	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	25, 24, 23	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	13-08-2024 19:23:53 IST, 13-08-2024 19:29:40 IST, 13-08-2024 19:35:43IST		
Date Processed:	15-08-2024 11:10:47 IST, 15-08-2024 11:11:06 IST, 15-08-2024 11:11:18 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420  
 Page: 1 of 2

Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:31:27 Asia/Calcutta



Peak Name: Abiraterone

Peak Name	RT	Area	USP Plate Count	USP Tailing
1 Abiraterone	2.186	5284191	11696	1.29
2 Abiraterone	2.203	5280298	9666	1.26
3 Abiraterone	2.204	5283451	10680	1.21

Peak Name: Niraparib

Peak Name	RT	Area	USP Plate Count	USP Tailing	USP Resolution
1 Niraparib	2.678	1136493	7476	1.87	4.3
2 Niraparib	2.643	1136020	6001	0.96	3.8
3 Niraparib	2.678	1131583	6773	1.04	4.3

Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420  
 Page: 2 of 2

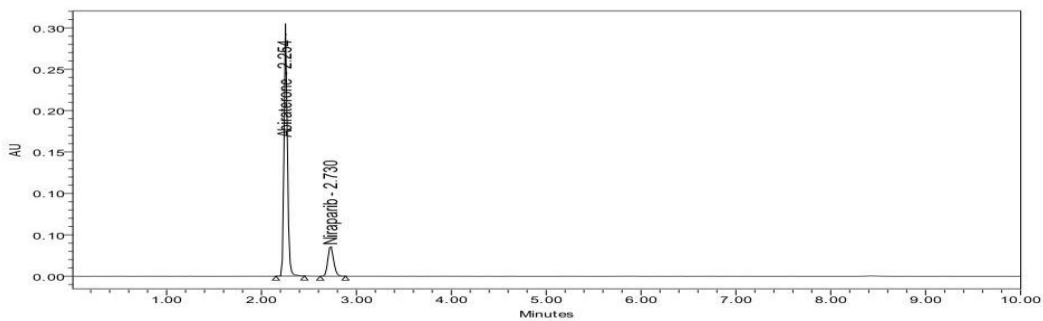
Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:31:27 Asia/Calcutta



Purity Report

SAMPLE INFORMATION

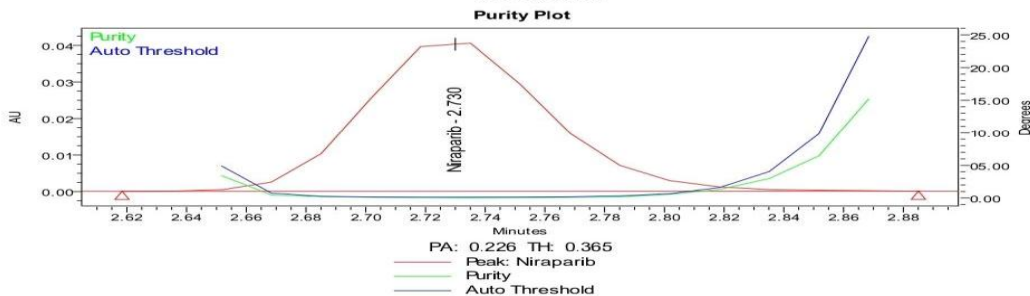
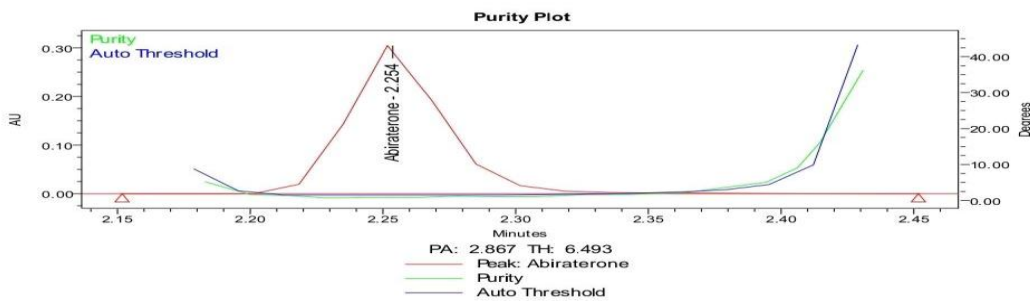
Sample Name:	Acid	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	28	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	10.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	14-08-2024 22:03:37 IST		
Date Processed:	15-08-2024 11:16:24 IST		



Peak Name	RT	Area	Purity1 Angle	Purity1 Threshold	USP Plate Count	USP Tailing	USP Resolution
1 Abiraterone	2.254	2114057	2.867	6.493	14985	1.1	
2 Niraparib	2.730	433087	0.226	0.365	9024	1.1	5.1

Reported by User: System  
 Report Method: Purity\_Report  
 Report Method ID: 1422  
 Page: 1 of 2

Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:36:21 Asia/Calcutta



Reported by User: System  
 Report Method: Purity\_Report  
 Report Method ID: 1422  
 Page: 2 of 2

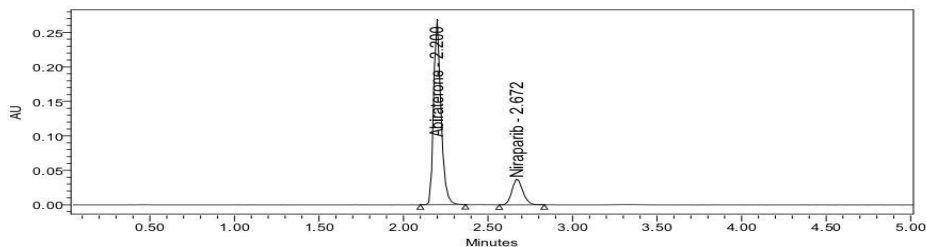
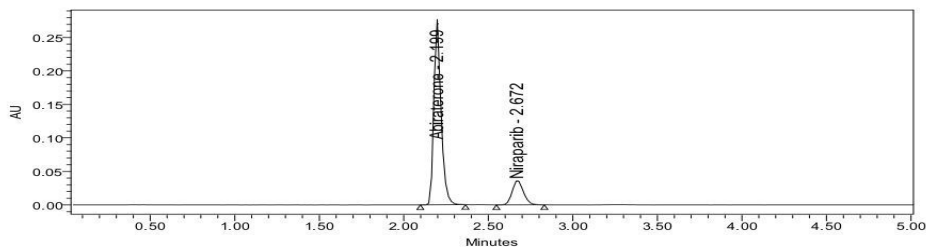
Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:36:21 Asia/Calcutta



STD Report 1

SAMPLE INFORMATION

Sample Name:	Linearity_75%	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	13	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1, 2	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	13-08-2024 18:03:15 IST, 13-08-2024 18:08:58 IST		
Date Processed:	15-08-2024 11:10:13 IST, 15-08-2024 11:10:14 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420

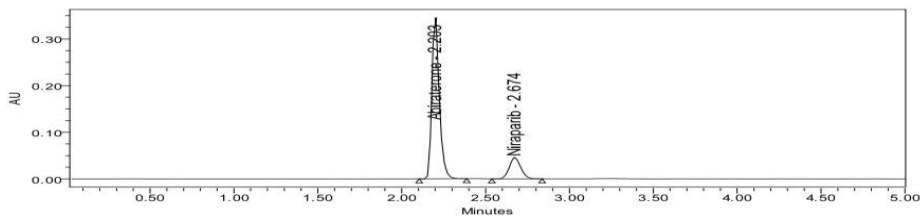
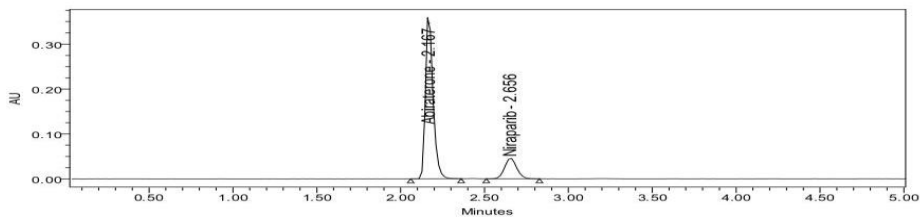
Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024



STD Report 1

SAMPLE INFORMATION

Sample Name:	Linearity_100%	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	14	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1, 2	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	13-08-2024 18:14:44 IST, 13-08-2024 18:20:29 IST		
Date Processed:	15-08-2024 11:10:15 IST, 15-08-2024 11:10:16 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420

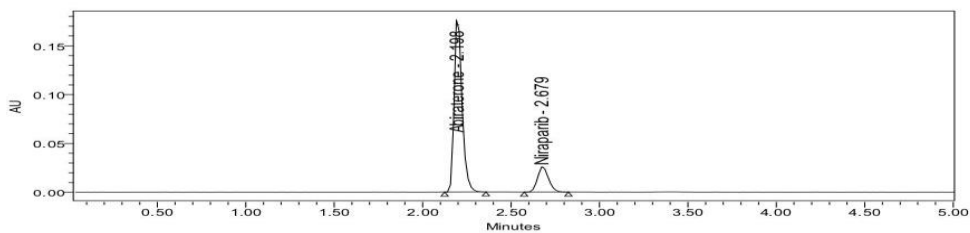
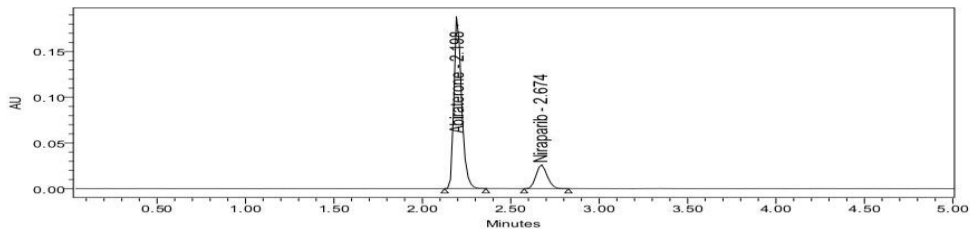
Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024



STD Report 1

SAMPLE INFORMATION

Sample Name:	Linearity_50%	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	12	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1, 2	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	FDA 260.0 nm
Date Acquired:	13-08-2024 17:51:45 IST, 13-08-2024 17:57:28 IST		
Date Processed:	15-08-2024 11:10:11 IST, 15-08-2024 11:10:12 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420  
 Page: 1 of 2

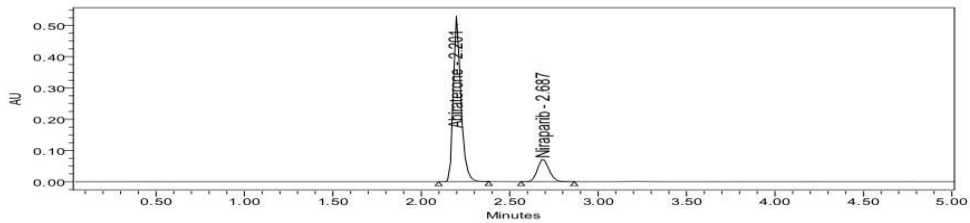
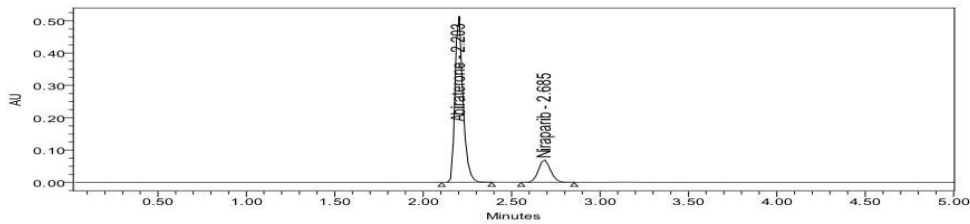
Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:29:29 Asia/Calcutta



STD Report 1

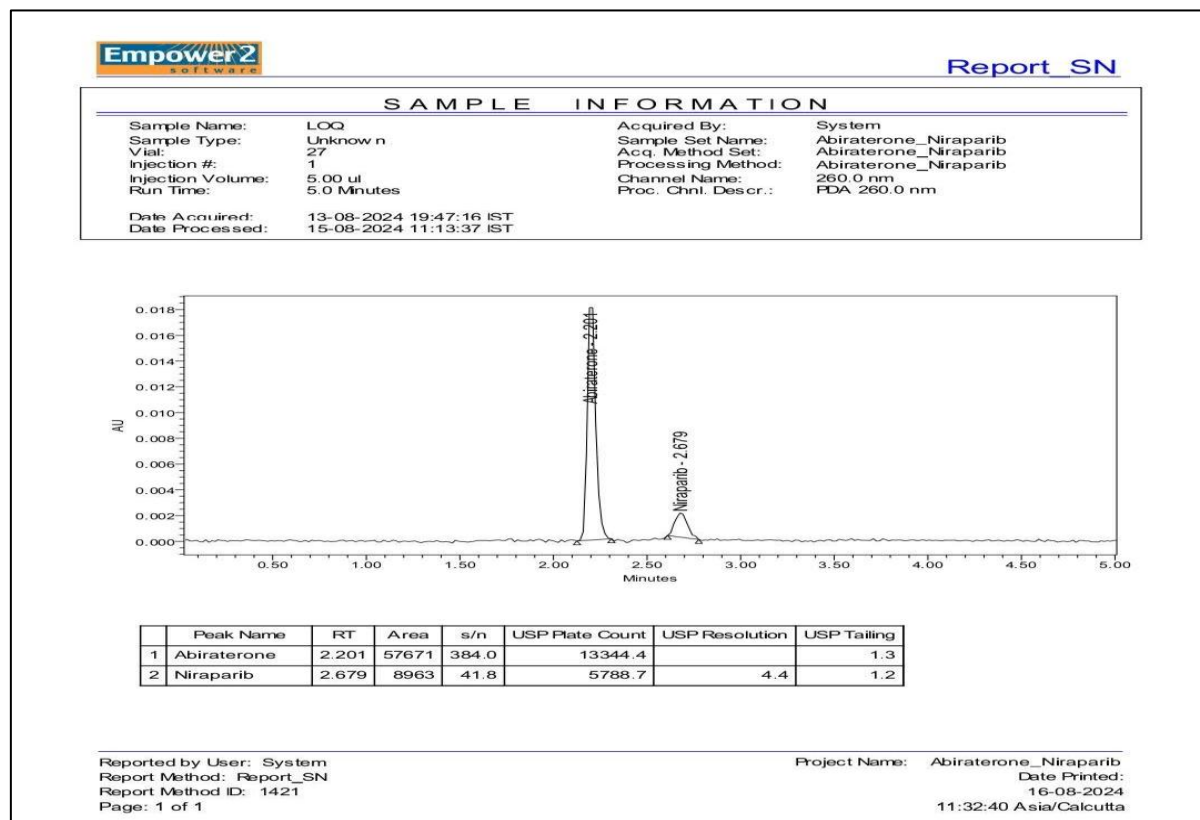
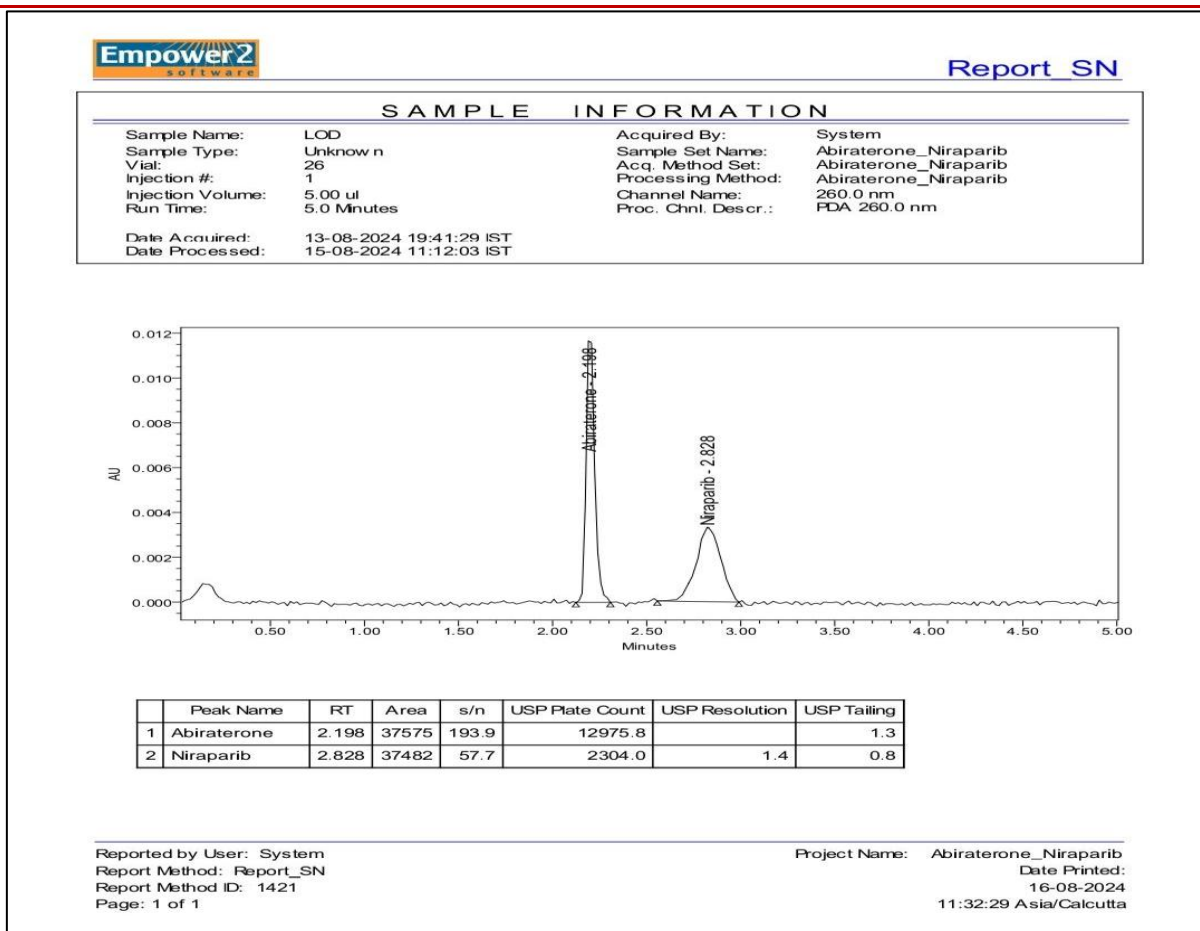
SAMPLE INFORMATION

Sample Name:	Linearity_150%	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	16	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1, 2	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	FDA 260.0 nm
Date Acquired:	13-08-2024 18:37:45 IST, 13-08-2024 18:43:27 IST		
Date Processed:	15-08-2024 11:10:27 IST, 15-08-2024 11:10:28 IST		



Reported by User: System  
 Report Method: STD\_Report\_1  
 Report Method ID: 1420

Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024

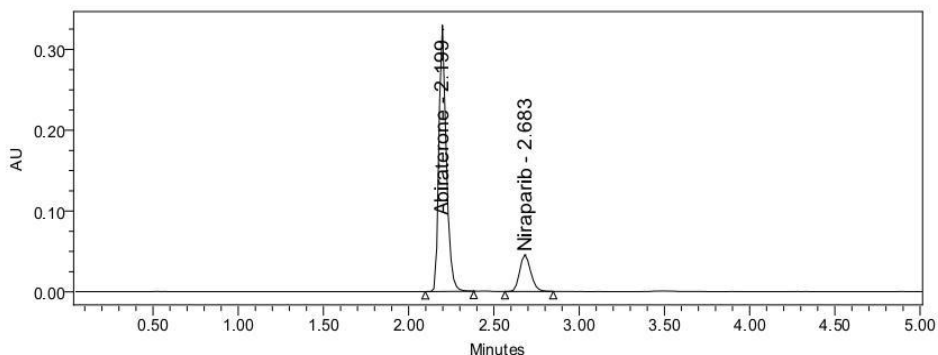
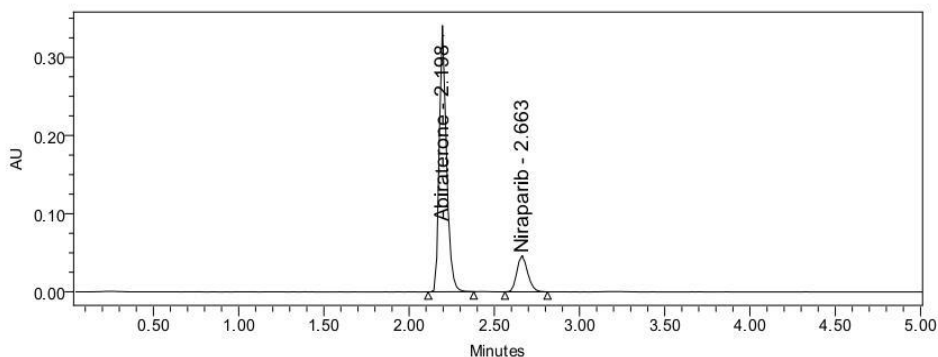




## STD\_Report

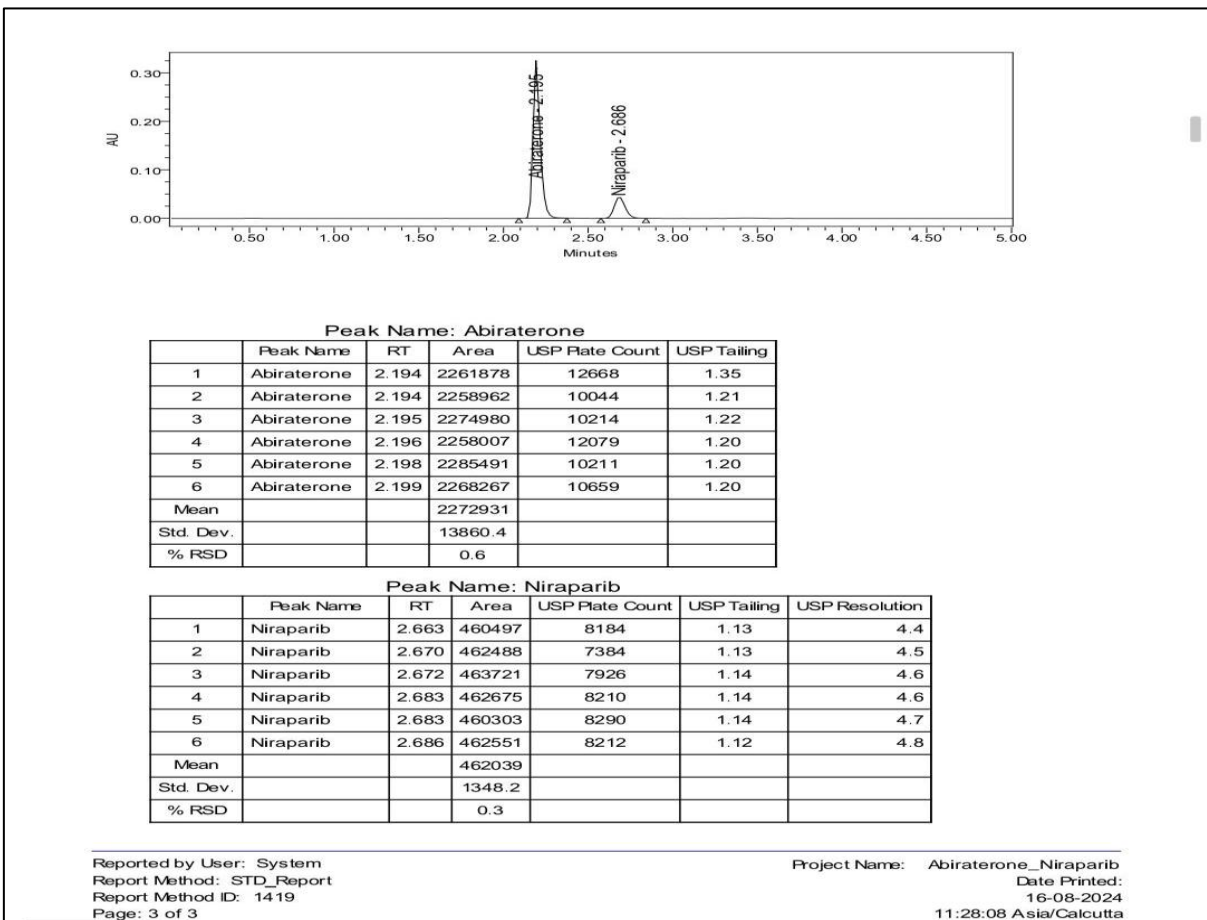
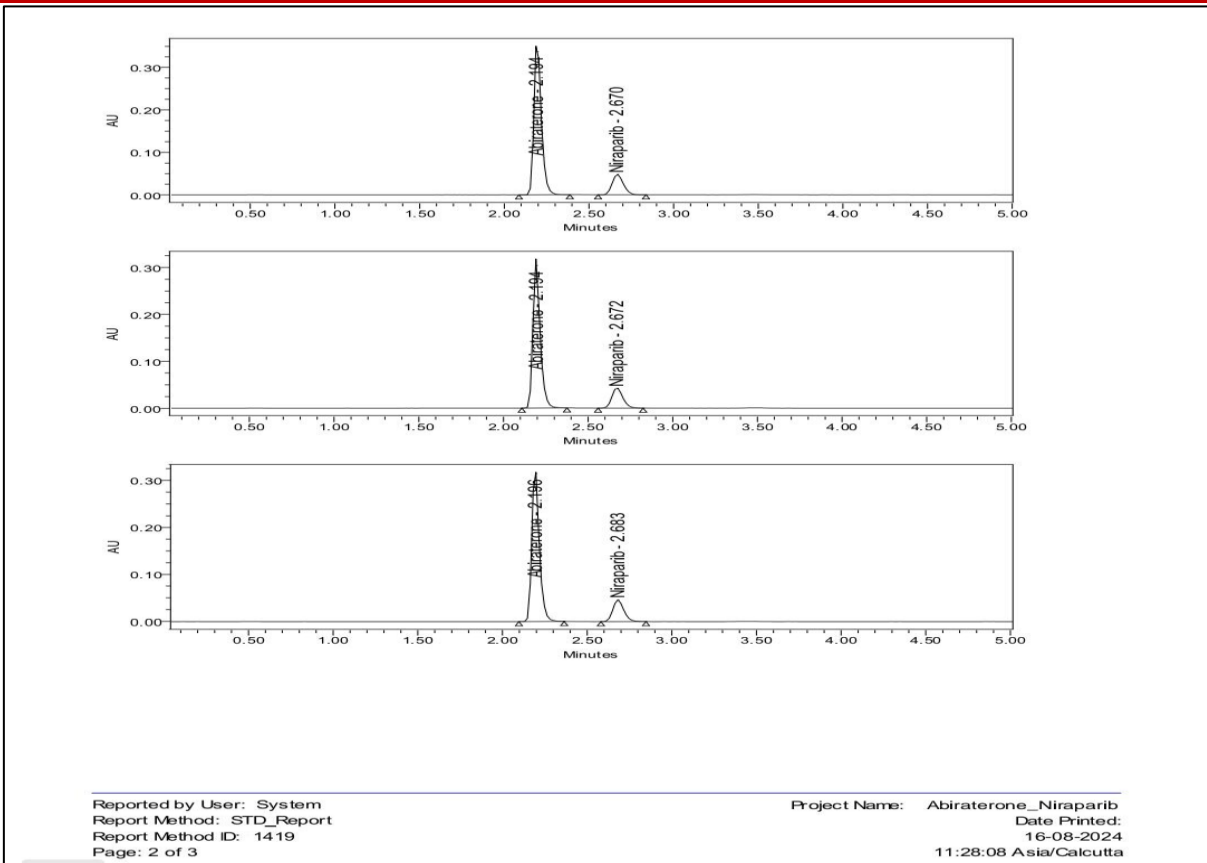
### SAMPLE INFORMATION

Sample Name:	Method Precision_1, Method	Acquired By:	System
Sample Type:	Unknown	Sample Set Name:	Abiraterone_Niraparib
Vial:	6, 8, 5, 7, 9, 4	Acq. Method Set:	Abiraterone_Niraparib
Injection #:	1	Processing Method:	Abiraterone_Niraparib
Injection Volume:	5.00 ul	Channel Name:	260.0 nm
Run Time:	5.0 Minutes	Proc. Chnl. Descr.:	PDA 260.0 nm
Date Acquired:	13-08-2024 16:59:43 IST, 13-08-2024 17:05:31 IST, 113-08-2024 17:11:18 IST		
Date Processed:	15-08-2024 11:09:31 IST, 15-08-2024 11:09:32 IST, 15-08-2024 11:09:33 IST		



Reported by User: System  
 Report Method: STD\_Report  
 Report Method ID: 1419  
 Page: 1 of 3

Project Name: Abiraterone\_Niraparib  
 Date Printed: 16-08-2024  
 11:28:08 Asia/Calcutta



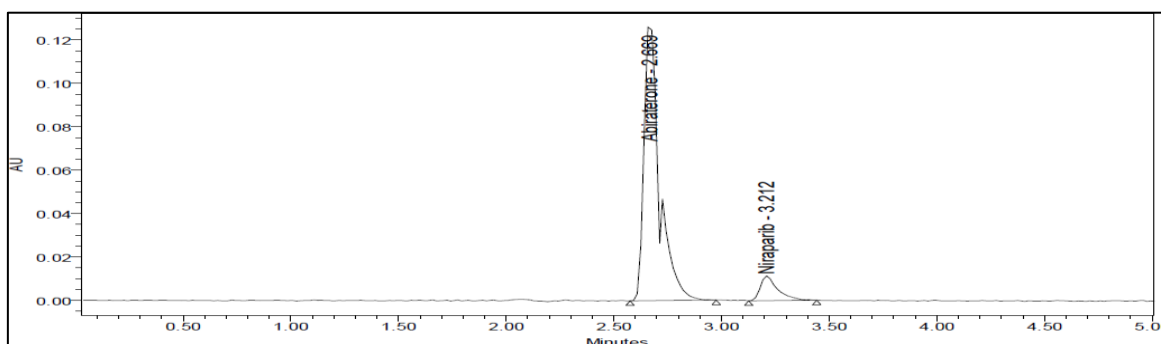
## RESULTS AND DISCUSSION

**Method development:** Method development was done by changing various, mobile phase ratios, buffers etc.

### Trial 1: Chromatographic conditions

<b>Mobile phase</b>	:	<b>Methanol: Water (50:50 v/v)</b>
Flow rate	:	1 ml/min
Column	:	BDS C18 (4.6 x 250mm, 5µm)
Detector wave length	:	260nm
Column temperature:	30°C	
Injection volume	:	10µL
Run time	:	5.0 min
Diluent	:	Water and Methanol in the ratio 50:50

**Results:** In this trail both peaks were eluted but Abiraterone peak were splinted so further trail was carried out.

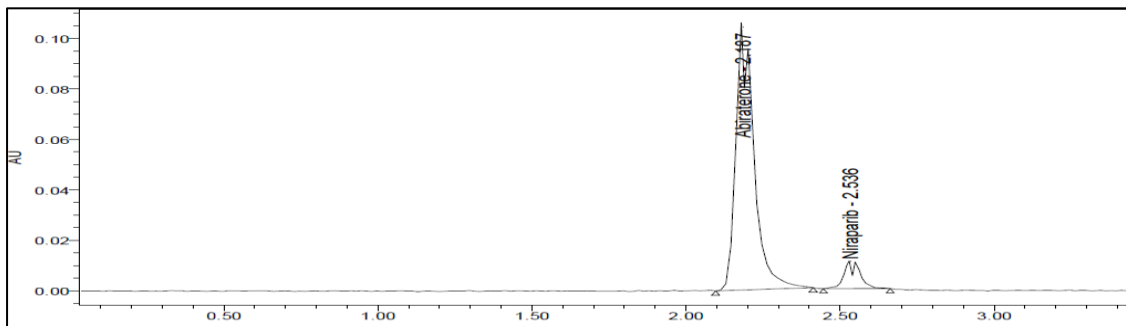


**Fig. 1: Trial chromatogram 1**

### Trial 2: Chromatographic conditions

<b>Mobile phase</b>	:	<b>Methanol: 0.1% Ortho phosphoric acid (50:50 v/v)</b>
Flow rate	:	1ml/min
Column	:	BDS C18 (4.6 x 250mm, 5µm)
Detector wave length	:	260nm
Column temperature:	30°C	
Injection volume	:	10µL
Run time	:	10.0 min
Diluent	:	Water and Methanol in the ratio (50:50)

**Results:** In this trail Niraparib peak was splinted, so further trail was carried out.



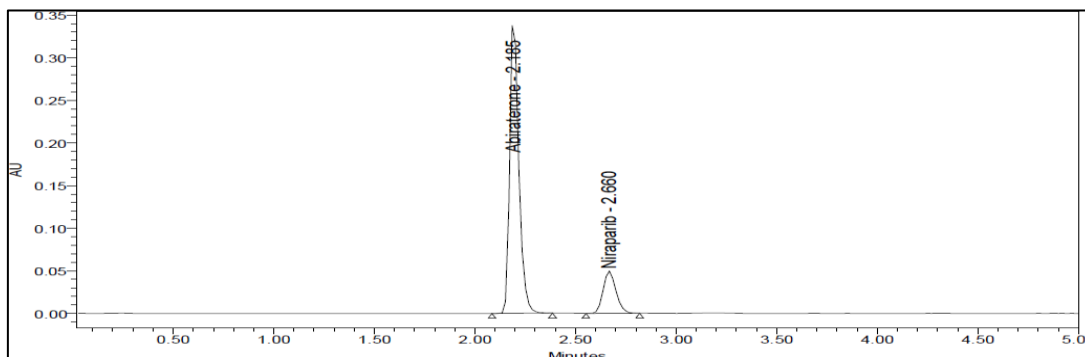
**Fig. 2: Trial chromatogram 2**

Optimized conditions:  
Chromatographic conditions:

Mobile phase: Water: 0.01N Potassium di hydrogen ortho phosphate (60:40 v/v)  
Flow rate: 1.0ml/min

Column: AgilentC18 (4.6mm x 150mm, 5µm) Detector  
 wave length: 260nm  
 Column temperature:3 0°CInjectionvol10µL  
 Run time:6 min  
 Diluent: Water and Acetonitrile in the ratio 50:50

**Results:** By changing Column as per ICH guidelines all the system suitability parameters are within the Limit and satisfactory. So this method was optimized.



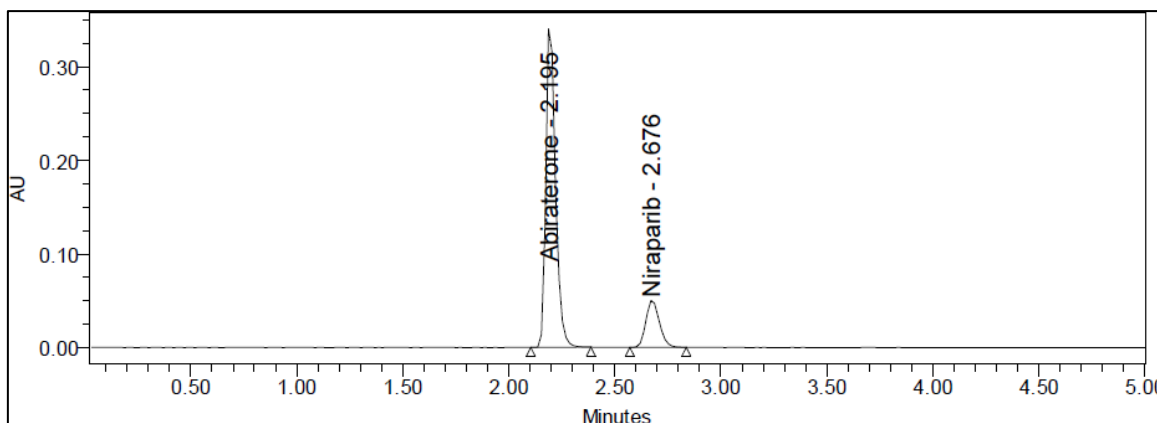
**Fig. 3: Optimized Chromatogram**

**Observation:** Abiraterone and Niraparib were eluted at 2.185 min and 2.660 min respectively with good resolution. Plate count and tailing factor was very satisfactory, so this method was optimized and to be

validated. System suitability: All the system suitability parameters were within the range and satisfactory as per ICH guidelines

**Table 1: System suitability parameters for Niraparib and Abiraterone**

S no	Abiraterone			Niraparib				
	Inj	RT(min)	USP Plate Count	Tailing	RT(min)	USP Plate Count	Tailing	Resolution
1		2.194	11818	1.33	2.669	7722	1.16	4.5
2		2.195	12365	1.36	2.671	7609	1.16	4.5
3		2.198	10971	1.19	2.676	8192	1.15	4.8
4		2.198	11368	1.28	2.681	8667	1.13	4.9
5		2.199	11208	1.19	2.682	9188	1.13	4.8
6		2.199	10146	1.18	2.686	9356	1.13	4.9

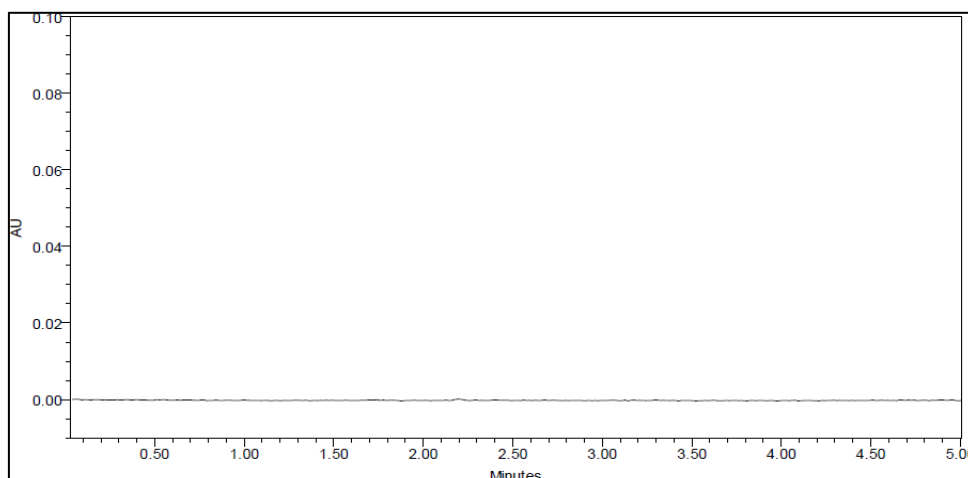


**Fig. 4: System suitability Chromatogram**

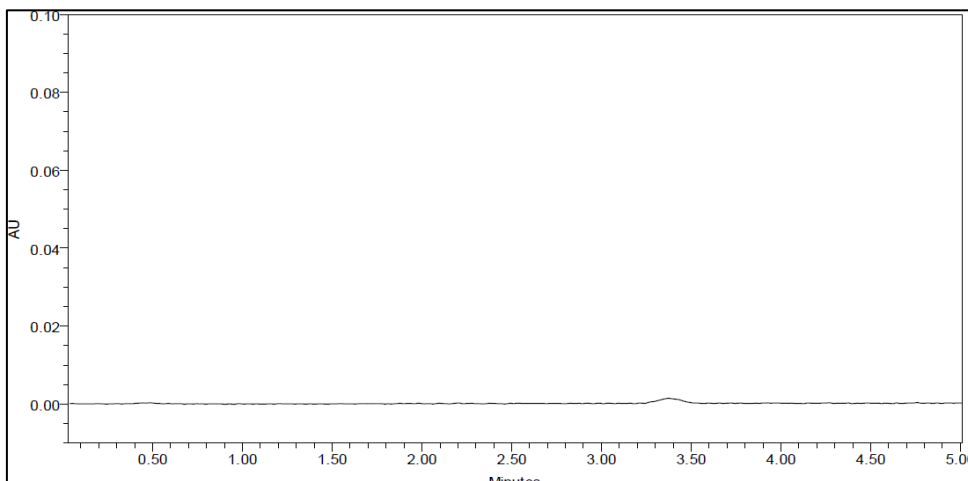
**Discussion:** According to ICH guidelines plate count should be more than 2000, tailing factor should be less than 2 and resolution must be more than 2. All the system

suitable parameters were passed and were within the limits.

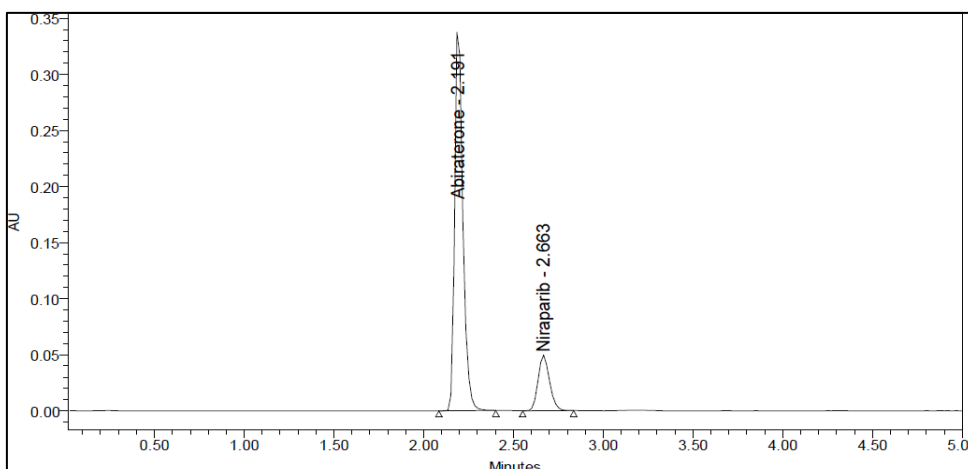
**Validation:  
Specificity:**



**Figure 5: Chromatogram of blank**



**Figure 6: Chromatogram of placebo**



**Figure 7: Typical Chromatogram**

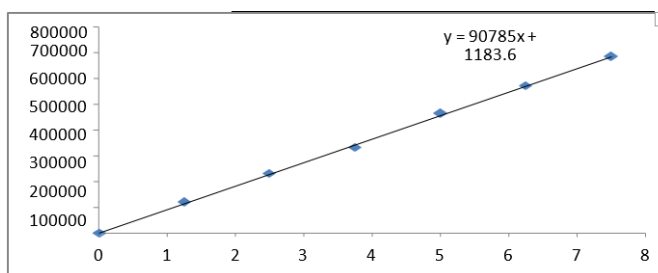
**Discussion:** Retention times of Abiraterone and Niraparib were 2.191 min and 2.663 min respectively. We

did not found and interfering peaks in blank and placebo at retention times of these drugs in this method. So this method was said to be specific.

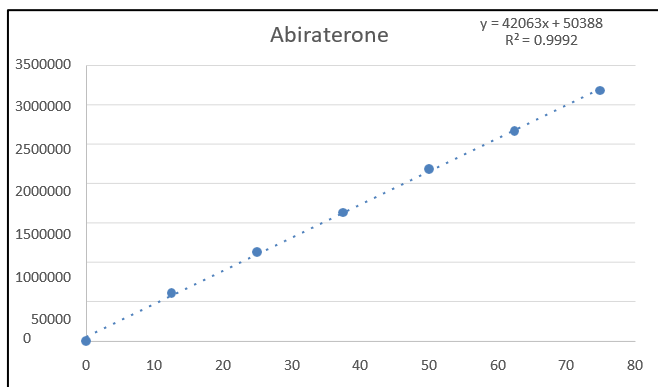
**Linearity:**

**Table 2: Linearity table for Niraparib and Abiraterone**

Niraparib		Abiraterone	
Conc (µg/mL)	Peak area	Conc (µg/mL)	Peak area
0	0	0	0
1.25	119859	12.5	604177
2.5	229145	25	1128119
3.75	329921	37.5	1629880
5	461200	50	2185959
6.25	568646	62.5	2665622
7.5	682611	75	3180394



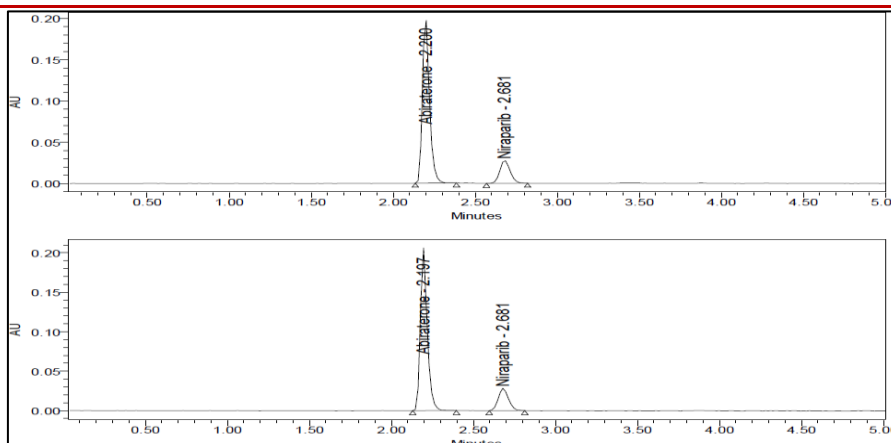
**Fig. 8: Calibration curve of Niraparib**



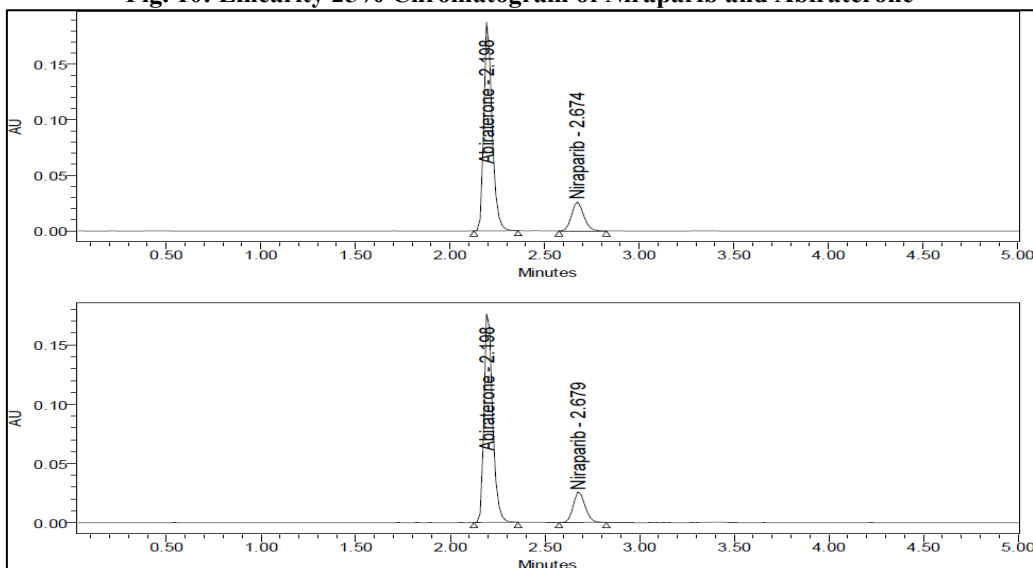
**Fig. 9: Calibration curve of Abiraterone**

**Discussion:** Six linear concentrations of Niraparib (1.25- 7.5µg/ml) and Abiraterone (12.5- 75µg/ml) were injected in a duplicate manner. Average areas were mentioned above and linearity equations obtained for

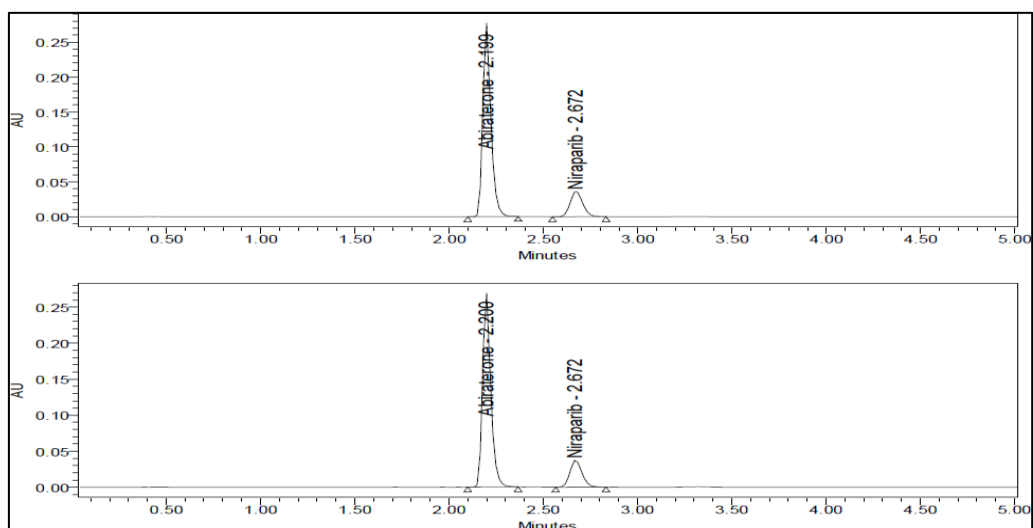
Niraparib was  $y = 42063x + 50388$ . and of Abiraterone was  $y = 90785x + 1183.6$  Correlation coefficient obtained was 0.999 for the two drugs.



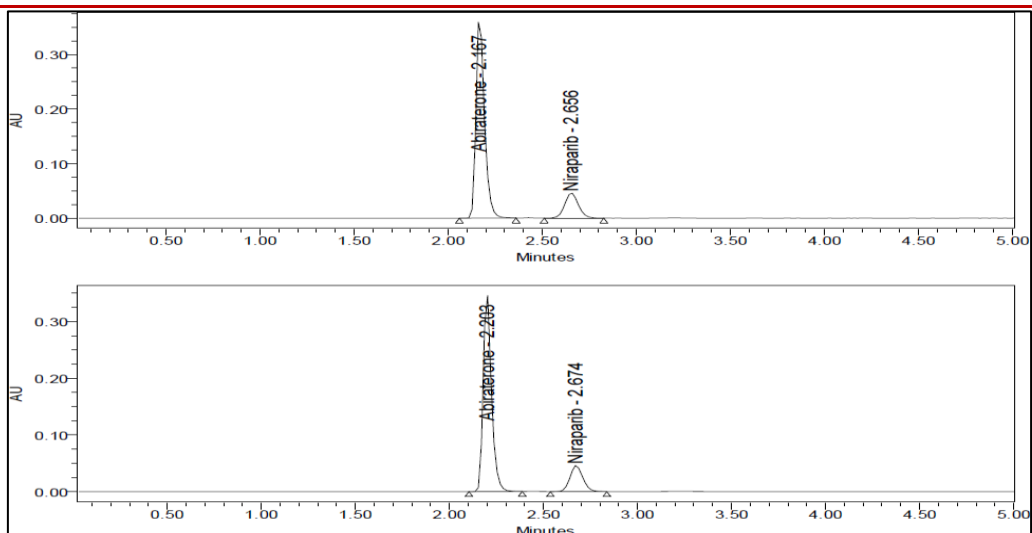
**Fig. 10: Linearity 25% Chromatogram of Niraparib and Abiraterone**



**Fig. 11: Linearity 50% Chromatogram of Niraparib and Abiraterone**



**Fig.12: Linearity 75% Chromatogram of Niraparib and Abiraterone**



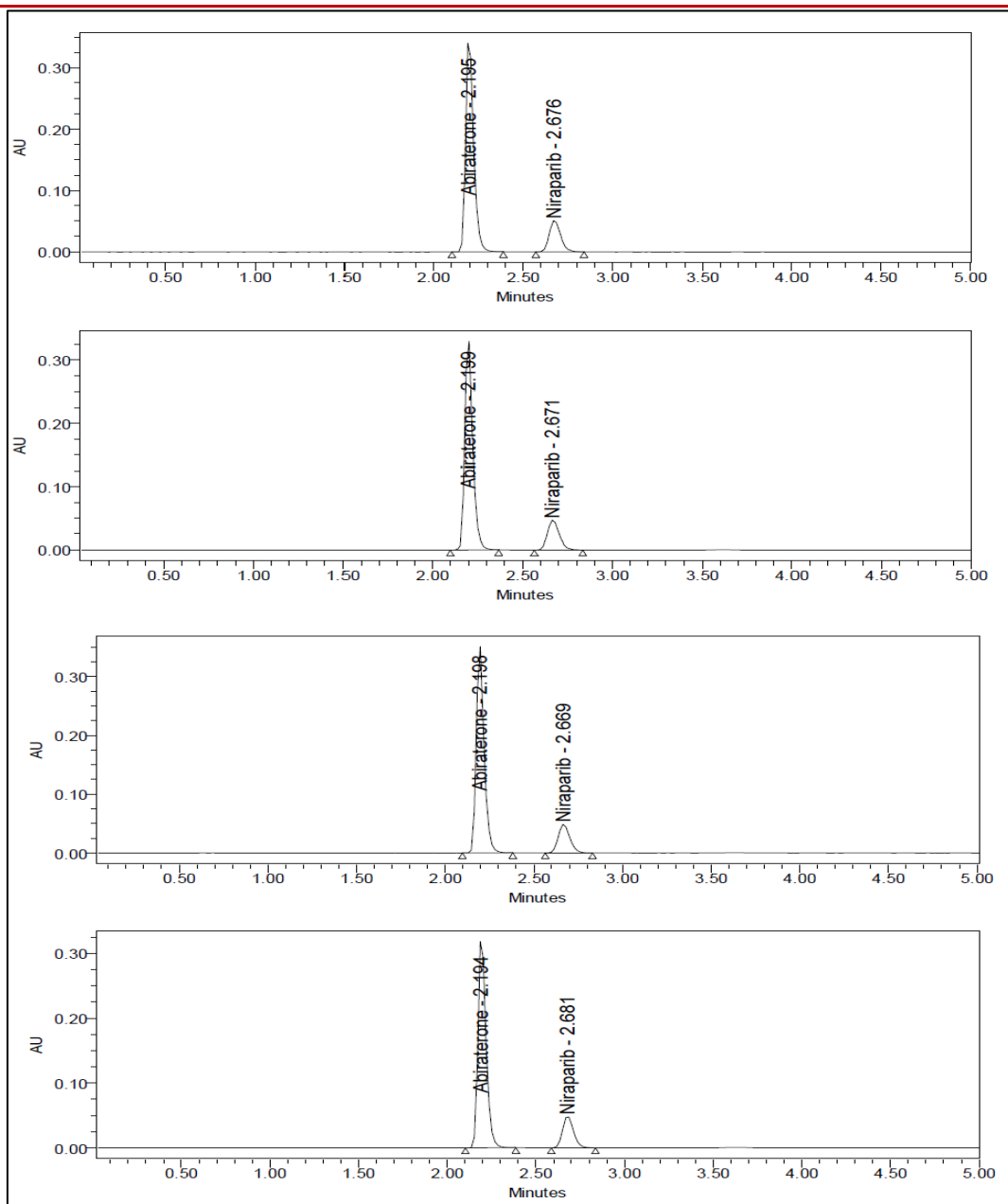
**Fig. 13: Linearity 100% Chromatogram of Niraparib and Abiraterone**

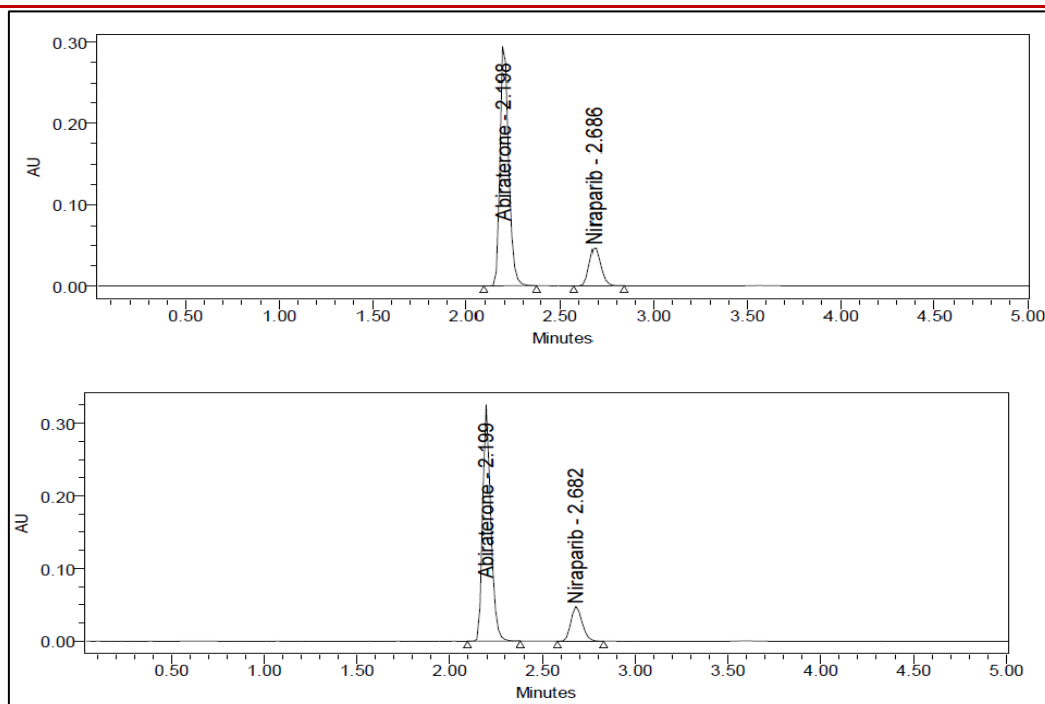
**Precision:**

**System Precision:**

**Table 3: System precision table of Niraparib and Abiraterone**

S. No	Area of Niraparib	Area of Abiraterone
1.	466756	2280894
2.	464105	2267152
3.	462548	2281516
4.	464530	2269722
5.	471866	2272854
6.	460692	2282024
Mean	465083	2275694
S.D	3893.0	6598.5
%RSD	0.8	0.3





**Fig. 14: System precision chromatogram**

**Discussion:** From a single volumetric flask of working standard solution six injections were given and the obtained areas were mentioned above. Average area, standard deviation and % RSD were calculated for two drugs. % RSD obtained as 0.8% and 0.3% respectively for Niraparib and Abiraterone. As the limit of Precision was less than  $\pm 2\%$  the system precision was passed in this method.

**Assay:** ANNOVERA, bearing the label claim Niraparib 50mg, Abiraterone 500mg. Assay was performed with the above formulation. Average % Assay for Niraparib and Abiraterone obtained was 99.31% and 99.31% respectively

**Table 4: Assay Data of Niraparib**

S.no	Standard Area	Sample area	% Assay
1	466756	460497	98.91
2	464105	462488	99.34
3	462548	463721	99.61
4	464530	462675	99.38
5	471866	460303	98.87
6	460692	462551	99.36
Avg	465083	462039	99.25
Stdev	3893.0	1348.2	0.29
%RSD	0.8	0.3	0.29

**Table 5: Assay Data of Abiraterone**

S.no	Standard Area	Sample area	% Assay
1	2280894	2261878	99.19
2	2267152	2258962	99.07
3	2281516	2274980	99.77
4	2269722	2258007	99.02
5	2272854	2285491	100.23
6	2282024	2248267	98.60
Avg	2275694	2264598	99.31
Stdev	6598.5	13368.7	0.586
%RSD	0.3	0.6	0.6

**Summary:****Table 6: Summary Table**

Parameters		Niraparib	Abiraterone	LIMIT
Linearity Range( $\mu\text{g/ml}$ )		1.25-7.5 $\mu\text{g/ml}$	25.75-154.5 $\mu\text{g/ml}$	R < 1
Regression coefficient		0.999	0.999	
Slope(m)		90785	42063	
Intercept(c)		1183.6	50388	
Regression equation ( $Y=mx+c$ )		$y = 90785x + 1183.6$	$y = 42063x + 50388$	
Assay (% mean assay)		99.25%	99.31%	90-110%
Specificity		Specific	Specific	No interference of any peak
System precision % RSD		0.8	0.3	NMT 2.0%
Method precision % RSD		0.3	0.6	NMT 2.0%
Accuracy % recovery		99.60%	99.09%	98-102%
LOD		0.03	0.26	NMT 3
LOQ		0.08	0.80	NMT 10
Robustness	FM	1.2	0.9	% RSD NMT 2.0
	FP	1.2	0.4	
	MM	0.2	0.4	
	MP	0.6	0.5	
	TM	0.4	0.9	
	TP	0.3	0.3	

**CONCLUSION**

A simple, Accurate, precise method was developed for the simultaneous estimation of the Abiraterone and Niraparib in tablet dosage form. Retention time of Abiraterone and Niraparib were found to be 2.185 min and 2.660min. %RSD of the Abiraterone and Niraparib were and found to be 0.6 and 0.3 respectively. %Recovery was obtained as 99.09% and 99.60% for Abiraterone and Niraparib respectively. LOD, LOQ values obtained from regression equations of Abiraterone and Niraparib were 0.26, 0.80 and 0.03, 0.08 respectively. Regression equation of Niraparib is  $y = 90785x + 1183.6$  and  $y = 42063x + 50388$  of Abiraterone. Retention times were decreased and that run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

**REFERENCES**

- B.k Sharma, Instrumental methods of chemical analysis, Introduction to analytical chemistry, 23rd Edition Goel publication, Meerut, (2007)
- Lindholm. J, Development and Validation of HPLC Method for Analytical and Preparative purpose. Acta Universitatis Upsaliensis, pg. 13-14, (2004). Rashmin, An introduction to analytical Method Development for Pharmaceutical formulations. Indoglobal Journal of Pharmaceutical Sciences, Vol.2, Issue 2, Pg 191-196 (2012).
- Malvia R, Bansal V, Pal O.P and Sharma P.K. A Review of High Performance Liquid Chromatography. Journal of Global Pharma technology (2010)
- Douglas A Skoog, F. James Holler, Timothy A. Niemen, Principles of Instrumental Analysis Pg 725-760.
- Dr.S. Ravi Shankar, Text book of Pharmaceutical analysis, Fourth edition, Pg 13.1-13.2
- David G. Watson. Pharmaceutical Analysis, A text book for Pharmacy students and Pharmaceutical Chemists. Harcourt Publishers Limited; 2nd Ed., Pg 221-232.
- Remington's The Sciences and Practice of Pharmacy, 20th Edition (2000) Connors Ka. A Textbook of Pharmaceutical Analysis, Wiley inter sciences Inc; Delhi, 3rd Ed, Pg 373-421, (1994)
- Gurdeep R. Chatwal, Sham K. Anand, Instrumental Methods of Chemical Analysis, Pg 2.566-2.638 (2007)
- David G. Watson Pharmaceutical Analysis, A text book for pharmacy students and Pharmaceutical Chemists. Harcourt Publishers Limited; 2nd Ed., Pg-267-311
- Nasal. A, Siluk. D, and Kaliszan. R. Chromatographic Retention Parameters in Medicinal Chemistry and Pharmacology, Pubmed, Vol.10, Issue 5 Pg no-381-426, March (2003)
- Green JM. A Practical guide to analytical method validation, Anal Chem (1996) 305A-309A
- ICH, Validation of analytical procedures: Text and Methodology. International Conference on Harmonization, ICH, Geneva, (1996)
- Ewelina rutkowska, Karolina paj k and Krzysztof Jlewiak\* Lipophilicity – Methods of determination and its role in medicinal chemistry Acta Poloniae Pharmaceutica n Drug Research, Vol. 70 No.1 pp. 3n18, (2013).
- IUPAC. Compendium of Chemical Terminology, 2nd edn. (The Gold Book). PAC69, 1137 (1997). Glossary of terms used in computational drug design (IUPAC Recommendations.
- K. D. Tripathi, Essentials of Medical Pharmacology, 6th Edition, Jaypee brother's medical publishers (P) LTD, p-254-255.