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*NOTE*

# UV Spectrophotometric Determination of Gefitinib and Rosuvastatin Calcium

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A simple and sensitive UV spectrophotometric method has been developed for the determination of gefitinib (GFB) and rosuvastatin calcium (RSV) in pure form and pharmaceutical formulations. These methods exhibit maximum absorption ($\lambda_{max}$) at 264 nm for GFB and 258 nm for RSV and both the methods obey Beer's law in the concentration range 5–25 μg/mL respectively. The methods are accurate and precise and are extended to pharmaceutical formulations and there was no interference from any common pharmaceutical additives and excipients. The results of the analysis have been validated statistically and by recovery studies.

**Key Words: UV Spectrophotometric determination, Gefitinib, Rosuvastatin calcium.**

Gefitinib[1, 2] (GFB) is an anticancer drug and is chemically known as 4-quinazolinamine, N-(3-chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholinyl)-propoxyl]. Rosuvastatin calcium[3, 4] (RSV) is an inhibitor of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-coA) reductase. Chemically (RSV) is known as 6-heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulphonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-calcium salt (2 : 1) (3R, 5S, 6E). Literature survey reveals that no spectrophotometric methods have been developed so far for their determination; however, one HPLC method coupled to tandem MS in human plasma has been reported for gefitinib[5] and an HPTLC[4, 6] method has been developed for rosuvastatin calcium. The authors have developed two simple, accurate and reliable UV spectrophotometric methods for the estimation of GFB and RSV in pure as well as in pharmaceutical dosage forms.

All the chemicals used were of analytical grade

Spectral and absorbance measurements were made on Systronics UV-Vis spectrophotometer-117 with 10 mm matched quartz cells.

**Preparation of standard solution:** Accurately weighed 100 mg of GFB/RSV was dissolved in 100 mL of glacial acetic acid. The stock soution was further diluted with glacial acetic acid to obtain a working standard of 100 μg/mL for GFB/RSV.

**Preparation of sample solution:** An accurately weighed tablet powder of GFB or RSV equivalent to 100 mg of drug was dissolved in 100 mL of glacial acetic acid and filtered. This solution was further diluted with glacial acetic acid to obtain a concentration of 100 μg/mL for GFB or RSV.

**Proposed methods for GFB and RSV:** Aliquots of solution 0.5–2.5 mL (100 μg/mL for GFB or 100 μg/mL for RSV) were transferred into a series of 10 mL volumetric flasks and the volume was brought up to 10 mL with glacial acetic acid. The absorbance was measured at 264 nm for GFB and 258 nm for RSV against a reagent blank. The amount of GFB and RSV present in the sample solution was computed from its calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation (calculated from eight measurements containing 3/4th of the amount of the upper Beer's law limits), regression equation, correlation coefficients, % range of error (0.05 and 0.01 confidence limits) were calculated and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERSTICS AND PRECISION OF THE PROPOSED METHODS

| Parameters | | GFB | RSV |
|---|---|---|---|
| $\lambda_{max}$ (nm) | | 264 | 258 |
| Beer's law limit (μg/mL) | | 5–25 | 5–25 |
| Molar absorptivity (L $mol^{-1}$ $cm^{-1}$) | | $1.360 \times 10^4$ | $2.703 \times 10^4$ |
| Sandell's sensitivity (μg $cm^{-2}$/0.001 absorbance unit) | | 0.034 | 0.037 |
| Regression eqn. (Y = a + bC): | Slope (b) | 0.02936 | 0.02736 |
| | Intercept (a) | –0.0006 | –0.0006 |
| Correlation coefficient (r) | | 0.9999 | 0.9999 |
| Relative standard deviation (%)* | | 0.9697 | 1.0692 |
| %Range of error (Confidence limits)*: | 0.05 level | 0.8108 | 0.8940 |
| | 0.01 level | 1.1995 | 1.3226 |

*Average of eight determinations

To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to previous pharmaceutical preparations and the mixtures were analyzed by the proposed methods and the results are presented in Table-2. Interference studies revealed that the common excepients and other additives did not interfere. Hence the method is most economic, simple, sensitive and accurate and can used for the routine determination of GFB or RSV in bulk form as well as in pharmaceutical preparations.

TABLE-2
ESTIMATION OF GFB AND RSV IN PHARMACEUTICAL FORMULATIONS

| Sample | | Labelled amount (mg) | Amount found (mg) Proposed method | Recovery (%)* |
|---|---|---|---|---|
| **Gefitinib:** | Tablets I | 250 | 252.05 | 100.80 |
| | Tablets II | 250 | 247.60 | 99.04 |
| **Rosuvastatin calcium:** | Tablets I | 10 | 10.70 | 100.70 |
| | Tablets II | 10 | 9.82 | 98.82 |

*Recovery amount was the average of five determinations.

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