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# Development and validation of UV spectroscopic method for the quantification of bempedoic acid in bulk and marketed product

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## Abstract

Simple, rapid and precise UV spectroscopic method using two solvent blends such as Methanol: Distilled water 3:1 (DW) and Acetonitrile: Distilled water 3:2 (DW) were developed for the estimation of Bempedoic acid in bulk and marketed tablets as per ICH guidelines. The two proposed solvent blends validated for linearity, accuracy, precision, robustness, ruggedness and solution stability. The percent recoveries in the marketed tablet formulations were found to be good agreement with the label claim. The UV method validated statistically and the results suggest proposed solvent blends can employed for the routine analysis of Bempedoic acid in bulk and marketed tablet formulations.

**Keywords:** Bempedoic acid; UV spectroscopy; Validation; Accuracy; Precision

## 1. Introduction

Bempedoic acid is a lipid lowering agent pivotal in managing patients with elevated low density lipoprotein cholesterol (LDL-C) levels. The U.S. Food and Drug Administration (FDA) has sanctioned its use as an adjunct to maximally tolerated statin therapy for the reduction of LDL-C, specifically in individuals afflicted by atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH). Bempedoic acid was also a viable alternative for patients intolerant to statins[1]. Generally, this drug requires activation in the liver, the very long chain acyl-CoA Synthetase-1 enzyme helps for the activation of the drug as BETC-1002-CoA, the active metabolite of the drug[2]. It is also indicated to reduce elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia in combination with fenofibrate, and to reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), in combination with atorvastatin or simvastatin[3]. Chemically it is an alpha, omega dicarboxylic acid i.e., pentadecanedioic acid which is substituted by methyl groups at positions 2 and 14, and by a hydroxy group at position 8 as shown in figure 1. Few HPLC[4], UPLC[5], RP-HPLC[6-10], UPLC-MS[11] and RP-UPLC[12] methods were reported for the estimation of Bempedoic acid alone and in combination with other drugs. Reported methods were found to expensive and tedious, so an attempt was made to develop and validate simple UV spectroscopic method for the estimation of Bempedoic acid in bulk and marketed tablets.

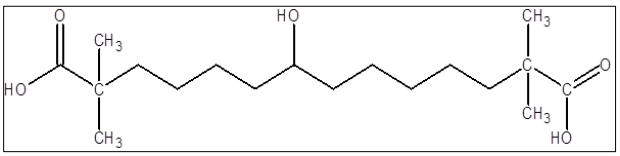


**Figure 1** Chemical structure of Bempedoic acid

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## 2. Material and methods

### 2.1. Materials

Bempedoic acid (BA) obtained as gift sample from Dr. Reddy's laboratories Hyderabad. Marketed Bemdac180mg tablets procured from local community pharmacy. All reagents, solvents used were of analytical grade.

### 2.2. Methods

- **Preparation of BA standard stock solution (BSTS):** Accurately weighed 25mg of BA was transferred into a 25 ml volumetric flask, to this add 20 ml of solvent blend viz., Methanol: DW 3:1 (Medium 1), shake for 5min and sonicate for 5min to dissolve completely, then make the volume with Medium 1 to obtain 1 mg/ml concentration. Similarly prepare BA standard stock solution in Acetonitrile: DW 3:2 (Medium 2).
- **Preparation of BA working standard solution (BWST):** 2.5 ml of BSTS was transferred into a 25 ml volumetric flask. To this add 20 ml of Medium 1, and then make the volume with Medium 1 solution to obtain 0.1 mg/ml concentration. Similarly prepare the BWST in Medium 2.
- **Preparation of working test standard solution for tablets (BWSTT):** Triturate accurately weighed 10 tablets to get fine powder. Transfer powder equivalent to 25 mg of BA into 25 ml volumetric flask, add 25 ml of Medium 1, extract the content by shaking for 90 min and sonicate for 10 min, filter the contents, dilute appropriately with Medium 1. Similarly prepare BWSTT in Medium 2.
- **Determination of absorption maxima (λ max):** BWST was appropriately diluted with Medium 1 and Medium 2 separately in 10 ml volumetric flask to get 10 µg/ml solutions, scan both the solutions in the range of 200 to 400 nm using double beam UV spectrophotometer, and observe the characteristic peak at standard wavelength (nm).

### 2.3. Validation

The validation of proposed methods carried out as per ICH guideline.

- **Range:** BWST was appropriately diluted with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks to obtain 2-40 µg/ml concentrations and measure the absorbance at 249 nm and 275 nm keeping Medium 1 and Medium 2 respectively as blanks.
- **Linearity:** The linearity is the ability of analytical procedure to produce test results, which are proportional to the concentration (amount) of analyte in samples within a given concentration range, linearity should be determined by using ten standards. BWST was appropriately diluted with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks to obtain 1-10 µg/ml concentrations and measure the absorbance at 249 nm and 275 nm keeping Medium 1 and Medium 2 respectively as blank, plot the concentration vs. absorbance curve and regression equation was computed.
- **LOD and LOQ:** Limit of detection (LOD) is the lowest amount of an analyte detected in a sample and Limit of quantitation (LOQ) is the lowest amount of an analyte quantified in a sample with a suitable precision and accuracy. Both are determined based on standard deviation (SD) of response and slope(S) by using following equations,

$$(LOD = 3.3 \times SD/S); \qquad (LOQ = 10 \times SD/S).$$

- **Precision:** Precision of proposed solvent systems were carried out at different concentrations prepared by diluting appropriately the BWST with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks and express the results in terms of % RSD, similarly inter-day and intra-day precision were also determined.
- **Robustness:** A robustness study performs to check the influence of method parameters varied intentionally on the Medium 1 and Medium 2. BWST was appropriately diluted with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks to obtain 1µg/ml, 5µg/ml for Medium 1 and 15µg/ml, 20µg/ml for Medium 2. Measure the absorbance at actual wavelength i.e., 249 nm and 275 nm and small varied wavelength i.e., ±5 nm keeping Medium 1 and Medium 2 respectively as blank. Interpret the results in terms of % RSD.
- **Ruggedness:** A ruggedness study performs to check the influence of parameters varied intentionally on the solvent blends under the study. BWST was appropriately diluted with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks to obtain 1µg/ml, 5µg/ml for Medium 1 and 15µg/ml, 20µg/ml for Medium 2. Measure the absorbance at actual wavelength i.e., 249 nm and 275 nm by two different analyst and two different UV spectrophotometer. Interpret the results in terms of % RSD.

- **Accuracy:** The most common technique for determining accuracy in analytical method development studies is the recovery method. Standard addition method applied for recovery studied, in which a sample assayed with known amount of BA (40%, 60% and 80%) was added to the BWSTT and the sample assayed as percent recovered.
- **Solution stability:** The stability of BWST was studied at room (25°C) and refrigerates temperature (2-8°C). The samples were stored in tightly sealed glass containers protected from light. BWST was appropriately diluted with Medium 1 and Medium 2 separately in a series of 10 ml volumetric flasks and the absorbance measured at 0 hr and 24 hr time interval and the results were expressed in terms of % RSD.

## 3. Results and discussion

The absorption maxima of the Medium 1 and Medium 2 were found to be 249 nm and 275 nm respectively with characteristic peak (figure 2). The best fit values for Medium 1 and Medium 2 are given in table 1, 2 and linearity curve in figure 3. A linear relationship found in the concentration range of 1-10 µg/ml for both mediums. The goodness of fit study suggests good correlation coefficient ($R^2$ was 0.9996 and 0.9998 for Medium 1 and Medium 2) shows the validity of Beer's law with intercept response < 2% calculated by the least square method indicating functional linearity between the concentration of analyte and the absorbance. Based on the standard deviation of the response and the slope, the LOD of BA in Medium 1 and Medium 2 were found to be 0.00165 ± 0.019 µg/ml; 0.00188 ± 0.020 µg/ml; LOQ of BA in Medium 1 and Medium 2 were found to be 0.0057 ± 0.019µg/ml; 0.0057 ± 0.020 µg/ml with % RSD values less than 2.

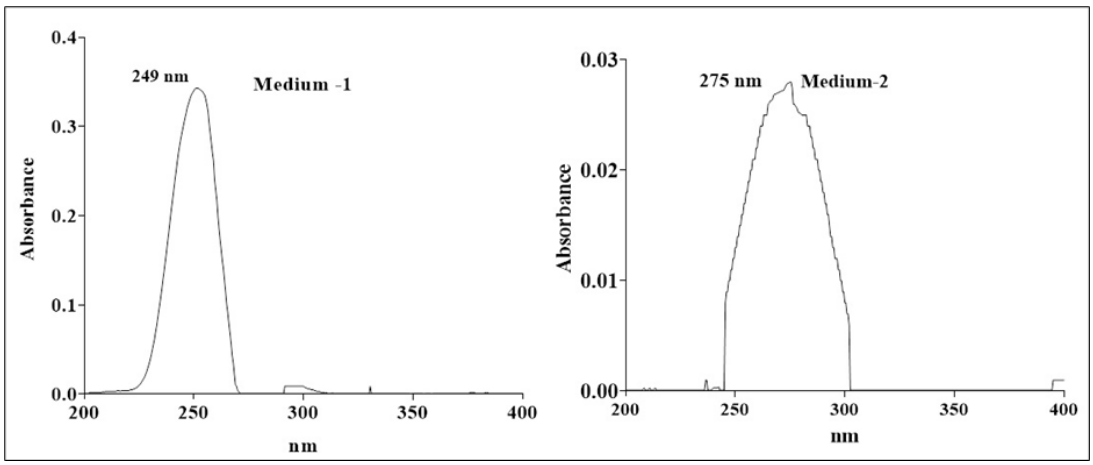


**Figure 2** Absorption maxima of BA in Medium 1 and Medium 2

**Table 1** Linearity curve data of BA in Medium 1 and Medium 2

| Concentration µg/ml | Mean ± SD n=3 | |
|---|---|---|
| | Medium 1 | Medium 2 |
| 1 | 0.039±0.00517 | 0.016±0.00132 |
| 2 | 0.081±0.00272 | 0.031±0.00157 |
| 3 | 0.119±0.00198 | 0.048±0.00131 |
| 4 | 0.16±0.00312 | 0.064±0.00223 |
| 5 | 0.203±0.00173 | 0.080±0.00172 |
| 6 | 0.233±0.00152 | 0.096±0.00209 |
| 7 | 0.274±0.00099 | 0.112±0.00187 |
| 8 | 0.314±0.00351 | 0.128±0.00166 |
| 9 | 0.352±0.00446 | 0.144±0.00312 |
| 10 | 0.391±0.00115 | 0.159±0.00109 |

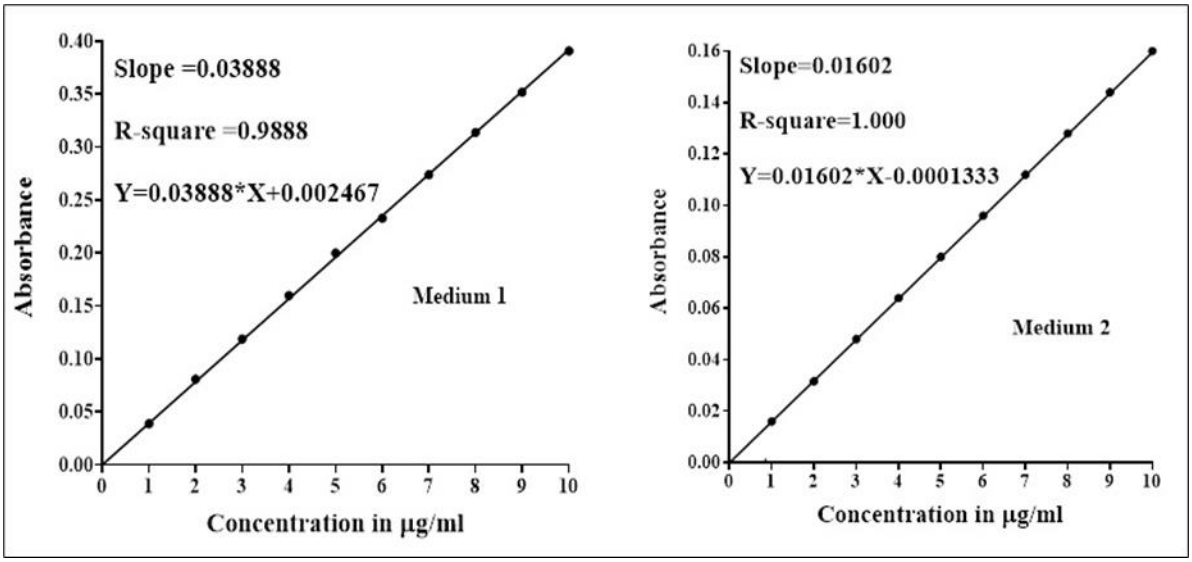


**Figure 3** Linearity curve of BA in Medium 1 and Medium 2

**Table 2** Statistical data of Linearity curve

| **Parameter** | **Medium 1** | **Medium 2** |
|---|---|---|
| Absorption maxima | 249 nm | 275 nm |
| Beer's range | 1-10 µg/ml | 1-10 µg/ml |
| Molar absorptivity | 3.9x10-2mol/cm-1 | 1.6x10-2mol/cm-1 |
| **Best fit values** | | |
| Slope | 0.03886 | 0.01602 |
| y-intercept | 0.002867 | -0.0001333 |
| x-intercept | -0.07377 | 0.008325 |
| 1/Slope | 25.73 | 62.43 |
| **Goodness of fit** | | |
| R square | 0.9996 | 0.9998 |
| Equation | Y = 0.03886*X + 0.002867 | Y = 0.01602*X - 0.0001333 |

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Six replicates in repeatability, three replicates in intra and inter day studies for a fixed amount of BA in Medium 1 and Medium 2 were recorded and relative data was given in table 3. The % RSD values for repeatability studies, intraday and inter day studies is less than 2 % indicate proposed solvent systems were precise and reproducible.

The Medium 1 and Medium 2 were used for accuracy study for marketed tablet formulations (BEMDAC 180mg) and data was given in table 4. The % recovery was within the permissible limit with RSD values less than 2%. The accuracy performed for the proposed solvent systems by standard addition method and the percentage recovery found within the permissible limits with RSD values less than 2% indicate non-interference of the excipients in the formulations. The BA content of two marketed products determined by the proposed solvent systems was in good agreement with the label claim with % RSD values less than 2 and data given in table 5.

Change in λ max of ± 5 nm to the actual λ max in robust analysis results significant different in the percentage recovery in both proposed solvent systems indicates the methods were not robust. In ruggedness, analysis by different analyst and change of instrument indicates the proposed solvent systems were significantly rugged. The robustness and ruggedness data was given in tables 6, 7.

**Table 3** Repeatability precision data

| **Solvent blends** | **Concentration *µg*** | **Amount recovered *µg*** | **% Recovered Mean ±SD (n=6)** | **% RSD** |
|---|---|---|---|---|
| Medium 1 | 1 | 0.993 | 99.33 ±1.966 | 1.079 |
| | 5 | 5.06 | 101.3 ± 1.870 | 1.846 |
| Medium 2 | 15 | 15.05 | 100.3 ± 0.4682 | 0.466 |
| | 20 | 19.97 | 99.88± 0.4279 | 0.428 |
| Medium 1 | 1 | 1.016 | 100.725 ± 1.227 | 1.218 |
| | 5 | 5.065 | 101.37 ± 1.166 | 1.150 |
| Medium 2 | 15 | 15.035 | 100.25 ± 0.2367 | 0.236 |
| | 20 | 19.99 | 99.97 ± 0.2728 | 0.272 |
| Medium 1 | Intraday precision | | | |
| Day 1 | 1 | 1 | 100 ± 0.0 | 0 |
| | 5 | 4.99 | 100 ±0.5150 | 0.5150 |
| Day 2 | 1 | 0.99 | 99.14 ±1.484 | 1.496 |
| | 5 | 5.1 | 102 ±1.732 | 0.169 |
| Day 3 | 1 | 0.99 | 99 ±1.732 | 1.749 |
| | 5 | 5.02 | 100 ±1.744 | 1.744 |
| Day 4 | 1 | 0.99 | 99 ±1.732 | 1.749 |
| | 5 | 5.156 | 103.2 ±0.577 | 0.55 |
| Medium 2 | Interday precision | | | |
| Day 1 | 15 | 14.99 | 99.99 ± 0.8201 | 0.82 |
| | 20 | 19.99 | 99.99 ± 0.3101 | 0.3101 |
| Day 2 | 15 | 14.99 | 100 ± 0.4150 | 0.4150 |
| | 20 | 19.97 | 99.89 ± 0.1848 | 0.185 |
| Day 3 | 15 | 15.02 | 100.1 ±0.2367 | 0.236 |
| | 20 | 20.02 | 100.1 ±0.1790 | 0.178 |
| Day 4 | 15 | 15.02 | 100.1 ±0.2367 | 0.236 |
| | 20 | 20.01 | 100.1 ±0.3637 | 0.362 |

The results of stability study of BA in Medium 1 and Medium 2 were within the acceptable limit and indicate solvent blends are stable over the period of 24 hr at room temperature as shown in table 8. The results of elevated temperature and forced degradation condition data for Medium 1 and Medium 2 were given in tables 9, 10 and results indicate the mediums were thermosensitive and at higher pH they are not stable undergo hydrolysis.

**Table 4** Accuracy data of marketed BA tablets (BEMDAC 180 mg) in Medium 1 and Medium 2

| **Medium 1** | | | | | | |
|---|---|---|---|---|---|---|
| **Amount of Mktd tablet added µg** | **% pure drug** | **Amount of pure drug µg** | **Total amount claimed µg/ml** | **Amount recovered µg** | **% recovered Mean ±SD** | **% RSD** |
| 6 | 40 | 2.4 | 8.4 | 8.52 | 101.5 ± 0.72 | 0.7 |
| 6 | 80 | 4.8 | 10.8 | 10.77 | 99.93 ± 0.40 | 0.4 |
| 6 | 120 | 7.2 | 13.2 | 13.19 | 99.95±0.092 | 0.09 |
| 8 | 40 | 3.2 | 11.2 | 11.19 | 99.94± 0.109 | 0.1 |
| 8 | 80 | 6.4 | 14.4 | 14.48 | 100.6± 0.288 | 0.28 |
| 8 | 120 | 9.6 | 17.6 | 17.57 | 99.86± 0.138 | 0.13 |
| Medium 2 | | | | | | |
| 6 | 40 | 2.4 | 8.4 | 8.39 | 99.87 ± 0.46 | 0.46 |
| 6 | 80 | 4.8 | 10.8 | 10.74 | 99.51 ± 0.60 | 0.60 |
| 6 | 120 | 7.2 | 13.2 | 13.24 | 100.3 ± 0.45 | 0.44 |
| 8 | 40 | 3.2 | 11.2 | 11.12 | 99.29 ± 0.53 | 0.53 |
| 8 | 80 | 6.4 | 14.4 | 14.37 | 99.80± 0.405 | 0.4 |
| 8 | 120 | 9.6 | 17.6 | 17.56 | 99.76 ± 0.35 | 0.35 |

**Table 5** Drug content data of marketed BA tablets (BEMDAC 180 mg) in Medium 1 and Medium 2

| **BEMDAC 180mg** | **Labelled claim µg** | **Amount recovered µg** | **% Recovery Mean ± SD** | **% RSD** |
|---|---|---|---|---|
| Medium 1 | 6 | 6.006 | 100.1 ± 0.23 | 0.22 |
| | 8 | 8.006 | 100.1 ± 0.173 | 0.172 |
| Medium 2 | 6 | 6.02 | 100.3 ± 0.60 | 0.59 |
| | 8 | 7.97 | 99.73 ± 0.461 | 0.46 |

**Table 6** Robustness data for proposed method

| **λmax** | **Concentration µg** | **Amount recovered µg** | **%Recovery Mean ±SD** | **% RSD** |
|---|---|---|---|---|
| Medium 1 | | | | |
| Actual (249 nm) | 1 | 0.99 | 99.33 ± 1.966 | 1.87 |
| | 5 | 5.064 | 101.3± 1.870 | 1.84 |
| 254 (+ 5 nm) | 1 | 0.94 | 94.10 ± 0.021 | 0.12 |
| | 5 | 5.09 | 101.8 ± 0.288 | 0.282 |
| 244 (- 5 nm) | 1 | 1.05 | 105.7 ± 1.212 | 1.14 |
| | 5 | 5.626 | 113 ± 0.280 | 0.24 |

| | | | | |
|---|---|---|---|---|
| Medium 2 | | | | |
| Actual (275nm) | 15 | 15.005 | 100.3± 0.468 | 0.46 |
| | 20 | 19.99 | 99.89 ± 0.4279 | 0.42 |
| 280 (+5 nm) | 15 | 16.27 | 92.50 ± 0.00 | 0.89 |
| | 20 | 21.25 | 99.06 ± 0.012 | 0.79 |
| 270 (-5 nm) | 15 | 13.87 | 108.4 ± 0.2309 | 0.21 |
| | 20 | 19.81 | 106.3 ± 0.021 | 0.24 |

**Table 7** Ruggedness data for proposed methods

| **Parameter** | **Concentration µg** | **Amount Recovered µg** | **% Recovery Mean ± SD** | **% RSD** |
|---|---|---|---|---|
| Medium 1 | | | | |
| Analyst 1 | 1 | 1.006 | 100.7 ± 1.212 | 1.20 |
| | 5 | 5.022 | 100.5 ± 1.744 | 1.735 |
| Analyst 2 | 1 | 0.99 | 99.03 ± 1.674 | 1.690 |
| | 5 | 5.022 | 100.5 ± 1.744 | 1.735 |
| Medium 2 | | | | |
| Analyst 1 | 15 | 15 | 100 ± 0.00 | 0.00 |
| | 20 | 19.953 | 99.79± 0.184 | 0.184 |
| Analyst 2 | 15 | 14.97 | 99.86 ± 0.242 | 0.242 |
| | 20 | 19.97 | 99.89 ± 0.184 | 0.184 |

**Table 8** Stability at different temperature

| **Different Temperature** | **Concentration µg** | **Amount Recovered µg** | **% Recovery Mean ± SD** | **% RSD** |
|---|---|---|---|---|
| Medium 1 | | | | |
| Room Temperature 35$^{o}$C | 1 | 0.98 | 98.0± 0.98 | 0.89 |
| | 5 | 4.96 | 99.3 ± 1.189 | 1.19 |
| 2-8$^{o}$C | 1 | 0.50 | 50.67 ± 2.517 | 4.95 |
| | 5 | 3.85 | 77.09 ± 0.294 | 3.37 |
| Elevated Temperature 45 $^{o}$C | 1 | 0.856 | 85.67 ± 2.88 | 3.36 |
| | 5 | 4.25 | 85.83 ± 0.3000 | 3.12 |
| Medium 2 | | | | |
| Room Temperature 35 $^{o}$C | 15 | 15.12 | 100.8 ± 0.800 | 0.79 |
| | 20 | 19.93 | 99.68 ± 0.3150 | 0.31 |
| 2-8$^{o}$C | 15 | 12.99 | 86.66 ± 1.111 | 1.28 |
| | 20 | 11.64 | 58.23 ± 0.7217 | 1.23 |

| | | | | |
|---|---|---|---|---|
| Elevated Temperature 45 °C | 15 | 12.83 | 85.53 ±0.2309 | 0.26 |
| | 20 | 17.83 | 89.16 ± 0.3580 | 0.40 |

**Table 9** Thermal degradation studies

| Different Temperature | Concentration µg | Amount Recovered µg | % Recovery Mean ± SD | % RSD |
|---|---|---|---|---|
| Medium 1 | | | | |
| AT 45°C | 1 | 0.62 | 62 ± 3.464 | 5.58 |
| | 5 | 3.91 | 78.29 ± 1.289 | 1.63 |
| AT 60 °C | 1 | 0.313 | 31.33 ± 5.774 | 18.41 |
| | 5 | 4.696 | 94.01 ± 1.484 | 1.57 |
| AT 80 °C | 1 | 0.286 | 28.67 ± 1.155 | 4.01 |
| | 5 | 4.236 | 84.78 ± 0.294 | 0.34 |
| Medium 2 | | | | |
| AT 45°C | 15 | 12.64 | 84.64 ± 1.198 | 1.41 |
| | 20 | 18.16 | 90.83 ± 0.363 | 0.39 |
| AT 60 °C | 15 | 11.93 | 79.58 ± 0.420 | 0.52 |
| | 20 | 17.85 | 89.27 ± 0.650 | 0.72 |
| AT 80 °C | 15 | 9.47 | 63.19 ± 1.20 | 1.89 |
| | 20 | 13.79 | 68.96 ± 0.358 | 0.51 |

**Table 10** Forced degradation studies

| Degradation conditions | Concentration µg | Amount Recovered µg | % Recovery Mean ± SD | % RSD |
|---|---|---|---|---|
| Medium 1 | | | | |
| 2N NaOH | 1 | 0.846 | 84.67 ± 7.506 | 8.85 |
| | 5 | 4.62 | 92.47 ± 0.3002 | 3.32 |
| 2N HCl | 1 | 0.31 | 31 ± 1.732 | 5.58 |
| | 5 | 3.88 | 77.77 ± 1.478 | 3.89 |
| 3%$H_2O_2$ | 1 | 0.32 | 32 ± 3.474 | 3.07 |
| | 5 | 3.28 | 65.6 ±1.513 | 5.13 |
| Medium 2 | | | | |
| 2N NaOH | 15 | 14.47 | 96.52 ± 1.201 | 3.24 |
| | 20 | 19.47 | 97.39 ± 0.9007 | 4.92 |
| 2N HCl | 15 | 10.29 | 68.61 ± 1.879 | 3.72 |
| | 20 | 13.08 | 65.41 ±0.1790 | 4.25 |
| 3%$H_2O_2$ | 15 | 10.28 | 68.68 ± 1.879 | 3.72 |
| | 20 | 13.12 | 65.52 ±0.1790 | 3.25 |

## 4. Conclusion

The results and the statistical parameters demonstrate that the proposed UV spectrophotometric solvent systems are simple, rapid, specific, accurate and precise. Therefore, these solvent systems can use for the quantification of Bempedoic acid in bulk and marketed tablet formulations without interference with commonly used excipients and related substances.

## Compliance with ethical standards

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*Disclosure of conflict of interest*

No conflict of interest

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