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# Development and Validation of UV- Spectrophotometric Method for The Estimation of Bosutinib

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**Abstract**

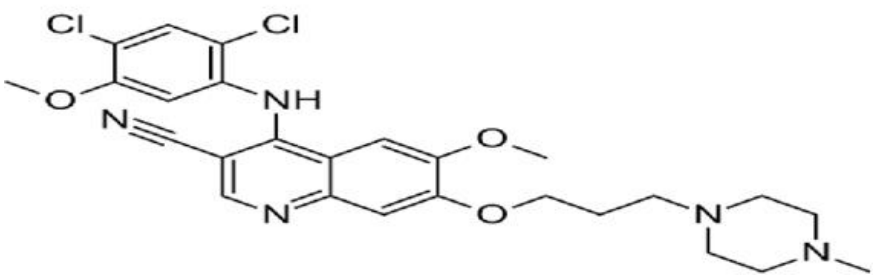
Estimation of Bosutinib was achieved by UV Spectroscopy. The linearity was checked in different concentrations and beer's law obeyed in the concentration range of 2-12µg/ml for bosutinib. The recovery studies were carried to ensure the reproducibility and reliability of the method by adding known amount of bosutinib.
This method was carried out by using methanol as solvent.
Drug stability studies were also established to evaluate the drug product at different stress conditions of Acid, base and oxidation studies.

**Key words:** drug ; stress ; uv spectroscopy

**Introduction:**
Pharmaceutical analysis is a branch of practical chemistry that involves a series of process for identification, determination, quantification and purification of a substance, separation of the components of a solution or mixture, or determination of structure of chemical compounds. The substance may be a single compound or a mixture of compounds and it may be in any of the dosage form.

The substance used for pharmaceutical purpose are from animals, plants, micro-organisms, minerals and various synthetic products. Spectroscopy is the measurement and interpretation of electromagnetic radiation absorbed or emitted when the molecules or atoms or ions of a sample move from one energy state to another energy state.

**Drugprofile:**
**Bosutinib**



**Mechanism Of Action:** Bosutinib is a tyrosine kinase inhibitor. Bosutinib inhibits the BCR-ABL kinase that promotes CML; it is also an inhibitor of Src-family kinases including Src, Lyn, and Hck. Bosutinib inhibited 16 of 18 imatinib-resistant forms of BCR-ABL kinase expressed in murine myeloid cell lines. Bosutinib did not inhibit the T3151 and V299L mutant cells

**Calibration Of Uv Visible Instrument:**

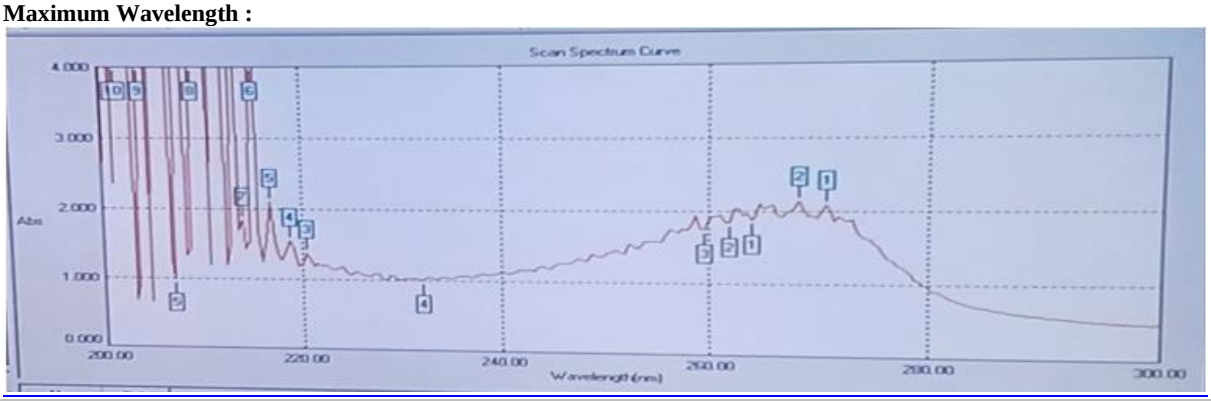
Standard Operating Procedure: Tests, and linearity tests.

Calibration of UV-visible spectrophotometer is done in four steps:

Standard operating procedure is to calibrate the UV-Visible Spectrophotometer to verify the performance by control of absorbance, limit of stray light, resolution power.

- Control of absorbance
- Limit of stray light
- C. Resolution power
- D. Linearity

**Maximum Wavelength :**




**λ max: The wavelength at which a substance has its strongest photon absorption**

**Method:**

Preparation of standard stock solutions

**Standard stock-1:**

- 10.0mg of bosutinib was accurately weighed and transferred to 10 ml of conical flask.
- Few ml of diluent(methanol) was added to dissolve by shaking manully for 10 mins
- And make up the volume upto the mark with the same diluent (1000µg/ml)

**Standard stock solution-2:**

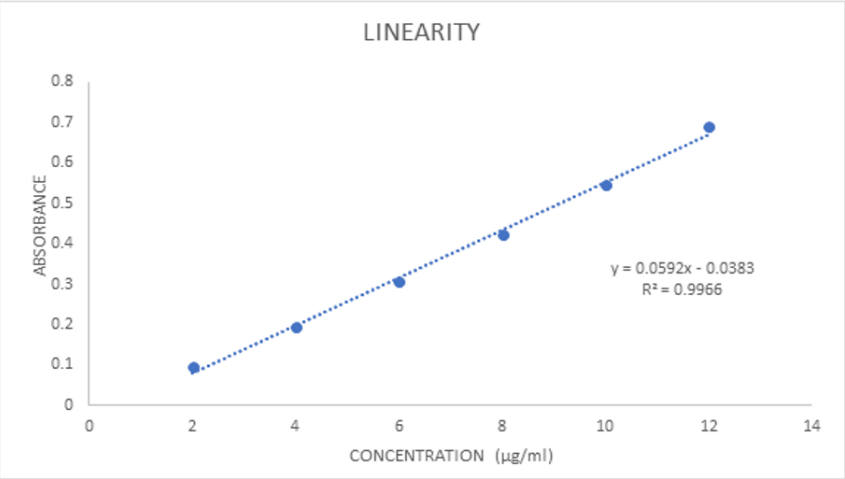
- 1.0ml of from standard stock-1 solution was pipetted to 10ml volumertric flask. And was made up to the mark with the same (100µg/ml)

**Validation Of The Method:**

The working standards of bosutinib were prepared from solution B to get concentration of 2, 4, 6, 8, 10,12 (µg/ml). These solutions were scanned in UV at 268nm.

| CONCENTRATION | ABSORBANCE |
|---|---|
| 2 | 0.096 |
| 4 | 0.193 |
| 6 | 0.308 |
| 8 | 0.423 |
| 10 | 0.548 |
| 12 | 0.689 |

**Calibration data of propylparaben at 254nm**




**Calibaration Graph Of Bosutinib**

**Result:**

**Precision**

The precision of analytical method is defined as the agreement between replicate measures of the same sample.

The precision was carried out by two methods: Intraday and Interday.

**Intraday:**

The intraday precision was carried by scanning the sample at different times within a day. %RSD is found to be 0.501%

Acceptance criteria:The % RSD for the Intraday precision is calculated and the calculated value is within the limits,i.e.≤2%.

| CONCENTRATION | ABSORBANCE |
|---|---|
| 6µg/ml | 0.306<br>0.304<br>0.303 |
| STDEV | 0.001 |
| %RSD | 0.501% |

**Interday:**

The interday precision was carried out by scanning the sample at different days with in a week. %RSD is found to be

Acceptance criteria: The %RSD for the Interday precision is calculated and the calculated value is with in the limits, i.e.,≤2%.

| CONCENTRATION | ABSORBANCE |
|---|---|
| 6µg/ml | 0.304<br>0.303<br>0.301 |
| STDEV | 0.001 |
| %RSD | 0.504% |

**Accuracy:**

The closeness of agreement between the true values which is accepted either conventional new value or an accepted reference value and the value found in order to ensure the suitability and reliability of proposed method. Recovery studies were carried out.

To an equivalent quantity of propylparaben a Known quantity of standardbosutinib was added to 50%, 100% and 150% level and the contents were reanalysed by the proposed method. The recovery was calculated as follow:

DRUG STABILITY STUDIES

Drug stability studies are conducted to evaluate how the quality of a drug substance or drug product varies with time under the influence of various envinormental factors,such as temperature ,light and pH.

A)**Acid degradation:**

1ml of stock solution -2+2ml of Hcl
after 24hrs

Add 2ml of NaOH and makeup the volume with distilled water and absorbance are noted by applying the developed method

B)**Base degradation:**

1ml of stock solution -2+2ml of NaOH
after 24hrs

Add2ml pf HCLand makeup the volume with distilled water and absorbance are noted by applying the developed method

**Conclusion:**

The method to detect bosutinib by UV -Spectroscopy was established and validated.The results obtained are proved that proposed method is accurate, Precise and rapid for the determination of bosutinib.The developed method can be applied successfully for the determination of bosutinib in bulk form.

The drug stability studies has shown the degradation for the drug bosutinib under different conditions.

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