STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF TALAZOPARIB IN BULK FORM AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A novel, simple, specific, accurate, precise method development and validated for the estimation of Talazoparib by RP-HPLC in bulk and marketed formulation. A High-Performance Liquid Chromatography WATERS Alliance 2695 separation module, Software: Empower 2, 996 PDA Detector with Inertsil ODS C18 (4.6mm x 250mm, 5µm) column, with mobile phase composition of Methanol: Acetate Buffer (pH-4.2) (40:60% v/v) was used. The flow rate of 1.0 ml min-1 and effluent was detected at 225 nm. The retention time of Talazoparib was 3.388 minutes. Linearity was observed over concentration range of 60-140ng ml-1. The Limit of detection and limit of quantification was found to be 1.5ng ml-1 and 4.5ngml-1 respectively. The accuracy of the proposed method was determined by recovery studies and found to be 98% to 102%. Then method was validated in terms of linearity, accuracy, precision, (repeatability, intermediate precision) specificity (by assay), robustness and system suitability. Thus, the validated method is can be successfully applied to routine analysis for regulate the quality. It also should be used for analytical research purpose.

Keywords: *Talazoparib, RP-HPLC, Method Development, Validation, ICH Guidelines.*

INTRODUCTION

Talazoparib was approved by the FDA for use in germline BRCA mutated, HER2 negative, locally advanced or metastatic breast cancer on October 16, 2018 under the trade name Talzenna 3. Talzenna was granted approval based on the results of the EMBRACA trial in which Talazoparib resulted in a mean 8.6 months progression-free survival time versus physician's choice chemotherapy which resulted in 5.6 months progression-free survival. Talazoparib is an orally bioavailable inhibitor of the nuclear enzyme poly (ADP-ribose) polymerase (PARP) with potential antineoplastic activity. Talazoparib selectively binds to PARP and prevents PARP-mediated DNA repair of single strand DNA breaks via the base-excision repair pathway. This enhances the accumulation of DNA strand breaks, promotes genomic instability and eventually leads to apoptosis. PARP catalyzes post-translational ADP-ribosylation of nuclear proteins that signal and recruit other proteins to repair damaged DNA and is activated by single-strand DNA breaks. The IUPAC Name of the Talazoparib is (11S,12R)-7-fluoro-11-(4-fluorophenyl)-12-(2-methyl-1,2,4-triazol-3-yl)-2,3,10-triazatricyclo[7.3.1.05,13]trideca-1,5(13),6,8-tetraen-4-one. The chemical structure of Talazoparib as follows

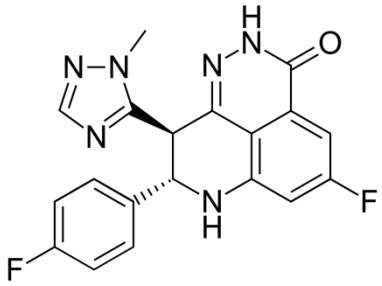

Fig-1: Chemical Structure of Talazoparib

EXPERIMENTAL

INSTRUMENTS USED

Table-1: Instruments used

S.No.	Instruments and Glass wares	Model
1	HPLC	WATERS, software: Empower 2, Alliance 2695 separation module. 996 PDA detector.
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	Enertech

CHEMICALS USED:

Table-2: Chemicals used

S.No.	Chemical	Brand Names
1	Talazoparib	Sura labs
2	Water and Methanol for HPLC	LICHROSOLV (MERCK)
3	Acetonitrile for HPLC	Merck

HPLC METHOD DEVELOPMENT:

Preparation of standard solution: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7ml of Methanol then sonicate to dissolve and removal of air completely and make volume up to the mark with Methanol. Further pipette 1ml of the above Talazoparib 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.

Mobile Phase Optimization: Initially the mobile phase tried was methanol: Water and Acetonitrile and water with varying proportions. Finally, the mobile phase was optimized to Methanol and Acetate Buffer in proportion 40:60 v/v respectively.

Optimization of Column: The method was performed with various C18 columns like ODS column, Xterra and AltimaC18 column. Inertsil ODS C18 (4.6mm x 250mm, 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 Acetate buffer (pH-4.2): Prepare 800 mL of distilled water in a suitable container. Add 2.593 g of Sodium Acetate (anhydrous) to the solution or Add 4.106 g of Acetic Acid to the solution. Adjust solution to final desired pH 4.2 using HCl or NaOH Add distilled water until volume is 1 L.

Preparation of mobile phase: Accurately measured 400 ml (40%) of Methanol and 600 ml of Acetate Buffer (60%) were mixed and degassed in a digital ultrasonicator for 10 minutes and then filtered through 0.45 µm filter under vacuum filtration.

Diluent Preparation: The Mobile phase was used as the diluent.

METHOD VALIDATION PARAMETERS

SPECIFICITY:

Preparation of Standard Solution: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7ml of diluent. Then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 1ml of the above Talazoparib stock solutions into a 10ml

volumetric flask and dilute up to the mark with diluents. 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.

Preparation of Sample Solution: Take average weight of Tablet and crush in a mortar by using pestle and weight 10 mg equivalent weight of Talazoparib sample into a 10mL clean dry volumetric flask and add about 7mL of Diluent sonicate to dissolve it completely and make volume up to the mark with the same solvent. Further pipette 1ml of the above Talazoparib stock solutions into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure: Inject the three replicate injections of standard and sample solutions and calculate the assay by using formula:

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

LINEARITY: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluent then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Preparation of Level – I (60 ppm of Talazoparib): Pipette out 0.6ml of stock solution in to 10ml of volumetric flask and make the volume up to mark with diluent.

Preparation of Level – II (80 ppm of Talazoparib): Pipette out 0.8ml of stock solution in to 10ml of volumetric flask and make the volume up to mark with diluent.

Preparation of Level – III (100 ppm of Talazoparib): Pipette out 1ml of stock solution in to 10ml of volumetric flask and make the volume up to mark with diluent.

Preparation of Level – IV (120 ppm of Talazoparib): Pipette out 1.2ml of stock solution in to 10ml of volumetric flask and make the volume up to mark with diluent.

Preparation of Level – V (140 ppm of Talazoparib): Take 1.4ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Procedure: Inject each level into the chromatographic system and measure the peak area. Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient.

PRECISION

REPEATABILITY

Preparation of Talazoparib Product Solution for Precision: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7ml of diluent then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Pipette out 1ml of stock solution in to 10ml of volumetric flask and make the volume up to 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.

INTERMEDIATE PRECISION:

To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different days by maintaining same conditions.

Procedure:

DAY 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.

DAY 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 50% Standard stock solution: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7mL of diluent. Then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.5ml of the above Talazoparib 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 Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7mL of diluent. Then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further Pipette out 1ml of stock solution in to 10ml of volumetric flask and make the volume up to mark with diluent.

For preparation of 150% Standard stock solution: Accurately weigh and transfer 10 mg of Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7mL of diluent. Then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 1.5ml of the above Talazoparib stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Procedure: 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 Talazoparib 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 Talazoparib working standard into a 10ml of clean dry volumetric flasks add about 7mL of diluent. Then sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 1ml of the above Talazoparib 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 0.9ml/min and 1.1ml/min instead of 1.0ml/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. 45:55 and 35:65 of Methanol: Acetate Buffer instead of (40:60 v/v). Then 10µl of the above sample was injected twice and chromatograms were recorded.

STABILITY STUDIES

The specificity of the method can be demonstrated by applying stress conditions using acid, alkaline, peroxide, thermal, UV degradations. The sample was exposed to these conditions the main peak of the drug was studied for peak purity that indicating the method effectively separated the degradation products from the pure active ingredient.

Acid Degradation Studies: To 1 ml of Talazoparib stock, 1 ml of 2N HCl was added and refluxed for 30 min at 60 ºC. The resultant solution was neutralized with 1 ml 2N NaOH and makeup to final volume to obtain (100µg/mL) solution. Cool the solution to room temperature and filtered with 0.45µm membrane filter. A sample of 10µl was injected into the HPLC system, and the chromatograms were recorded to assess the stability of the sample.

Alkali Degradation Studies: To 1 ml of stock solution of Talazoparib 1 ml of 2N sodium hydroxide was added and refluxed for 30 min at 60 ºC. The resultant solution was neutralized with 1 ml 2N HCl and makeup to final volume to obtain (100µg/mL) solution. Cool the solution to room temperature and filtered with 0.45µm membrane filter. The sample of 10µl was injected into the system, and the chromatograms were recorded to an assessment of sample stability.

Oxidation Degradation Studies: To 1 ml of stock solution of Talazoparib 1 ml of 20% hydrogen peroxide (H2O2) was added separately. The solution was kept for 30 min at 60ºC. For HPLC study, the resultant solution was diluted to obtain (100µg/mL) solution. Cool the solution to room temperature and filtered with 0.45µm membrane filter. A sample of 10µl solution was injected into the system, and the chromatograms were recorded to assess the stability of the sample.

Dry Heat Degradation Studies: The 1 ml of Talazoparib drug solution was placed in the oven at 60ºC for 6h to study dry heat degradation. For HPLC study, the resultant solution was makeup to final volume to obtain (100µg/mL) solution. Cool the solution to room temperature and filtered through a 0.45µm membrane filter. A sample of 10µl solution was injected into the system, and the chromatograms were recorded for the assessment of sample stability.

Photo Degradation Studies: The photo stability of the Talazoparib was studied by exposing the stock solution to UV light for 1day or 200Watt-hours/m2 in photo stability chamber. For HPLC study, the resultant solution was diluted to obtain (100µg/mL) solution and filtered with 0.45µm membrane filter. A sample of 10µl solution was injected into the system, and the chromatograms were recorded for the assessment of sample stability.

RESULTS AND DISCUSSION

METHOD DEVELOPMENT

Optimized Chromatographic Conditions:

Mobile phase ratio : Methanol: Acetate Buffer (pH-4.2) (40:60 v/v)

Column : Inertsil ODS C18 (4.6mm x 250mm, 5µm)

Column temperature : 35ºC
Wavelength : 225nm
Flow rate : 1.0ml/min
Injection volume : 10µL
Run time : 10min

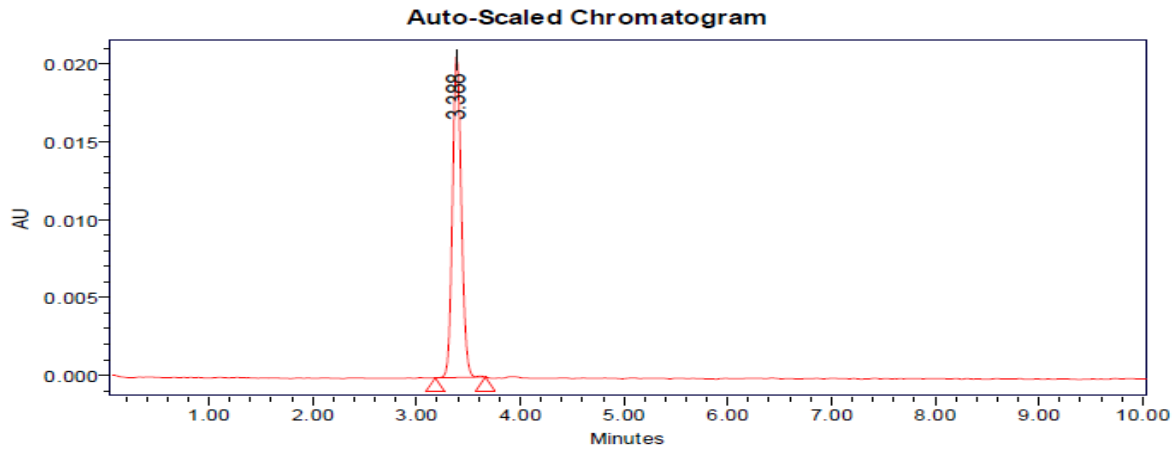

Fig-2: Optimized Chromatogram

Table-3: Results of Optimized Chromatogram

S.No.	Name	RT	Area	Height	USP Tailing	USP Plate Count
1	Talazoparib	3.388	145867	32546	1.76	8457

METHOD VALDATION:

System Suitability:

Table-4: Results of System Suitability for Talazoparib

S. No	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Talazoparib	3.398	145965	32653	8475	1.78
2	Talazoparib	3.324	146857	32785	8495	1.79
3	Talazoparib	3.349	145985	32598	8492	1.80
4	Talazoparib	3.388	146697	32695	8463	1.76
5	Talazoparib	3.364	145982	32675	8458	1.77
Mean			146380.25			
Std. Dev.			462.762			
% RSD			0.316137			

SPECIFICITY:

Table-5: Peak results for assay standard

S.No	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Talazoparib	3.379	145857	32654	8546	1.76
2	Talazoparib	3.303	145874	32587	8574	1.77
3	Talazoparib	3.322	145685	32564	8759	1.76
4	Talazoparib	3.327	145876	32854	8598	1.76
5	Talazoparib	3.310	145682	32415	8564	1.77
Mean			145794.8			
Std. Dev.			101.8759			
% RSD			0.069876			

Table-6: Peak results for Assay sample

S.No.	Name	RT	Area	Height	USP Tailing	USP Plate Count	Injection
1	Talazoparib	3.310	146425	32658	1.78	8457	1
2	Talazoparib	3.398	146874	32547	1.77	8495	2
3	Talazoparib	3.388	146524	32658	1.78	8475	3

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

The % purity of Talazoparib in pharmaceutical dosage form was found to be 99.57%.

LINEARITY:

CHROMATOGRAPHIC DATA FOR LINEARITY STUDY:

Table-7: Chromatographic Data for Linearity Study

Concentration µg/ml	Average Peak Area
60	85784
80	112564
100	139867
120	165248
140	189586

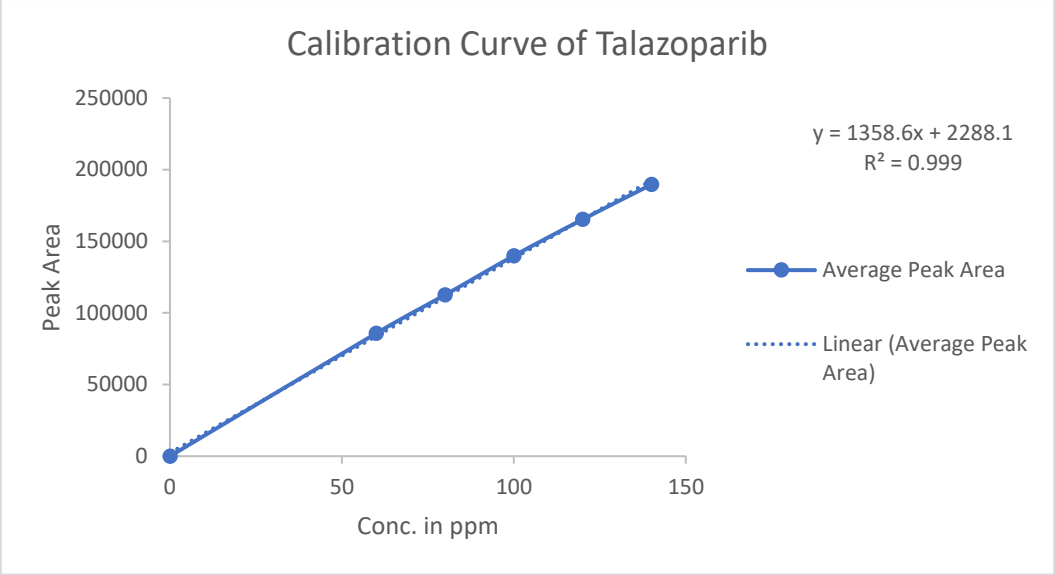

Fig-3: Calibration Curve of Talazoparib

PRECISION:

REPEATABILITY:

Table-8: Results of repeatability for Talazoparib:

S. No.	Peak name	Retention time	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Talazoparib	3.397	145865	32652	8547	1.78
2	Talazoparib	3.390	145874	32541	8498	1.78
3	Talazoparib	3.384	145842	32564	8547	1.77
4	Talazoparib	3.378	145869	32548	8572	1.77
5	Talazoparib	3.364	145265	32569	8569	1.78
Mean			145743			
Std. Dev			267.4911			
%RSD			0.183536			

Intermediate precision:

Day 1:

Table-9: Results of Intermediate precision for Talazoparib

S.No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Talazoparib	3.371	147856	32685	8569	1.79
2	Talazoparib	3.376	147584	32654	8574	1.79
3	Talazoparib	3.382	147965	32685	8654	1.78

4	Talazoparib	3.359	147523	32654	8542	1.79
5	Talazoparib	3.333	147854	32689	8571	1.78
6	Talazoparib	3.341	147856	32784	8534	1.79
Mean			147773			
Std. Dev.			176.3088			
% RSD			0.119311			

Day 2:

Table-10: Results of intermediate precision Day 2for Talazoparib

S.No	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Talazoparib	3.310	146589	35254	8569	1.79
2	Talazoparib	3.388	146985	35264	8574	1.78
3	Talazoparib	3.378	146857	35287	8564	1.79
4	Talazoparib	3.333	146524	35685	8574	1.79
5	Talazoparib	3.341	146982	35246	8569	1.78
6	Talazoparib	3.396	146856	36521	8547	1.79
Mean			146798.8			
Std. Dev.			197.1917			
% RSD			0.134328			

ACCURACY:

Table-11: The accuracy results for Talazoparib

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	70031.67	50	49.884	99.768%	99.86%
100%	138413.33	100	100.239	100.239%	
150%	205138	150	149.374	99.582%	

LIMIT OF DETECTION FOR TALAZOPARIB

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: LOD = 1.5µg/ml

QUANTITATION LIMIT

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

$$\mathbf{LOQ = 10 \times \sigma / S}$$

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

Result: LOQ = 4.5µg/ml

ROBUSTNESS

Table-12: Results for Robustness

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	145867	3.388	8457	1.76
Less Flow rate of 0.9 mL/min	146854	3.595	8152	1.74
More Flow rate of 1.1 mL/min	135262	3.122	7985	1.73
More organic phase (about 5 % Increase in Methanol)	143652	3.119	8142	1.72
Less organic phase (about 5 % decrease in Methanol)	142546	3.545	7985	1.75

STABILITY STUDIES

Fig-13: Results of Forced Degradation Studies for Talazoparib

S.No.	Stress Condition	Peak Area	% of Degraded Amount	% of Active Amount	Total % of Amount
1	Standard	145867.00	0	100%	100%
2	Acidic	112259.24	23.04	76.96	100%
3	Basic	124687.11	14.48	85.48	100%
4	Oxidative	133803.79	8.27	91.73	100%
5	Thermal	136341.88	6.53	93.47	100%
6	Photolytic	134956.14	7.48	92.52	100%

SUMMARY AND CONCLUSION

The analytical method was developed by studying different parameters. First of all, maximum absorbance was found to be at 225nm 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 Inertsil ODS C18 (4.6mm x 250mm, 5µm) because it was giving good peak. 35°C 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 Methanol: Acetate Buffer (pH-4.2) (40:60% v/v) was fixed due to good symmetrical peak. So, this mobile phase was used for the proposed study. Methanol and water were selected because of maximum extraction sonication time was fixed to be 10min at which all the drug particles were completely soluble and showed good recovery. Run time was selected to be 10.0min because analyze gave peak around 3.388 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.

In the present investigation, a simple, sensitive, precise and accurate RP-HPLC method was developed for the quantitative estimation of Talazoparib in bulk drug and pharmaceutical dosage forms. This method was simple, since diluted samples are directly used without any preliminary chemical derivatization or purification steps. Talazoparib was found to be soluble in organic solvents such as ethanol, DMSO, and acetonitrile, dimethyl formamide and soluble in water and it is freely soluble in dichloromethane, sparingly soluble in ethyl alcohol. Methanol: Acetate Buffer (pH-4.2) (40:60 v/v) was chosen as the mobile phase. The solvent system used in this method was economical. The %RSD values were within 2 and the method was found to be precise. The results expressed in Tables for RP-HPLC method was promising. The RP-HPLC method is more sensitive, accurate and precise compared to the Spectrophotometric methods. This method can be used for the routine determination of Talazoparib in bulk drug and in Pharmaceutical dosage forms. The analytical method was found linearity over the range of 60-140µg/ml of the Talazoparib target concentration. The analytical passed both robustness and ruggedness tests. On both cases, relative standard deviation was well satisfactory.

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