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ESTIMATION OF ATORVASTATIN IN SOLID DOSAGE FORM BY UV -SPECTROSCOPY.

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Abstract: Estimation of Atorvastatin calcium by UV-Spectroscopic method in tablet dosage form was described in this study. In this method the solubility of tried in water, methanol, phosphate buffer but it was observed that soluble in methanol and λ max=266nm, methanol is used to prepare standard and tablets stock solutions, the calibration curve was drawn. Form the linearity curve it was observed that "Atorvastatin Calcium" follows linearity for concentration range of 5-25µg/ml. In terms of precision and linearity, this method was validated. In the estimation of drug in formulation the interference of impurities or excipients was not found.

INTRODUCTION

Atorvastatin is a class of medications called statins having chemical name "3-hydroxy-3-methylglutaryl coenzyme A" [HMG-COA] reductase inhibitor [2]. With a dosage of 10-80 mg/day, It is effective to maintain the level of cholesterol by minimizin the "total cholesterol" (TC) levels of LDL-C, TGs and VLDL-C and increases HDL-C in the body.

Physical properties like "Molecular weight"(MW): - 558.63g/mol, "Melting point"(MP): - 159.2-160.7° C, "Molecular formula"(MF): - C33H35FN2O5, "Solubility"(S): - slightly soluble in distilled water, PH 7.4, Shelf Life: -half-life of about 14 hours as compare to other statins.

STRUCTURE:

Figure 1: Structure of Atorvastatin

Mechanism of Action

Atorvastatin The liver produces less cholesterol when HMG-CoA is prevented from being converted to mevalonate by statin drugs. The study found that Atorvastatin decreased TC, LDL-C, apo B, VLDL-C, and TGs, while increasing HDL-C in the body with "homo or heterozygous familial hypercholesterolemia, mixed dyslipidemia, isolated hypertriglycerid". It is also observed that atorvastatin reduces IDL-C within patient's body with dysbetalipoproteinemia.

Materials And Methods

1.INSTRUMENTS: The instrument SHIMADZU is a "double-beam UV-Visible spectrophotometer" with a fixed slit width of 2nm and with a system that processes data. UV of standard and solution sampled in 1 cm quartz cells between wavelength ranges of 220-320 nm.

2.CHEMICALS: Atorvastatin is procured from Medrich Limited. Atorvastatin Calcium tablets (Liponorm 10mg, 20mg and Remetor 10mg, 20mg) were obtained from the local Pharmacist. An analytical standard Methanol was utilized.

PROCEDURE:

Identification of λmax of Atorvastatin calcium:

Take 20mg of Atorvastatin calcium dissolved in 50 ml of methanol (0.4mg/ml). The concentration has been increased to 100ml by withdrawing 10ml from solution. Methanol was diluted appropriately to produce a solution of 10 μ g/ml, which further examined under UV region, (200 and 400 nm) range, and finally spectra was recorded[5].

Preparation of standard stock solution:

Take 20mg of "Atorvastatin Calcium" put into a 50ml volumetric flask and mix with methanol solution to increase conc.. Similarly, Pipe the 2.5ml solution into a 25ml flask to increase the conc. as desired with methanol . Thus we obtain the $40\mu g/ml$ strength of Atorvastatin calcium[5].

Procedure for the plotting calibration curve of pure drug:

Consider different range of dilutions like"1.25ml, 2.5ml, 3.75ml, 5ml and 6.25ml" from standard stock solution in the 10ml flask and increase conc. upto the range $5-25\mu g/ml$ using methanol. The absorbances were coputed at 266nm and to plot calibration curve [5].

Procedure for plotting calibration curve of the Atorvastatin calcium tablet:

Take 10 tablets of Atorvastatin were weighted. The 20mg power equivalent is dissolved in 50ml of methanol, shaken for 10min and filtered. Pipe the 2.5ml solution into 25ml in a flask to increase the total conc. using methanol. Thus, Atorvastatin achieved $40\mu g/ml$ of strength. Finally, solution was diluted in 10ml solution with methanol to obtain different conc. of 5, 10, 15, 20 and $25\mu g/ml$. Absorbance was calculated at 266nm against reagent blank and plot calibration curve [5].

VALIDATION OF ANALYTICAL METHOD:

Procedure for Precision study of pure drug:

A10 μ g/ml drug solution is chosen for precision investigation. To achieve 10 μ g/ml, the requisite dilutions were picked from base solution and repeating the process for six times. At 266 nm, absorbance was determined.

Procedure for Precision study of the Atorvastatin calcium tablet:

The tablets power equivalent is 20 µg. The Atorvastatin calcium is mixed 50 ml methanol, for 10 minutes, and filtered. At 266 nm, absorbance was assessed in comparison to a reagent blank and steps were repeated 6 times.

INFRARED SPECTROSCOPY

Table 1: IR Interpretation Data

| SI. | Standard | Observed value | Interpretation |
|-----|----------------------------|--------------------|----------------|
| No | values (cm ⁻¹) | (cm ¹) | |
| 1. | 900-690 | 840.56, 811.97, | Ar-sub |
| | | 743.35 | |
| 2. | 1600-1475 | 1578.19, 1549.60, | Ar –C=C |
| | | 1429.52 (s) | |
| 3. | 1250-1100 | 1217.95 | C-F-str |
| 4. | 1320-1210 | 1160.77 | C-O str |
| 5. | 1200-1025 | 1160.77, 1109.31, | C-N str |
| | | 1063.56 | |
| 6. | 3500-3000 | 3362.24 | NH str |
| 7. | 1730-1700 | 1744.02 | C=O str |
| 8. | 860-680 | 691.89 | С-Н |

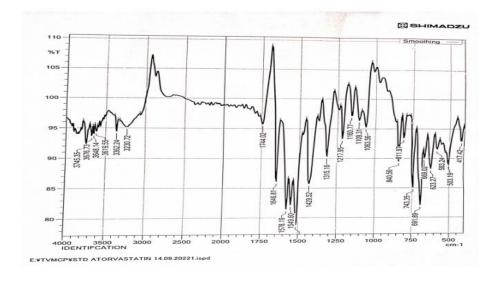


Figure 2: Infrared interpretation data

6. RESULTS AND DISCUSSION

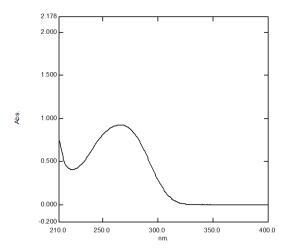


Figure 3: λmax of Atorvastatin calcium

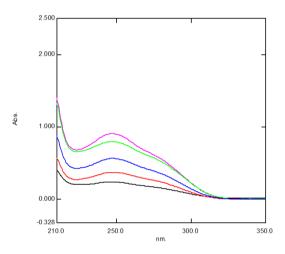


Figure 4: Calibration curve of Pure drug at 266nm

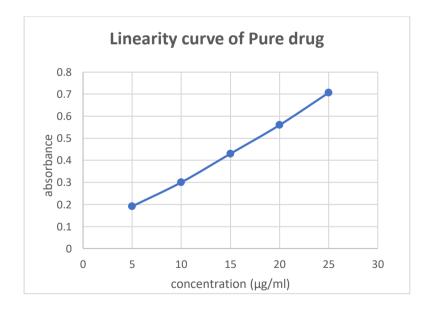


Figure 5: Linearity curve of Pure drug

Table 2: Calibration curve of Pure drug and Liponorm 10mg

| Sr. | Concentration | Pure drug | Tablets (Liponorm |
|-----|---------------|---------------|---------------------|
| No. | (µg/ml) | absorbance at | 10mg) absorbance at |
| | | 266nm | 266nm |
| 1. | 5 | 0.191 | 0.393 |
| 2. | 10 | 0.303 | 0.588 |
| 3. | 15 | 0.432 | 0.755 |
| 4. | 20 | 0.560 | 0.890 |
| 5. | 25 | 0.707 | 1.255 |

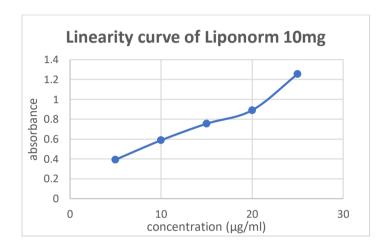


Figure 6: Linearity curve of Liponorm 10 mg

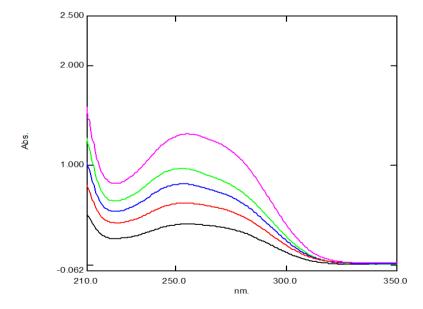


Figure 7: Calibration curve of Atorvastatin calcium tablet (Liponorm 10mg) at 266nm

Table 3: Calibration curve for Pure drug and Liponorm 20mg

| Sr. No. | Concentration (µg/ml) | Pure drug absorbance at 266nm | Tablets (Liponorm 20mg) absorbance at 266nm |
|------------|-----------------------|-------------------------------------|---|
| 1. | 5 | 0.191 | 0.181 |
| 2. | 10 | 0.303 | 0.314 |
| 3 | 15 | 0.432 | 0.494 |
| 4. | 20 | 0.560 | 0.677 |
| s5. | 25 | 0.707 | 0.781 |

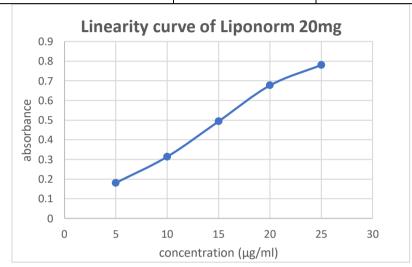


Figure 8: Linearity curve of Liponorm 20mg

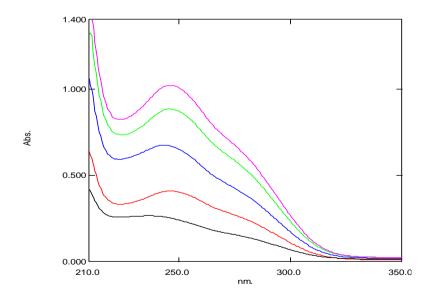


Figure 9: Calibration cure of Atorvastatin calcium tablet (Liponorm 20mg) at 266nm

Table 4: Calibration curve for Pure drug and Remetor 10mg

| Sr. | Concentration | Pure drug | Tablets (Remetor | |
|-----|---------------|---------------------|---------------------|--|
| No. | (µg/ml) | absorbance at 266nm | 10mg) absorbance at | |
| | | | 266nm | |
| 1. | 5 | 0.191 | 0.197 | |
| 2. | 10 | 0.303 | 0.328 | |
| 3. | 15 | 0.432 | 0.461 | |
| 4. | 20 | 0.560 | 0.607 | |
| 5. | 25 | 0.707 | 0.696 | |

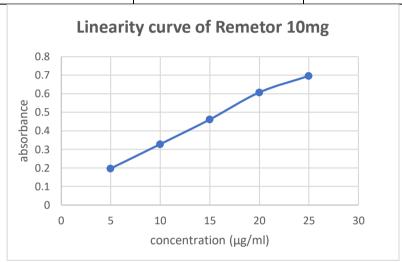


Figure 10: Linearity curve of Remetor 10mg

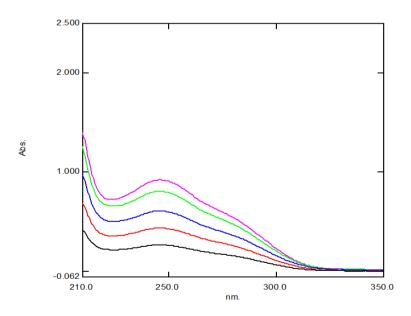


Figure 11: Calibration cure of Atorvastatin calcium tablet (Remetor 10mg) at 266nm

Table 5: Calibration curve for Pure drug and Remetor 20mg

| Sr. | Concentration | Pure drug | Tablets (Remetor | |
|-----|---------------|---------------------|---------------------|--|
| No. | $(\mu g/ml)$ | absorbance at 266nm | 20mg) absorbance at | |
| | | | 266nm | |
| 1. | 5 | 0.191 | 0.241 | |
| 2. | 10 | 0.303 | 0.383 | |
| 3. | 15 | 0.432 | 0.530 | |
| 4. | 20 | 0.560 | 0.699 | |
| 5. | 25 | 0.707 | 0.815 | |

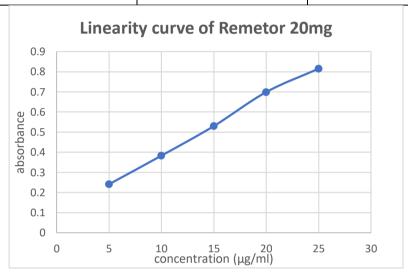


Figure 12: Linearity curve of Remetor 20mg

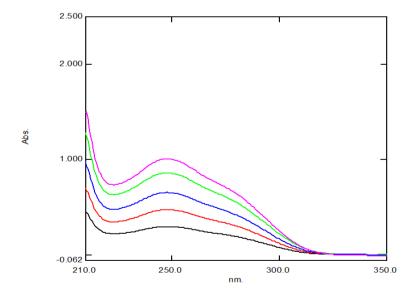


Figure 13: Calibaration curve of Atorvastatin calcium tablet (Remetot 20mg) at 266nm

Table 6: Precision study for Pure drug and Liponorm 10mg

| Sr.No. | Label Claim | Precision fo | or Pure drug | | for Liponorm mg |
|---------|----------------|--------------|--------------|---------|--------------------|
| (μg/ml) | | Amount | % ofLabel | Amount | % of Label |
| | | (μg/ml) | Ciaiii | (μg/ml) | Ciaini |
| 1 | 10 | 9.96 | 99.60 | 9.93 | 99.30 |
| 2 | 10 | 9.94 | 99.40 | 9.95 | 99.50 |
| 3 | 10 | 10.01 | 100.1 | 10.02 | 100.2 |
| 4 | 10 | 9.97 | 99.70 | 9.92 | 99.20 |
| 5 | 10 | 9.93 | 99.30 | 9.93 | 99.30 |
| 6 | 10 | 10.03 | 100.3 | 9.91 | 99.10 |

Table 7:Precision study for Pure drug and Liponorm 20mg

| Sr.No. | Label | Precision fo | Precision for Pure drug | | for Liponorm |
|--------|---------|--------------|-------------------------|---------|--------------|
| | Claim | | | | mg |
| | (µg/ml) | Amount | Amount % ofLabel | | % ofLabel |
| | | found | claim | found | claim |
| | | $(\mu g/ml)$ | | (µg/ml) | |
| 1 | 10 | 9.96 | 99.6 | 10.02 | 100.2 |
| 2 | 10 | 9.94 | 99.4 | 99.1 | 99.1 |
| 3 | 10 | 10.01 | 100.1 | 99.3 | 99.3 |
| 4 | 10 | 9.97 | 99.7 | 99.1 | 99.1 |
| 5 | 10 | 9.93 | 99.3 | 99.5 | 99.5 |
| 6 | 10 | 10.03 | 100.3 | 99.3 | 99.3 |

Table 8: Precision study for Pure drug and Remetor 10mg

| Sr.No. | Label Claim | Precision for Pure drug | | Precision fo | or Liponorm ng |
|--------|----------------|-------------------------|------------------|--------------|-------------------|
| | (µg/ml) | Amount | Amount % ofLabel | | % ofLabel |
| | | found | claim | found | claim |
| | | (µg/ml) | | (µg/ml) | |
| 1 | 10 | 9.96 | 99.6 | 9.95 | 99.5 |
| 2 | 10 | 9.94 | 99.4 | 9.93 | 99.3 |
| 3 | 10 | 10.01 | 100.1 | 9.91 | 99.1 |
| 4 | 10 | 9.97 | 99.7 | 10.01 | 100.1 |
| 5 | 10 | 9.93 | 99.3 | 9.92 | 99.2 |
| 6 | 10 | 10.03 | 100.3 | 10.02 | 100.2 |

Table 9: Precision study for Pure drug and Remetor 20mg

| Sr.No. | Label Precision for Pure drug Precision fo Claim 20m | | Precision for Pure drug | | or Liponorm |
|--------|--|---------|------------------------------|------------------|-------------|
| | (μg/ml) | Amount | Amount % ofLabel found claim | | % ofLabel |
| | | (μg/ml) | Claim | found (µg/ml) | Claim |
| 1 | 10 | 9.96 | 99.6 | 10.02 | 100.2 |
| 2 | 10 | 9.94 | 99.4 | 9.93 | 99.3 |
| 3 | 10 | 10.01 | 100.1 | 9.95 | 99.5 |
| 4 | 10 | 9.97 | 99.7 | 9.91 | 99.1 |
| 5 | 10 | 9.93 | 99.3 | 9.94 | 99.4 |
| 6 | 10 | 10.03 | 100.3 | 9.92 | 99.2 |

It is observed that the Atorvastatin calcium is soluble in methanol at λ_{max} = 266nm. The linearity curve for Pure drug and Tablets (Liponorm 10mg, Liponorm 20mg, Remetor 10mg and Remetor 20mg) was shown in figure 1, 2, 3, 4 and 5 respectively. From the linearty curve it was observed that "Atorvastatin calcium" follows linearity for conc. range of 5-25µg/ml. The precision study results for pure drug and tablets (Liponorm 10mg, Liponorm 20mg, Remetor 10mg and Remetor 20mg) was shown in table 5, 6, 7, and 8. The obtained outcomes shows high precision.

SUMMARY AND CONCLUSION

Estimation of "Atorvastatin calcium" in tablet form has been used and validated by "UV-Spectroscopic method". The standard stock solution was prepared by using methanol. Different marketed products were used in this method like Liponorm 10mg, 20mg and Remetor 10mg, 20mg. Calibration curve and linearity were plotted for dilutions ranging from $5-25\mu g/ml$. The proposed strategy follows "Beer Law" within conc. range of $5-25\mu g/ml$. The results outcomes having good precision, accuracy and validated against linearity.

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