Research Article

Development and Greenness Evaluation of a HPTLC Method for Olaparib Analysis

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ABSTRACT

Background: The alarming increase in global incidence of cancer has necessitated development of environmentally safer and economical analytical techniques for quality assessment of anticancer medications.

Objective: The present study aimed to develop and validate a rapid, sensitive, and eco-friendly HPTLC method for quantitative estimation of olaparib in tablet dosage forms following ICH Q2(R1) guidelines.

Methods: Chromatographic separation was achieved on pre-coated silica gel 60 F254 HPTLC plates using a mobile phase consisting of toluene:acetone:methanol:ammonia (60:20:20:0.1, v/v/v/v). Densitometric detection was carried out at 276 nm. The developed method was validated for specificity, linearity, accuracy, precision, sensitivity, and robustness as per regulatory recommendations. Quantitative analysis was performed using Lynparza tablets.

Results: Olaparib produced a sharp and well-resolved chromatographic band with an Rf value of 0.48 ± 0.02. The method demonstrated good linearity over the concentration range of 25–500 ng/band with a correlation coefficient (R^2) of 0.9993. The limits of detection and quantification were found to be 3 ng/band and 9.08 ng/band, respectively. Recovery studies showed satisfactory accuracy with a mean recovery of 99.85%. Assay analysis of Lynparza® tablets revealed drug content of 99.85 ± 1.1% of the labelled claim. All validation parameters were found to comply with ICH acceptance criteria.

Conclusion: The developed HPTLC method was found to be simple, reliable, economical, and environmentally sustainable for the estimation of olaparib in pharmaceutical dosage forms. Owing to its accuracy, precision, and suitability for routine analysis, the method can be effectively applied for quality control evaluation of olaparib tablet formulations.

Keywords: HPTLC, Olaparib, Validation, Method Development, ICH Guidelines.

INTRODUCTION

Olaparib, commercially available as Lynparza®, represents a major advancement in Poly ADP-ribose polymerase (PARP) inhibition and is widely prescribed for the treating ovarian, breast, pancreatic, and prostate cancers[1]. PARP is a critical enzyme acting as a key player in maintaining genomic integrity following DNA damage[2]. Through ADP-ribosylation, PARP facilitates the restoration of single-strand breaks via converting NAD^+ into poly(ADP-ribose) chains that modify nuclear proteins and promote the assembly of DNA repair factors at the damaged site[3]. This activity is particularly significant in the context of cellular stress and inflammation, where PARP helps regulate cell survival and apoptosis. Beyond its role in DNA repair, PARP also influences various biological events, namely chromatin remodeling, regulating transcription, as well as intracellular signaling cascades[3].

Aberrant regulation of PARP activity has been linked to diverse pathological conditions such as cancer, neurodegenerative disorders, and inflammation, positioning it as a promising therapeutic target[4]. In the field of oncology, PARP inhibitors have gained prominence as a therapeutic approach, particularly in cancers showing homologous recombination repair faults like BRCA1/2 mutations, thereby emphasizing the dual importance of PARP in normal cellular physiology and pathological conditions. As a targeted agent, Olaparib selectively and effectively inhibits PARP1 and PARP2, the key enzymes involved in DNA repair. The U.S. FDA granted approval to olaparib on December 19, 2014, marking its entry as pioneering PARP inhibitor in oncologic therapies[5].

Olaparib was first authorized for the management of late stage ovarian cancer in individuals carrying germline BRCA mutations after failure of three or more prior chemotherapy regimens. Olaparib being selective PARP inhibitor, works by exploiting the synthetic lethality paradigm in tumors lacking homologous recombination repair, such as those found in BRCA-mutated tumors. Since its initial approval, olaparib has also received indications for other cancers, including breast cancer and prostate cancer, further expanding its therapeutic use[6].

The other drug candidates from potent PARP inhibitors category include veliparib, niraparib, and rucaparib. These agents have progressed into advanced clinical trials both as monotherapies and combined regimens, demonstrating particular promise in breast and ovarian cancers[7].

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Chemically olaparib is known as 4-[3-[4- (cyclopropane carbonyl) piperazine-1- carbonyl]-4-fluorophenysssl] methyl]-2H-phthalazin-1- one[6]. An extensive literature survey was undertaken for the analytical methods reported for olaparib. As per scientific literature olaparib has been estimated by using HPLC[8], HPLC-tandem mass spectroscopy[9], UPLC- tandem mass spectroscopy[10], LC-MS/MS[11] in pharmaceutical dosage form as well as biological fluids. One UPLC-MS/MS method in plasma and three RP-HPLC methods were found for olaparib[12,13,8].

At the time of the literature survey and during the entire timeframe of research work, no HPTLC method was cited for olaparib in dosage forms. This research work aimed at designing and validating a novel, sensitive and environmentally sustainable HPTLC methodology for quantitation of olaparib in tablet dosage form[14].

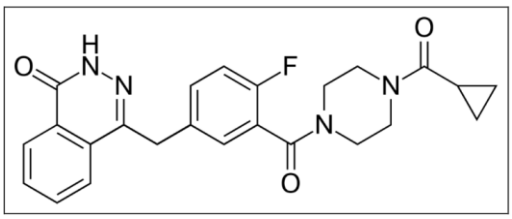

Figure 1: Olaparib structure [12]

MATERIALS AND METHODS

Chemicals and Reagents:

Olaparib reference standard with 99.03 percent potency was received from the Central Drug Testing Laboratory, Mumbai, for research purposes. Lynparza 100 mg tablets containing Olaparib, manufactured by Golden Era Pharma, Mumbai, were procured from the local market. Methanol was supplied by Merck Life Science Pvt. Ltd., glacial acetic acid was procured from Finar Chemicals, and toluene and acetone were procured from Rankem. 0.45 micrometer filters manufactured by Axiva Sichem Pvt. Ltd. was used for filtering mobile phase.

Instrumentation:

Sample application onto silica gel 60 F254 HPTLC plates measuring 20x10 centimeters with a thickness of 250 micrometers was carried out using a CAMAG Linomat 5 sample applicator equipped with a nitrogen aspirator and a CAMAG Hamilton Bonaduz Schwetz microliter syringe of 100 microliter capacity. Plate development and saturation were performed in a CAMAG twin trough glass chamber with a closed lid. HPTLC plates were activated using the CAMAG HPTLC Plate Heater and dried in a well-ventilated wooden chamber and using air dryer. Spectro densitometric analysis was conducted using the CAMAG HPTLC Scanner 4 in reflectance-absorbance mode with a deuterium lamp. Photo documentation of the chromatograms was achieved using the CAMAG HPTLC Visualizer 3, and data analysis with CAMAG vision CATS software version 3.0[15]. All weighing procedures were carried out using a Sartorius Analytical Balance BSA2245-CW.

Preparation of mobile phase

For mobile phase preparation, toluene, acetone, methanol, and ammonia were mixed in 60:20:20:0.1 v/v/v/v proportion in a stoppered glass container. The mixture was subjected to sonication for fifteen minutes to ensure homogeneity and followed by filtration (0.45 micrometer membrane filter). The filtered mobile phase was subsequently degassed and used for chromatographic development.[16].

Diluent Preparation

Olaparib was dissolved in HPLC-grade ethanol and used as the diluent for the standard and sample solutions preparation.

Preparation of Standard Solution

An accurately weighed 10 mg of olaparib reference standard was introduced into a 100 mL volumetric flask. To this flask 50 mL of diluent was added, followed by 15 minutes[16] of sonication until contents were fully dissolved. The volume was made up to get 100 µg/mL standard stock solution. From stock, a working standard solution of 50 µg/mL was prepared.

Preparation of Sample Solution

20 tablets of Lynparza® (100 mg qlaparib each) weighed to determine the average tablet weight. Tablet powder equivalent to 100 mg of olaparib, approximately 440.5 mg, was taken in a 100 mL volumetric flask. Around 50 mL of diluent was added, and the mixture was sonicated for fifteen minutes. Diluent was then added to make up 100 mL volume resulting in sample stock solution of 1000 µg/mL. An aliquot of 1 mL from the stock solution was accurately taken into a 20 mL volumetric flask, and the volume was made up with diluent. The final solution (50 µg/mL olaparib) was passed through a 0.45 micrometer syringe filter.

Selection of wavelength

A 10 µg/mL solution of olaparib was scanned over 200 - 400 nm wavelength using the CAMAG TLC Scanner 4. The absorbance maxima 276 nm was selected for chromatographic analysis.

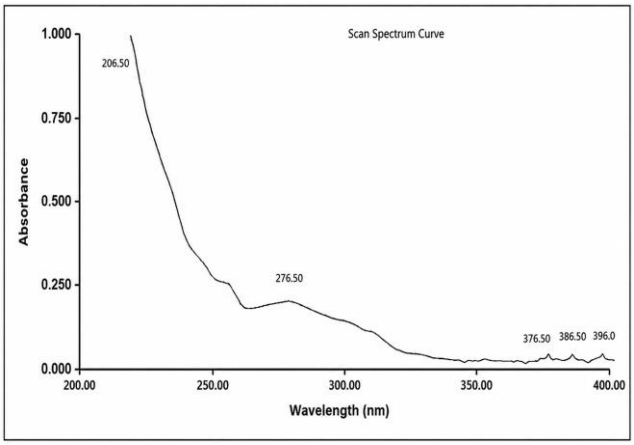

Figure 2: UV Spectrum of Olaparib shows λ_{max} at 276nm

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Method development and Optimization

An HPTLC method was systematically optimized for the determination of olaparib using silica gel 60 F254 precoated plates[17]. Different solvent systems were investigated to obtain sharp, symmetrical, and reproducible chromatographic peaks with suitable migration characteristics.

In the initial experiment, a mobile phase containing n-hexane:ethylacetate:acetone:glacial acetic acid (60:20:20:0.1, v/v/v/v) was employed with a chamber saturation time of 20 min. This combination produced an Rf value of 0.227; however, the chromatographic band showed inadequate peak symmetry along with partial peak splitting. To improve separation, the solvent composition was modified to n-hexane:ethylacetate:acetone:ammonia (50:30:20:0.1, v/v/v/v) and chamber saturation was reduced to 10 min. Although the analyte migration increased substantially (Rf 0.91), the resulting peak characteristics were still not satisfactory.

Further trials identified toluene:acetone: methanol:ammonia (60:20:20:0.1, v/v/v/v) as the most suitable mobile phase. Under these optimized conditions, olaparib exhibited a compact, well-resolved, and symmetrical peak with consistent chromatographic performance and acceptable system suitability parameters. The optimized method produced an Rf value of 0.48 ± 0.02. Chromatographic development was carried out in linear ascending mode using a CAMAG twin trough chamber, followed by densitometric scanning at 276 nm using a CAMAG TLC Scanner 4. The finalized chromatographic conditions are presented in Table 1.

Table 1: Optimized chromatographic conditions for HPTLC analysis of Olaparib

Parameter	Condition
Stationary phase	Silica gel 60 F254 HPTLC plates
Mobile phase	Toluene:Acetone:Methanol:Ammonia (60:20:20:0.1, v/v/v/v)
Applicator	CAMAG Linomat 5
Syringe	100 µL Hamilton syringe
Application volume	5 µL
Band length	8 mm
Chamber saturation time	10 min
Development mode	Linear ascending
Development distance	80 mm
Detection wavelength	276 nm
Scanner	CAMAG TLC Scanner 4
Radiation source	Deuterium lamp
Plate activation	110 °C for 10 min
Rf value	0.48 ± 0.02

Method validation

The developed HPTLC method for olaparib was validated in compliance with ICH Q2 (R1) guidelines[18].

System Suitability:

Six replicate bands of standard solutions were applied, developed, and analyzed in an HPTLC system, and acceptance criteria for all parameters were studied[19].

Specificity:

Specificity, the capability to detect the analyte of interest amidst co-existing impurities and degradants without their interference was done on blank, standard and sample solutions.

Linearity and Range:

Linearity was tested over concentrations spanning 50 to 150 ng/band of the nominal standard level. Calibration curves were constructed, and the correlation coefficient, slope, and intercept were evaluated.

Precision:

Precision was derived from repeated sampling of the same homogeneous material under defined conditions[20]. Precision was evaluated at three hierarchical levels: repeatability, intermediate precision, and reproducibility.

Accuracy:

The accuracy expresses the degree to which the test result agree with the true value[21]. To measure accuracy, we made standardization addition at four level viz., 100%, 110%, 120%, and 130%. At each level, the amount recovered, %recovery, and %RSD were estimated.

LOD and LOQ:

LOD represents smallest concentration of an analyte detectable by the method, though not precisely quantifiable, while LOQ corresponds to the lowest concentration that can be determined quantitatively with adequate precision and accuracy. LOD and LOQ were determined from the calibration curve using the following formulas[22]:

$$LOD = 3.3 \times \sigma/s \text{ and } LOQ = 10 \times \sigma/s$$

where s is the slope of the calibration curve and σ is the standard deviation of the regression response.

Robustness:

The robustness indicates how well the method remains un-affected by small intentional variations in the method parameters[23]. The parameters changed were chamber saturation period by ± 2 minutes, distance travelled by the solvent by ± 5mm, and volume of mobile phase by ± 5ml, and mobile phase ratio by ± 2ml.

Analysis of pharmaceutical formulation:

The developed analytical method was employed to analyze a tablet formulation of olaparib. The optimized HPTLC chromatogram of olaparib showed a resolved peak at a Rf value of 0.48 while performing the assay of tablets. The %assay of tablets was found to be 99.85% of the label claim of Lynparza 100mg tablets of olaparib.

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Eco-friendliness of the developed methodology:

To ascertain the ecological sustainability of the formulated analytical methodology, an exhaustive assessment was conducted employing advanced multifaceted evaluation frameworks, namely Complementary Green Analytical Procedure Index (Complex GAPI), and Analytical GREEnness (AGREE).

Complex GAPI: Complex GAPI software represents a progressive version of the GAPI that functions as a state-of-the-art ecological assessment tool for analytical methods. ComplexGAPI uses a systematic approach to environmental impact measurement through the examination of essential parameters, including sample processing, reagent choice, energy utilization and waste production, and complete ecological impact assessment. ComplexGAPI gives researchers the ability to measure environmental impact using score metrics that let them identify sustainable analytical methods through comparison. The evaluation tool makes use of a three-color scale that assigns red labels to methods with elevated environmental threats but gives green and yellow classifications when risks remain low or negligible.

***AGREE*:** The Analytical Greenness metric enables quantitative evaluation of the environmental sustainability characteristics in analytical methodologies. A mathematical program enables systemized evaluation of Green Analytical Chemistry (GAC) 12 principles through its computational assessment tool. The 0 to 1 score scale from AGREE analysis evaluates methods based on energy efficiency together with reagent reduction and waste reduction while considering safety improvements. A radar chart displays grouped scores for an assessment that generates a complete ecological footprint overview to guide better sustainable laboratory improvements.

RESULTS AND DISCUSSION

System Suitability:

It was confirmed by applying six replicate bands of 250 ng/band olaparib, with a blank included for standard preparation. The Rf value was 0.408, and %RSD of Rf and peak area remained within acceptable limits (Table 1), demonstrating consistent HPTLC system performance.

Table 1: System suitability data

Sr. No.	Peak Area	Rf value
1.	0.00221	0.407
2.	0.00220	0.406
3.	0.00223	0.409
4.	0.00223	0.411
5.	0.00218	0.403
6.	0.00219	0.414
Average	0.00220667	0.408333
S.D.	2.07E-05	0.003882
%RSD	0.93606848	0.950591

Specificity:

Standard and sample solutions of olaparib were analysed alongside a blank. The olaparib band was confirmed by comparing its Rf value and spectral profile with that of the standard. Peak purity was assessed by examining the spectra at 3 distinct positions of the band: peak start (S), apex (M), and peak end (E).

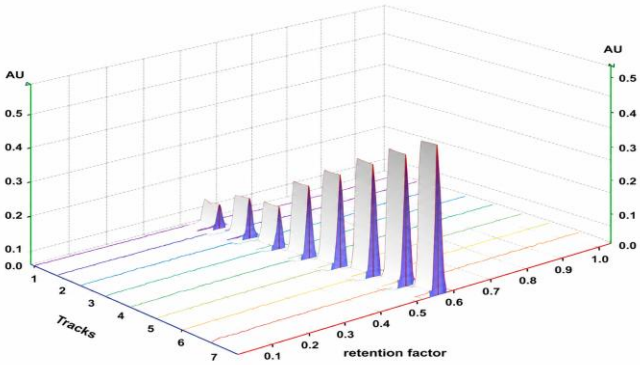

Figure 3: Three Dimensional densitogram of olaparib

Linearity:

The developed chromatographic method showed linearity over 25-500ng/band concentrations; this range has 50-150 ng/band of the standard solution. The correlation coefficient was determined as 0.9993, and the regression equation observed was y = 1E-05x + 3E-05. The graph was plotted with the concentrations (ng/band) of Olaparib verses peak areas on the X-axis and Y-axis respectively. The linearity data is represented in Table 2.

Table 2: Linearity data

Sr. No.	Concentration (ng/band)	Peak Area
1	25	0.00025
2.	50	0.00051
3.	125	0.00124
4.	200	0.00196
5.	250	0.00249
6.	300	0.00295
7.	375	0.0038
8.	500	0.00512

LOD and LOQ[24]:

The method developed demonstrates sensitivity as evidenced by the low values of LOD (3.00ng/band) and LOQ (9.08ng/band) as depicted in Table 3.

Table 3: Regression analysis data

Regression Statistics	
Linear Range	25-500ng/band
Regression Equation	y = 1E-05x + 3E-05
Slope	0.00001
R^2	0.9993
Standard Deviation	1.70E-05
LOD	3.00ng/band
LOQ	9.08ng/band

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Precision:

The precision was evaluated using repeatability and intermediate precision[25]. For repeatability assessment, 50 ng/band of olaparib standard solution was applied 6 times, For interday precision 250, 300, and 375 ng/band of olaparib, each was applied on same day in triplicate. Interday precision, was evaluated by analyzing the same concentrations in triplicate over different days within one week. The results, summarized in Tables 4 and 5, indicate that %RSD values for both repeatability and intermediate precision did not exceed 2.0%, confirming that the method is precise.

Accuracy:

The %Recovery at each level was observed to be within the range of 98%-102%. The average %Recovery was found to be 99.85% as depicted in Table 6. Hence, it proves that the method is accurate.

Robustness

Overall %RSD observed for robustness was not more than 2.0% for the outcomes obtained at the variable conditions as depicted in Table 7 indicating that all the above-mentioned findings for method were robust in all variable conditions[26].

Table 4: Precision Repeatability Data of Olaparib

Sr. No.	Concentration (ng/band)	Area
1.	250	0.00222
2.	250	0.00220
3.	250	0.00224
4.	250	0.00219
5.	250	0.00223
6.	250	0.00221
Average (n=6)		0.00221
S.D.		1.86E-05
%RSD		0.839

Table 5: Intermediate precision studies of olaparib

Concentration (ng/band)	Intraday Precision			Interday Precision		
	Area	S.D.	%RSD	Area	S.D.	%RSD
25	0.00149	2.16E-05	1.45	0.0014	2.42E-05	1.73
50	0.00228	3.66E-05	1.605	0.00225	1.30E-05	0.58
75	0.00449	4.92E-05	1.096	0.00448	1.36E-05	0.30

Table 6: Recovery studies of olaparib

Level	Amount Recovered (µg/ml)	Found %	% Recovery	Average	S.D.	%RSD	Mean %Recovery
100%	101.67	101.67	100.32	99.97	0.432	0.432	99.85
	100.75	100.75	99.49				
	100.3	100.3	100.11				
110%	109.46	109.46	99.51	100.06	0.635	0.634	
	109.91	109.91	99.92				
	110.83	110.83	100.75				
120%	121.36	121.36	101.13	100.37	0.763	0.760	
	119.53	119.53	99.6				
	120.45	120.45	100.38				
130%	129.61	129.61	99.70	99.70	0.704	0.706	
	130.52	130.52	100.40				
	128.69	128.69	98.99				

Table 7: Robustness Data of Olaparib

Sr. No	Parameters	Rf value	Area	Average Area	SD*	% RSD*
1.	Saturation Time (15 min ± 2)	0.49	0.00225	0.00223	2.08E-05	0.93
		0.48	0.00221			
		0.42	0.00222			
2.	Distance travelled (80 cm ± 5)	0.41	0.00223	0.00221	3.00E-05	0.9
		0.48	0.00221			
		0.46	0.00219			
3.	Mobile Phase (60:20:20:0.1 ± 2 v/v)	0.45	0.00220	0.00222	1.53E-05	0.94
		0.48	0.00221			
		0.42	0.00223			

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Table 8: Assay of Lynparza Tablets 100mg (Olaparib)

Sr. No.	Weight of Standard (mg)	Sample Weight (equivalent to 10mg of Olaparib)	Mean Area of Standard at 276nm	Area of Sample at 276nm	%Assay
1.	10.70	440.50	0.00217	0.00212	98.88
2.		441.23		0.00215	100.11
3.		439.65		0.00217	101.41
4.		440.95		0.00214	99.71
5.		441.12		0.00211	98.28
6.		440.58		0.00216	100.73
Average					99.85
S.D.					1.16E+00
%RSD					1.159

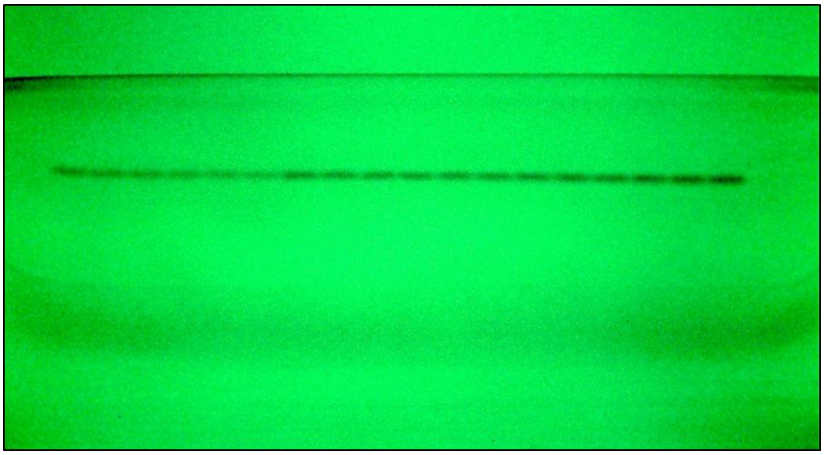


Figure 4: TLC of olaparib

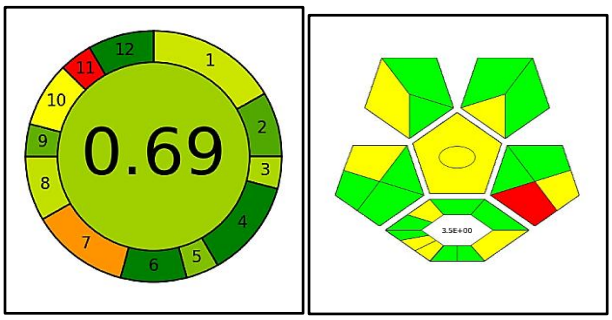
Analysis of pharmaceutical formulation

Under optimized chromatographic conditions, Olaparib in tablet formulations was analyzed. Six replicate applications of 250 ng/band were performed for both the standard and sample solutions. The %Assay, mean, standard deviation (S.D.), and %RSD were estimated in accordance with ICH guidelines as depicted in Table 8. The assay of the tablet formulation was determined to be 99.85%.

Assessment of the Greenness of the developed method

The environmental sustainability of the newly developed HPTLC method was evaluated using the ComplexGAPI approach, which provides a visual representation of green analytical chemistry compliance through a color-coded pentagram pictogram. This assessment considers factors such as dissolution techniques, instrument specifications, balancing agents, method categorization, and prior analytical procedures, summarized in a hexagonal diagram. The method exhibited high environmental compatibility, as indicated by the predominance of green regions in the pictogram, whereas yellow and red areas were minimal (Figure 5a).The method's E-factor was calculated as 3.5, reflecting moderate solvent consumption and demonstrating a balance between operational efficiency and sustainability principles.

Further evaluation using the AGREE metric yielded a score of 0.69. This circular pictogram assessment incorporates twelve parameters and classifies the method within the moderately green category. While the method complies with most principles of green analytical chemistry, certain sustainability aspects require further optimization to enhance overall eco-friendliness (Figure 5b).



(a) **(b)**

Figure 5: Greenness Evaluation the developed method

CONCLUSION

The developed HPTLC method provides a precise, robust, and efficient approach for quantifying olaparib in tablet formulations, validated as per ICH Q2(R1) guidelines. The method effectively resolves the drug from excipients, accommodates up to 18 bands per plate, and supports both qualitative and quantitative analysis with straightforward sample preparation. Analytical performance showed excellent regression, low percent relative standard

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deviation, and acceptable standard deviation values, ensuring reliability for routine use. Environmental sustainability assessment using ComplexGAPI and AGREE tools indicated high compliance with green analytical chemistry principles, minimal solvent consumption, an E-factor of 3.5, and an AGREE score of 0.69, reflecting moderate solvent usage and eco-friendly operation. Overall, this method combines analytical efficiency with environmental responsibility, making it useful for routine quality control, research applications, and academic studies of olaparib.

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