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ESTIMATION OF BROMOCRIPTINE MESYLATE IP BY UV SPECTROSCOPY

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ABSTRACT

The main objective was to develop and validate the UV-spectrophotometric method for the estimation of Bromocriptine Mesylate in bulk and pharmaceutical formulations as per ICH guidelines Materials and methods: A simple, rapid, accurate, and economical UV-spectrophotometric method has been developed for the estimation of Bromocriptine Mesylate from bulk and pharmaceutical formulations. Result: The λmax of Bromocriptine Mesylate in methanol was found to be 305 nm. The drug follows linearity in the concentration range 50-200 µg/ml with a correlation coefficient value of 0.998. The accuracy of the method was checked by recovery experiment performed at three different levels, i.e., 98.51%, 99.12% and 98.92%. The precision of the method was studied as an intraday; intraday variations, and repeatability.

Keywords: Bromocriptine Mesylate, Method Development, Spectrophotometry.

I. INTRODUCTION

Bromocriptine Mesylate, 2-bromo-2β-isopropyl-5aisobutyl-ergopeptine methanesulfonate is an amino acid, alkaloid derivative of lysergic acid. It consists of a heterocyclic nucleus to which a single bromine and peptide side chain is attached (Fig. 1). Bromocriptine Mesylate acts as a weak partial agonist at D1-type and a partial agonist at D2- type dopamine receptor. It is indicated for the treatment of Parkinson's disease and conditions associated with hyperlactinemia (e.g. amenorrhea, galactorrhea, and infertility). It is also effective in the treatment of acromegaly and neuroleptic malignant syndrome. Bromocriptine mesylate is available as tablets and capsules, containing 2.5 mg (tablets) and 5 mg (capsules) of bromocriptine

Bromocriptine Mesylate is a dopamine receptor agonist, which activates post-synaptic dopamine receptors. Bromocriptine mesylate is a nonhormonal, nonestrogenic agent that inhibits the secretion of prolactin in humans, with little or no effect on other pituitary hormones, except in patients with acromegaly, where it lowers elevated blood levels of growth hormone in the majority of patients.

Bromocriptine mesylate produces its therapeutic effect in the treatment of Parkinson's disease, a clinical condition characterized by a progressive deficiency in dopamine synthesis in the substantia nigra, by directly stimulating the dopamine receptors in the corpus striatum. In contrast, levodopa exerts its therapeutic effect only after conversion to dopamine by the neurons of the substantia nigra, which are known to be numerically diminished in this patient population.

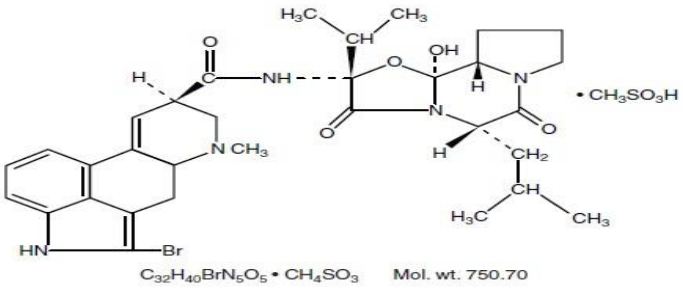

Figure 1. Chemical Structure of Bromocriptine Mesylate

II. METHODOLOGY

Tablets – SICRIPTIN, manufactured by Serum International LTD. Containing 2.5mg per tablet was purchased from the market. Spectroscopic grade methanol and ethanol were purchased from Merck India Ltd. UV absorbance was recorded using BioEra UV-spectrophotometer.

III. MODELING AND ANALYSIS

Procedure for assay (From IP):

Weigh accurately a quantity of the mixed contents of 20 capsules equivalent to 25 mg of Bromocriptine and shake vigorously with 30 ml of methanol. Dilute to 100 ml with methanol and filter. Dilute further with

methanol to yield a final concentration of 50µg/ml and measure the absorbance of the resulting solution at the maximum at about 305nm, appendix 5.5. Calculate the content of Bromocriptine from the absorbance obtained by repeating the operation using Bromocriptine Mesylate RS equivalent to 25 mg of Bromocriptine instead of the substance being examined and from the content of Bromocriptine in Bromocriptine Mesylate RS. [2]

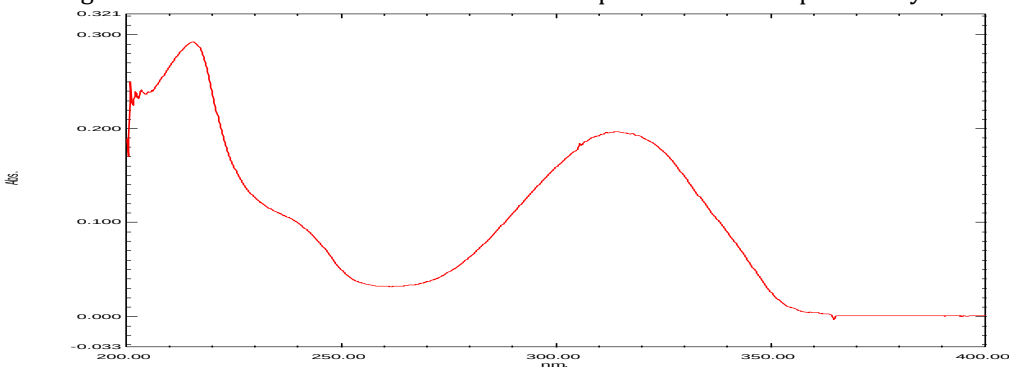

Figure 2. UV Absorption Spectra Of Bromocriptine Mesylate

PROCEDURE FOR THE DILUTIONS:

1) Take the 20 capsules of Bromocriptine Mesylate.

2) Triturate it using mortar and pestle.

3) Weigh accurately 25 mg of Bromocriptine Mesylate powder which is previously triturated in the mortar.

A) Procedure for the dilution of 50µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 2 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 50µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

B) Procedure for the dilution of 75µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 3 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 75µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

C) Procedure for the dilution of 100µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 4 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 100µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

D) Procedure for the dilution of 125µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 5 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 125µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

E) Procedure for the dilution of 150µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 6 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 150µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

F) Procedure for the dilution of 175µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 7 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 175µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

G) Procedure for the dilution of 200µg/ml:

i) Mixed 25 mg of Bromocriptine Mesylate powder in 30 ml of methanol and shake it vigorously.

ii) Dilute the above solution by using methanol up to 100 ml.

iii) Filter the above solution by using filter paper.

iv) From the above solution (filtrate) pipette out 8 ml and again dilute with 10 ml of methanol.

v) This makes the final concentration of 200µg/ml and measure the absorbance of resulting solution at the maximum at about 305 nm.

CALCULATIONS: (50µg/ml)

Absorbance at 305 nm = 0.094

0.25 gm of powder was dissolved in 100 ml of methanol hence,

0.25 gm of powder present in 100 ml of methanol then,

Calculation for the concentration of powder present in 1 ml,

0.25 gm = 100 ml

X gm = 1 ml

Therefore, X = 0.25 ÷ 100

X = 0.0025 gm/ml

Then from the above 100 ml solution pipette out 2 ml solution and diluted to the 10 ml using methanol therefore,

Calculation for the Theoretical concentration,

Y = (0.0025 × 2) ÷ 10

Y = 0.0005 gm/10 ml,

For gm/100 ml,

Y = (100 × 0.0005) ÷ 10

Y = 0.005 gm/100 ml.

Calculation for the practical concentration (Beers lamberts law),

A = abc,

Where,

c = A ÷ (a×b)

c = 0.094 ÷ (215.77 × 1)

c = 0.00043 gm/10 ml,

For 100 ml,

c = 0.0043 gm/100 ml

Calculation for the percentage purity:

1) Theoretical concentration = 0.005 gm/100 ml

2) Practical concentration = 0.0043 gm/100 ml

0.005 gm is 100% pure then,

00.005 = 100%

0.0043 = X%

Therefore, X% = (0.0043 × 100) ÷ 0.005

X=86%

Hence the percentage purity of Bromocriptine Mesylate tablet was found to be 86%

OBSERVATION TABLE:

Table1

Sr.No	Concentration (µg/ml)	Theoretical Concentration (gm/ml)	Absorbance	Practical concentration (gm/ml)	Percentage purity (%)
1.	50 µg/ml	0.005 gm/ml	0.112	0.0043 gm/ml	86%
2.	75 µg/ml	0.0075 gm/ml	0.162	0.0068 gm/ml	136%
3.	100 µg/ml	0.01 gm/ml	0.230	0.010 gm/ml	200%
4.	125 µg/ml	0.0125 gm/ml	0.281	0.013 gm/ml	260%
5.	150 µg/ml	0.0150 gm/ml	0.339	0.015 gm/ml	300%
6.	175 µg/ml	0.0175 gm/ml	0.383	0.017 gm/ml	340%
7.	200 µg/ml	0.02 gm/ml	0.436	0.020 gm/ml	400%

Absorptivity value was determined from the above table and it was found to be 215.77

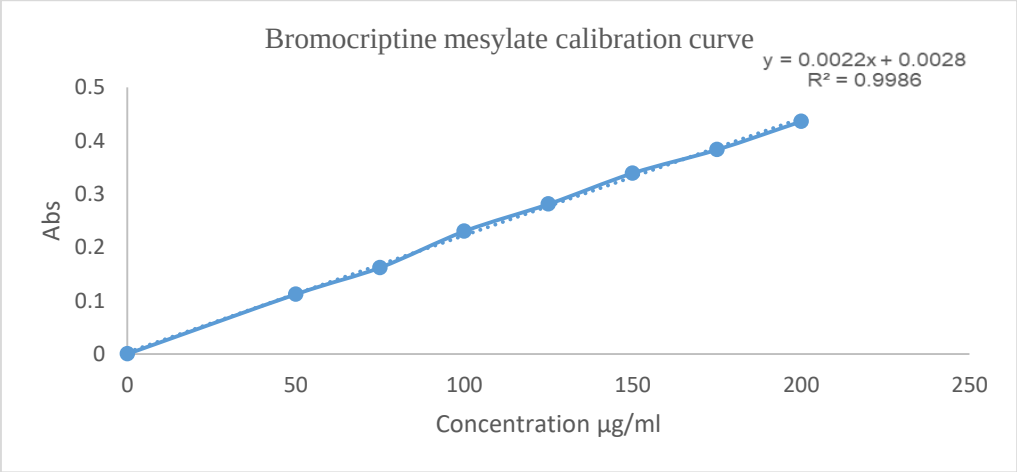

Figure 3. Calibration curve of Bromocriptine Mesylate

IV. RESULTS AND DISCUSSION

Absorptivity value was practically determined as we did not get perfect absorptivity value from IP and that's why it may be the reason we get high value of percentage purity. The method involves measurement of UV absorbance at 305nm for Bromocriptine Mesylate corresponding to the absorption maxima of the marketed

formulation. The absorbance characteristics showed that Bromocriptine Mesylate obeys Beer Lambert's law. regression value of 0.9986 and calibration equation
Y = 0.0022X+0.0028.

Table 2. Table for standard curve of Bromocriptine Mesylate

Standard	Conc. (µg/ml)	Mean	SD
Std.1	50	0.112	0.0003
Std.2	75	0.162	0.0004
Std.3	100	0.230	0.0006
Std.4	125	0.281	0.0007
Std.5	150	0.339	0.0002
Std.6	175	0.383	0.0004
Std.7	200	0.436	0.0006

Values expressed as mean of three readings Recovery studies were carried out by standard addition method and the average percentage recovery of the three samples of marketed Bromocriptine Mesylate IP CV-1, CV-2 and CV-3 were found to be 98.51%, 99.12% and 98.92% respectively. Results obtained from the recovery study indicating the accuracy and precision of the method.

V. CONCLUSION

Bromocriptine Mesylate is a medication used for the type 2 diabetes mellitus. The assay of Bromocriptine Mesylate is done by the UV spectroscopy at maxima of 305 nm. According to the assay performed on the Bromocriptine Mesylate tablet by UV spectroscopy, we plot the graph of concentration vs absorbance (concentration on x axis and absorbance on y axis). From the graph it is concluded that the maximum four points obeys the Beers Lamberts law and two points shows the negative deviation from the Beers Lamberts law. Over all we can say that all reading of Bromocriptine Mesylate obey Beers and Lamberts law.

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