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Research Article

From Lab to Shelf: A Reliable UV Spectrophotometric Technique for Gallic Acid Analysis in Medicines and Nutraceuticals

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ABSTRACT

The development and validation of a UV spectrophotometric technique for gallic acid are crucial to enable accurate, precise, and reliable quantification of this molecule in diverse matrices, such as medicines, herbal items, and food samples. Gallic acid, a phenolic molecule with considerable antioxidant capabilities, is frequently employed in medicinal and nutraceutical compositions. A validated UV technique offers a cost-effective, quick, and sensitive analytical tool for quality control, assuring consistency and effectiveness of goods containing gallic acid. Validation, undertaken as per ICH criteria, establishes the methods dependability by analyzing factors such as linearity, accuracy, precision, specificity, LOD, LOQ and robustness. Using distilled water as the solvent, the absorbance of gallic acid at 260 nm was measured. Over a given concentration range, the method's correlation coefficient of 0.9999 showed outstanding linearity. Following assessment, it was concluded that the validation parameters—range, accuracy, precision, limit of quantification (LOQ) recovery studies, and limit of detection (LOD)—were within reasonable boundaries. Because of its precision, accuracy, and sensitivity, the suggested approach may be used for regular analysis of gallic acid in both bulk and mixed dose forms. The pharmaceutical sector may use this approach because it is reliable and economical for quality monitoring.

Keywords: *Gallic Acid, Ultraviolet Spectrophotometric method, calibration curve, validation*

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INTRODUCTION:

With the formula C_6H_2 (OH) $_3CO_2H$, gallic acid, sometimes called 3,4,5-trihydroxy benzoic acid, is a Tri hydroxyl benzoic acid. It falls within the category of phenolic acid. For ages, humans have consumed fruits and vegetables such as plums walnuts, tea, mangoes, blackberries, blueberries, strawberries, grapes, cashew nuts, hazelnuts, and others that contain gallic and phenolic acids. It has well documented health advantages that consist of anticancer, antimicrobial, antioxidant, anti-inflammatory, and antiviral effects. The high antioxidant properties of GA enable it to counter the free radicals, alleviate oxidative stress, and save the cells damage. In addition to that, it has anti-inflammatory properties that take effect by suppressing inflammatory cytokines and enzymes hence makes it a possible choice of treatment in inflammatory diseases. Another anti-cancer activity observed in GA is the inhibition of cell growth in cancer cells and apoptosis. It also helps in cardiovascular matters by decreasing blood pressure, decreasing cholesterol levels and enhancing endothelial consumption thus helping in the prevention and treatment of cardiovascular disorders[1-6][1]. Fig.01, gives structure of GA.

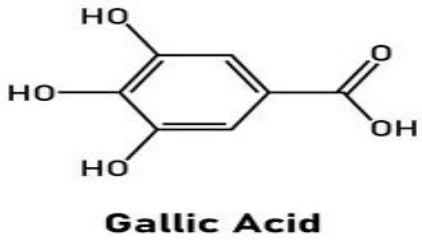

Figure 1: A Chemical structure of Gallic Acid

The most crucial component of any medication development process is analysis, whether it is done in bulk or in combination. To guarantee that any drug, whether in bulk or dosage form, can be identified, an appropriate procedure must be created. The creation of the approach guarantees that the quantity of a certain medicine may be readily ascertained. Gallic acid is a naturally occurring phenolic molecule found in many plant materials such as tea, grapes, and oak wood, and is recognized for its antioxidant effects. The measurement of gallic acid is significant in the examination of plant-based products, since it acts as a marker compound for the determination of total phenolic content. This work intended to design and verify a simple, accurate, and repeatable UV spectrophotometric technique for the detection of gallic acid[2, 3].However, this approach has been exposed to different changes, and the need for a robust and verified spectrophotometric method for the precise measurement of gallic acid persists.In this work, we improved and validated a UV spectrophotometric approach for the measurement of gallic acid, which may be employed in future to quantify the gallic acid concentration in diverse plant-based materials.

MATERIALS AND METHODS

Equipment:

The spectrophotometric procedure was performed using a UV-Visible Spectrophotometer (UV-1900i SHIMADZU) equipped with 10mm matched quartz cells. A Shimadzu India electronic balance was utilised for each weigh-in[4].

Reagents & chemicals:

Gallic Acid was purchasedfrom Research-Lab Fine Chem Mumbai (India). Standard Gallic Acid was obtained from Sigma Aldrich.

Stock solution (Standard):

In order to create a stock solution (100 µg/ml), 10 mg of gallic acid were precisely weighed, diluted in distilled water (100 ml) to adjust final volume[5].

Wavelength Detection:

1 ml of the standard stock solution was pipetted into a 10 ml volumetric flask. Distilled water was used to get the volume up to 10ml. Between 200 and 400 nm, the resultant solution, which contained 10µg/ml, was scanned[6].

Calibration Curve:

A succession of 10 ml volumetric flasks were filled with aliquots of 1 to 6 ml amounts of stock solutions, and the volume was adjusted with distilled water. The dilutions we created were 10, 20, 30, 40, 50, and 60 µg/ml. At λmax 260 nm, the absorbance was measured [7, 8].

Validation (UV Method)

Linearity:

The drug's linear response was verified at concentrations ranging from µg/ml. Plotting absorbance against concentration resulted in the calibration curve, which was subsequently subjected to linear regression analysis for obtaining regression for Gallic acid [12].

Precision:

Recovery experiments aimed to ascertain the accuracy of the approach. Each of the solutions was analyzed thrice and the percent recovery was computed. The accuracy of the technique was proved by the intra-day and inter-day variation investigations [10-13].

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

LOD and LOQ computed as;

$LOD = 3.3\sigma / S$ and $LOQ = 10\sigma/S$

S = slope of the calibration curve

σ = Residual standard deviation [8].

Recovery:

Recovery tests were conducted to examine the method's accuracy. The recovery was carried out in three depths including 80, 100 and 120 percent of standard concentration of gallic acid. Each recovery level was prepared in a recovery sample, and the preparation was conducted in one of the before mentioned procedures. The analyses of the solutions was completed and the percent recoveries determined by the use of calibration curve[9[9].

RESULTS & DISCUSSION:

Precision:

The method's precision was assessed for gallic acid (standard). In the same lab, the method's repeatability (intra-day accuracy) and reproducibility (inter-day precision) were assessed. The results were 0.329457 and 0.341124, respectively.

Accuracy (Recovery Study):

Recovery experiments were used to study the method's accuracy. Three levels of gallic acid standard concentration—80, 100, and 120%—were used for the recovery. For every recovery level, three samples were made. Following analysis of the solutions, the calibration curve's % recoveries were computed. The technique has high repeatability, as shown by the recovery value for gallic acid of 99.9995±0.052 and RSD of 0.05221, both of which are < 2. (Table 1)[4, 5, 10, 11].

Table 1: Recovery data

Stock solution	Total conc	Recovered Drug	Recovery (%)	Mean Recovery (%)	SD	RSD (%)
32	72	72	100	100.041	0.08448	0.084447
32	72	72.1	100.138			
32	72	71.99	99.986			
40	80	80	100	99.995	0.007216	0.007217
40	80	79.99	99.987			
40	80	80	100			
48	88	87.90	99.9887	99.9625	0.0649519	0.0649763
48	88	88	100			
48	88	88	100			
			Mean	99.9995	0.0522159	0.05221343

LOQ & LOD:

Limit of detection and limit of quantification was found to be 0.246089&0.745723 respectively [2-4]

Specificity:

The capacity of a technique to precisely assess the analytical response when all possible sample components (excipients) are present is known as specificity. Gallic acid's UV spectrum is shown in Figure 02, and the calibration curve is highlighted in Figure 3. The findings were contrasted with a typical gallic acid analysis. The analyte was unaffected by the excipients in the solid dosage form (Table 2)[6, 12-15-16]

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Table 2: Parameters of validation

Specification	Outcome
λmax	260 nm
Linearity	10-60 µg/ml
Coefficient correlation	0.9999
Equation of regression	y=0.0221x-0.0009
Intraday accuracy	0.329457
Interday accuracy	0.341124
LOQ	0.745723
LOD	0.246089
Sandell's sensitivity	0.125
Molar absorption	2379.32
Slope (m)	0.00812
SD (Average)	0.000606
% RSD	0.364392

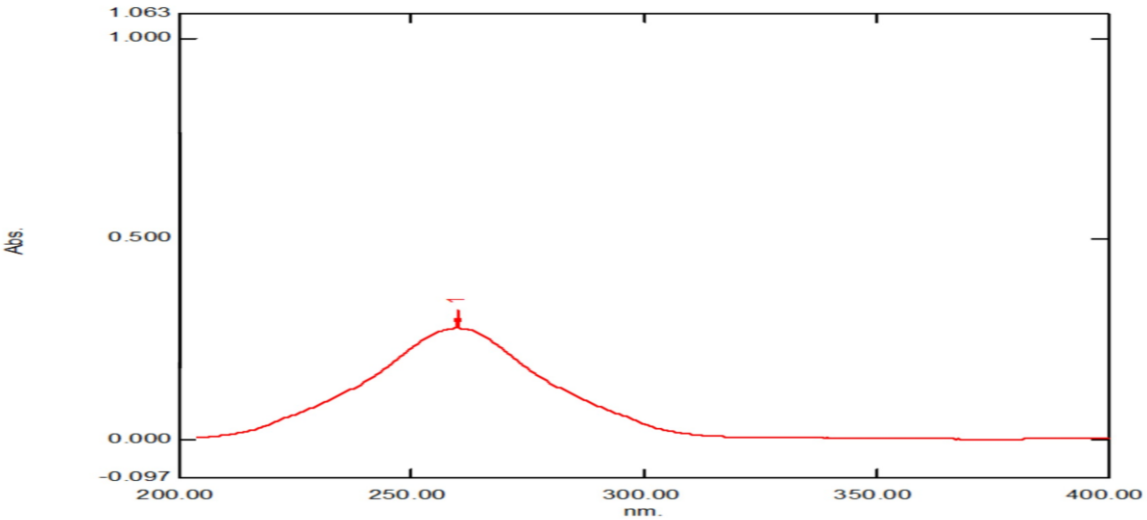

Figure 2: A typical UV Spectrum of Gallic Acid

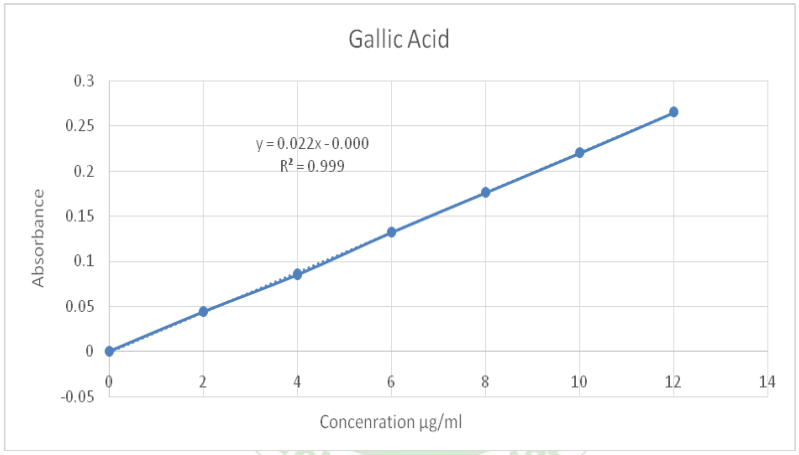

Figure 3: Gallic acid standard curve

CONCLUSION:

The UV spectrophotometric method developed in the current study to measure gallic acid was very precise, accurate and specific, so it proved to be robust and to be applied in routine analyses. The procedure displayed high reproducibility between days and accuracy in the assays with the presence of excipients, which are requirements of the method to be used in quality control on pharmaceutical formulations. Moreover, the sensitivity of the method is evinced through the low detection and quantification limits, and thus the method would be suitable in trace-level analysis. On the whole, the study represents a major step in the creation of a rather easy, inexpensive and accurate method of analysis of gallic acid in complex matrices.

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AUTHOR CONTRIBUTIONS

Conception: S.M.S; Design: S.M.S.; Methodology: S.M.S..; Data Collection: D.J..; Analysis and/or interpretation: S.K., S.G., P.T. S.S.; Manuscript writing: D.J.Critical review: P.T.

CONFLICT OF INTEREST

The "Authors declare that there is no conflict of interest." statement should be included.

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