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# Spectrophotometric Estimation of Bupropion Hydrochloride in Bulk and Tablet Dosage Form

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**ABSTRACT**

A simple, accurate, precise, sensitive and a highly selective Spectrophotometric method was developed for the bupropion hydrochloride in bulk and tablet dosage form. The estimation of bupropion hydrochloride was carried out at 251nm.The method was found to be linear in the range of 4-20 µg/ml with recovery of 99.6%. The developed method was validated according to ICH guidelines and it found to be accurate and precise Thus the proposed method can be successfully applied for determination of bupropion hydrochloride in routine analysis work.

**Keywords:** Bupropion hydrochloride, Spectrophotometric, ICH, Validation.

## INTRODUCTION

Bupropion hydrochloride, 1-propanone1-(3chlorophenyl) - 2- [(1,1dimethylethyl) amino] hydrochloride, is non-trycyclic antidepressant that belongs to chemical class of aminoketones. Bupropion is a dopamine and norepinephrine reuptake inhibitor and releaser. It is about twice as potent as inhibitor of dopamine as of norepinephrine reuptake. Bupropion hydrochloride is metabolized in liver and excretes into the urine (PubMed health, 2011).

The scope of developing and validating a method is to ensure a suitable strategy for a particular analyte which is more stable ,cheap, specific, accurate, precise and less time consuming. The existing available literature reveals that very few analytical methods are available for the drug, which is very costly and less stable (Qi Meiling *et al*., 2001). So, it was felt that to improve method for Bupropion hydrochloride.

## EXPERIMENTAL

### Instrumentation

The present work was carried out on Shimadzu UV- 1700 series spectrophotometer having double beam detector configuration. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 251nm.

### Reagent and chemicals

Bupropion hydrochloride obtained as gift sample from Mylon laboratories, Hyderabad.

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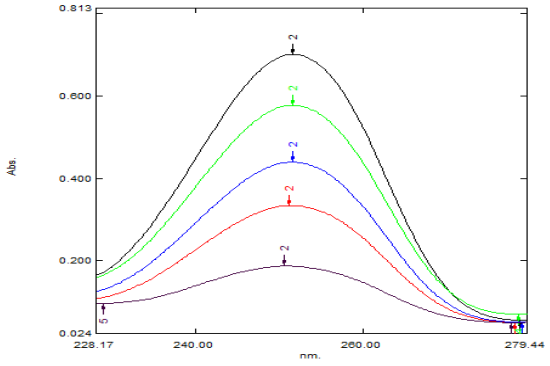
### Experimental condition

According to the solubility characteristics of drug Purified water was selected as solvent for analysis. From the overlay spectra wavelength was selected for the estimation of bupropion hydrochloride at 251nm.

### Standard stock and sub stock solution

UV analysis was done by using the standard stock solution of 100 µg/ml of bupropion hydrochloride by dissolving 10mg of standard drug in distilled water. Aliquots of 4, 8, 12, 16 and 20 µg/ml were prepared by using the above stock solution and diluted with distilled water, for the preparation of calibration curve.

**Figure.1 Calibration curve of bupropion hydrochloride**




### Method validation studies

### Linearity

The linearity of the method is its ability to elicit test results that are directly proportional to the

concentration of the analyte in samples. The calibration curve was taken in the range of 4-20µg/ml for bupropion hydrochoride at the respective λmax i.e., 251nm. The correlation coefficient of the linearity was found to be 0.999.

**Precision**

The precision of an analytical method is determined by assaying a sufficient number of aliquots of a homogeneous sample to be able to calculate statistically valid estimate of %Relative Standard Deviation (%RSD). Intermediate precision was done to express within laboratory variation, on different days. Five replicates of 12µg/ml concentration of the working standard mixture and sample solution were analysed. %RSD was found to be less than 2.

**Recovery Studies**

In order to ensure the reliability and suitability of the proposed method, recovery studies were carried

**Table.1 Calibration curve data of standard Bupropion hydrochloride bulk drug**

| S. No. | Concentration (µg/ml) | Absorbance at 251 nm |
|---|---|---|
| 1 | 4.0 | 0.178 |
| 2 | 8.0 | 0.290 |
| 3 | 12.0 | 0.413 |
| 4 | 16.0 | 0.550 |
| 5 | 20.0 | 0.671 |

**Table.2 Intra-day precision (n=6)**

| Sample | concentration | Absorbance | %RSD |
|---|---|---|---|
| Bupropion Hydrochloride | 4µg/ml | 0.178<br>0.176<br>0.179<br>0.175<br>0.177<br>0.173 | 1.2 |
| | 12µg/ml | 0.413<br>0.414<br>0.410<br>0.418<br>0.414<br>0.415 | 0.6 |
| | 20µg/m | 0.671<br>0.670<br>0.673<br>0.674<br>0.670<br>0.678 | 0.4 |

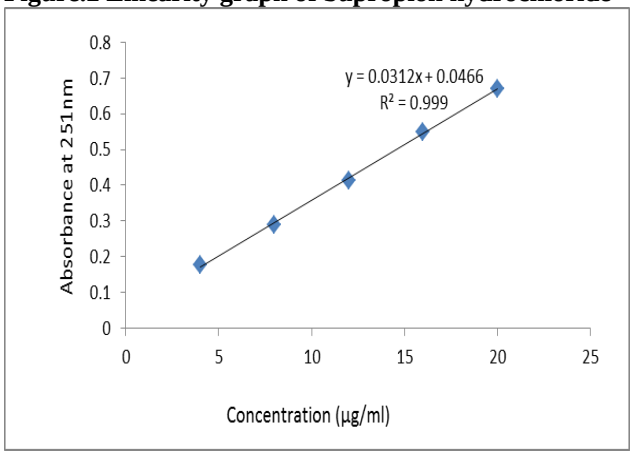
**Table.3 Inter-day precision (n=6)**

| S.NO | Sample | Concentration Mcg/ml | Day | Absorbance | %RSD |
|---|---|---|---|---|---|
| 1 | Bupropion Hydrochloride | 12µg/ml | 1 | 0.410<br>0.415<br>0.416<br>0.413<br>0.417<br>0.413 | 0.6 |
| | | | 2 | 0.411<br>0.413<br>0.415<br>0.413<br>0.417<br>0.418 | 0.6 |
| | | | 3 | 0.410<br>0.418<br>0.416<br>0.414<br>0.417<br>0.416 | 0.6 |

**Table.4 Recovery studies**

| Recovery range | Test Concentration (µg/ml) | Amount of concentration spiked (µg/ml) | Amount of sample recovered (µg/ml) | Avg. amount of sample from calibration graph | % Recovery | % RSD |
|---|---|---|---|---|---|---|
| 75% | 8 | 4 | 8.19 | 12.19 | 99.5 | **0.81** |
| | | 4 | 8.23 | 12.23 | 100.8 | |
| | | 4 | 8.21 | 12.21 | 99.3 | |
| 100% | 8 | 6 | 8.16 | 14.16 | 99.8 | **0.60** |
| | | 6 | 8.11 | 14.11 | 99.2 | |
| | | 6 | 8.12 | 14.12 | 100.1 | |
| 125% | 8 | 8 | 8.64 | 16.64 | 100.5 | **0.58** |
| | | 8 | 8.61 | 16.61 | 100.7 | |
| | | 8 | 8.62 | 16.62 | 99.6 | |

**Figure.2 Linearity graph of bupropion hydrochloride**




out. It was done by mixing known quantity of standard drug with formulation sample and the content were reanalysed by the proposed method. To a quantity of formulation equivalent to 10 mg of bupropion hydrochloride, standard drugs of bupropion hydrochloride added at 75%, 100% and 125% levels. This was extracted diluted and reanalysed as per the formulation procedure. Absorbances were noted at respective wavelength. Recovery studies were repeated for six times and shown in below table.

## RESULTS & DISCUSSION

The proposed methods for simultaneous estimation of bupropion hydrochloride in tablet dosage form were found to be simple accurate economical and rapid. The % RSD was found to be less than 2% in the developed method. Hence proposed method may be used for routine analysis of the drug.

**Table.5 Results of the method validation parameter**

| S.NO | VALIDATION PARAMETERS | RESULTS |
|---|---|---|
| 1 | Linearity | 4-20µg/ml |
| 2 | Correlation coefficient | 0.999 |
| 3 | Precision | <2% |
| | Intraday precision 4mcg/ml (n=6) | 0.0475 (4µg/ml) |
| | 12mcg/ml (n=6) | 0.0697(6µg/ml) |
| | 20mcg/ml (n=6) | 0.0713(8µg/ml) |
| | Interday precision (n=6) | 0.0465(1st day) |
| | | 0.0479(2nd day) |
| | | 0.0455(3rd day) |
| 4 | LOD | 0.02µg/ml |
| 5 | LOQ | 0.1µg/ml |

## CONCLUSION

A simple, rapid and economical spectrometric method was developed for the estimation of bupropion hydrochloride in bulk and tablet dosage forms. The results obtained were found to be good and sensitive. The method was validated and was found to be accurate, precise and sensitive. The tablet dosage form was assayed by this method. And the results showed good correlation between bulk and tablet dosage forms. The proposed method can be extended to different quality control labs for routine analysis of bupropion hydrochloride in bulk and tablet dosage form.

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