IJBPAS, September, 2025, 14(9): 4818-4824

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

# DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR BEMPEDOIC ACID IN PURE AND DOSAGE FORM

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**Received 15th March 2024; Revised 20th April 2024; Accepted 11th Aug. 2024; Available online 1st Sept. 2025**

https://doi.org/10.31032/IJBPAS/2025/14.9.8844

## ABSTRACT

This study primarily focuses on developing a novel UV method for the assay of Bempedoic acid in both pure form and pharmaceutical dosage forms. The process involves preparing standard and working solutions of Bempedoic acid, followed by the analysis of different concentrations of the working solution. The established method is then subjected to validation as per ICH guidelines. The results indicate that the developed method is sensitive and accurate, particularly within the concentration range of 10-80 µg/ml. The correlation coefficient (R2) was determined to be 0.999. Notably, there was no interference observed with the excipients present in the formulation. The proposed method holds potential for the analysis of Bempedoic acid in bulk and formulation, making it suitable for routine analysis

**Keywords: Ultraviolet Spectroscopy, validation, Bempedoic acid, method development, assay**

## INTRODUCTION:

Bempedoic acid (BDA) is a pentadecanedioic acid, characterized by methyl groups at positions 2 and 14, and a hydroxy group at position 8, making it an alpha,omega-

dicarboxylic acid **(Figure 1)**. It is a medication prescribed for managing elevated levels of LDL cholesterol, commonly known as "bad cholesterol". It functions as an antilipemic medication. Elevated LDL cholesterol levels pose a significant risk for cardiovascular incidents. Hypercholesterolemia, whether stemming from genetic variations or lifestyle choices, can markedly diminish life quality and elevate the likelihood of cardiovascular mortality. BDA, as a pioneering medication, inhibits adenosine triphosphate-citrate lyase and is administered once daily to lower LDL cholesterol levels in patients who do not respond adequately to statin therapy **[1-3]**.

Through a comprehensive examination of existing literature, it has been observed that only a small amount of research has been recorded on this topic regarding the assessment of BDA using HPLC and Mass spectrometry **[4-5]**. There are few UV spectrophotometric methods reported for analysis of BDA **[6]**.

This investigation aimed to analyze BDA in both its pure form and pharmaceutical formulation, specifically tablets. Following the development of the UV method, all optimization parameters were taken into account. The validated method proved successful, affirming its appropriateness for determining the overall drug content in commercially accessible BDA formulations. Consequently, the development and validation processes adhered to ICH guidelines **[7-10]**.

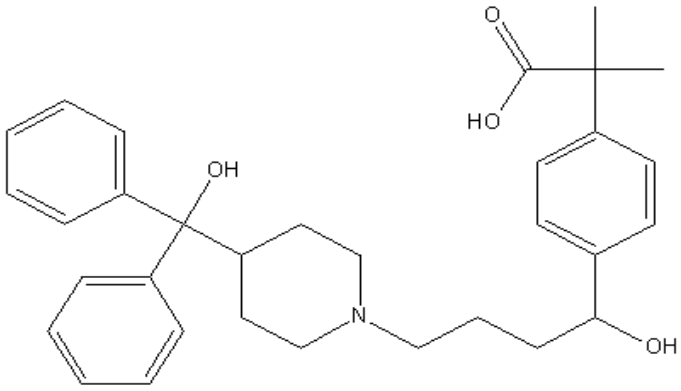


**Figure 1: Chemical structure of BDA**

## MATERIALS AND METHODS:

### Instruments and Reagents:

A complimentary sample of BDA with a purity level of 99.98% was obtained from a manufacturing facility located in Visakhapatnam. The instruments employed in the study included UV/Visible spectrophotometer, Lab india, model T60 and

analytical balance, shimadzu, japan. The investigation utilized analytical-grade chemicals and reagents. BEMDAC-branded BDA tablets, each containing 180 mg, were obtained for the formulation.

**Standard stock solution (1000µg/ml):**

A quantity of 100 mg of the drug was introduced into a 100 ml calibrated flask, where it was dissolved and topped up to the calibration mark with acetonitrile, resulting in 1000 µg/ml. This establishes the standard stock solution of BDA.

**Working standard solution (100µg/ml):**

A quantity of 2.5 ml was extracted from the standard stock solution mentioned earlier and transferred into a 25 ml calibrated flask. Acetonitrile was added to the flask to achieve a concentration of 100 µg/ml, and the solution was adjusted to the mark.

**Calibration curve:**

Following that, it was subjected to scanning using a UV Spectrophotometer covering the 200-400 nm range, with acetonitrile employed as the blank. The peak absorbance was pinpointed at a wavelength of 272 nm. To generate different concentrations spanning from 10 to 60 µg/ml, portions were formulated using distilled water as the solvent. These samples were then assessed at the specified wavelength of 272 nm to ascertain their respective absorbance values. The collected data was subsequently used to construct a calibration curve.

## RESULTS AND DISCUSSION

**Method Validation:**

**Linearity:**

Various samples of BDA were created within the 10-60 µg/ml range using the working standard solution (40 µg/ml). These solutions underwent scanning on a UV-spectrophotometer spanning the 200-400 nm range, with acetonitrile serving as the reference. The spectrum was captured at 272 nm **(Figure 2)**. The data illustrated the relationship between concentration and absorbance, is depicted in **Table 1**. The results indicate a high degree of linearity in the established relationship.

**Precision:**

The method's precision was showcased through assessments of intra-day and inter-day variations. In the intra-day analysis, six separate solutions with 40 µg/ml were created and assessed twice daily. For the inter-day study, solutions of 40 µg/ml were formulated and was tested six times over two successive days, and the absorbance was noted (refer to **Table 2**). The calculated percentage of relative standard deviations was found to be below 2%.

**Accuracy:**

The method's accuracy was assessed using

the standard addition method, wherein the percent recovery of BDA was computed. Pre-quantified sample solutions of BDA were supplemented with known quantities of standard solutions at 80%, 100%, and 120% levels. These solutions were prepared in triplicate, and the accuracy, as indicated by the %recovery, was calculated and presented in **Table 3**. The %recovery was determined to be satisfactory.

**Robustness:**

The method's reliability was evaluated through the examination of a sample with a concentration of 40 µg/ml at three distinct wavelengths, including one at λ max, and recording the corresponding absorbance values. The outcomes presented in **Table 4** suggest that the method demonstrated robustness.

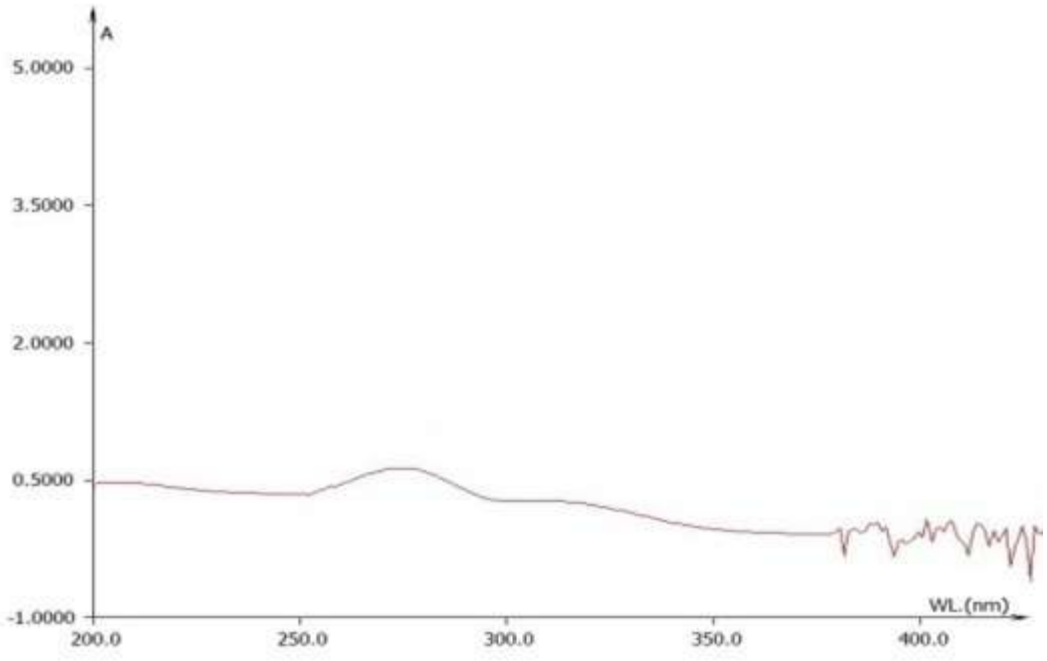


**Figure 2: Spectrum obtained for pure drug**

**Table 1: Linearity**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 10 | 0.1512 |
| 20 | 0.2341 |
| 30 | 0.3282 |
| 40 | 0.4223 |
| 50 | 0.5214 |
| 60 | 0.6034 |
| Regression equation | Y = 0.0092x + 0.0551 |
| Correlation coefficient($R^2$) | 0.9993 |

**Table 2: Intermediate Precision**

| Conc. [µg/ml] | Absorbance | |
|---|---|---|
| | Examiner-1/Day-1 | Examiner-2/Day-2 |
| 40 | 0.4163 | 0.4124 |
| 40 | 0.4124 | 0.4167 |
| 40 | 0.4147 | 0.4113 |
| 40 | 0.4114 | 0.4146 |
| 40 | 0.4161 | 0.4167 |
| 40 | 0.4167 | 0.4113 |
| Mean | 0.4146 | 0.4138 |
| S.D | 0.0022 | 0.0025 |
| %RSD | 0.53 | 0.61 |

**Table 3: Accuracy of method**

| Addition Level | Amount of formulation | Quantity added | Hypothetical quantity. | Experimental amount | % recovery |
|---|---|---|---|---|---|
| 80% | 40 | 32 | 56 | 55.91 | 99.83 |
| 100% | 40 | 40 | 40 | 40.12 | 100.3 |
| 120% | 40 | 48 | 68 | 67.94 | 99.91 |

**Table 4: Robustness Study**

| Conc. (µg/ml) | Absorbance | | |
|---|---|---|---|
| | 271nm | 272nm | 273nm |
| 40 | 0.4022 | 0.4163 | 0.4221 |
| 40 | 0.4074 | 0.4124 | 0.4267 |
| 40 | 0.4027 | 0.4147 | 0.4213 |
| 40 | 0.4075 | 0.4114 | 0.4246 |
| 40 | 0.4034 | 0.4161 | 0.4267 |
| 40 | 0.4018 | 0.4167 | 0.4213 |
| AVG | 0.4041 | 0.4146 | 0.4237 |
| SD | 0.0025 | 0.0022 | 0.0025 |
| %RSD | 0.64 | 0.53 | 0.60 |

**Ruggedness:**

To assess the ruggedness of the method, the sample was analyzed by two different analysts using the identical apparatus, and by the same examiner using two different cuvettes, with the respective absorbance values recorded. The results from the first analyst revealed a %RSD of 0.17, while the second analyst showed a %RSD of 0.26. These results indicate that the utilized methodology was robust, as no notable distinction is evident among various operators.

**Sensitivity:**

The drug's LOD and LOQ were determined from the standard curve and found to be 1.67 µg/ml and 5.15 µg/ml, respectively.

**Assay of formulation*:***

The analysis of the obtained formulation involved assaying an equivalent weight of 25 mg of BDA formulation in a 25 ml calibrated flask, utilizing acetonitrile as the diluent. The final concentration was adjusted to 40 µg/ml using distilled water. The assessment was

conducted at a UV wavelength of 272 nm, revealing an assay result of 99.72%.

**CONCLUSION:**

The proposed method proved to be simple, exhibiting accuracy, precision, and robustness while being easily implementable. The calibration plot covered a broad range, and the recoveries of samples were consistent. The equipment and reagents utilized are likely to be accessible, even in basic laboratory setups. Therefore, the established method is recommended for regular use in quality control analysis of BDA. Additionally, it is deemed suitable for analyzing samples in accelerated stability studies, routine formulation analyses, and the assessment of drug substance.

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