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# STABILITY INDICATING UV-SPECTROPHOTOMETRIC AND RP-HPLC METHOD FOR ESTIMATION OF OPIPRAMOL DIHYDROCHLORIDE IN PURE AND PHARMACEUTICAL DOSAGE FORM

**Purvangi S. Patel*, Dr. Dilip G. Maheshwari**
L.J. Institute of Pharmacy, Nr. Sanand Cross Road, Sarkhej-Gandhinagar Highway, Ahmedabad Gujarat-382210, INDIA
*Corresponding Author Email: **patelpurvangi94@gmail.com**

**ARTICLE INFO**

**Key Words**

Opipramol dihydrochloride, Stability indicating method, UV-Spectrophotometric, RP-HPLC, Validation

## ABSTRACT

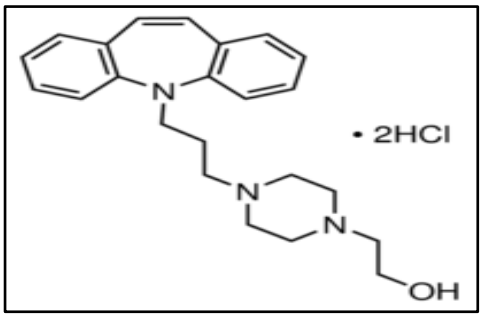
A simple, sensitive, precise, accurate and stability indicating UV-Spectrophotometric and RP-HPLC method has been developed and validated for Opipramol dihydrochloride. . Opipramol dihydrochloride was subjected to different ICH prescribed stress conditions like hydrolytic, oxidative, thermolytic and photolytic stability condition and found that degraded peaks did not interfere with the peaks of drug under the study. UV-Spectrophotometric method has been developed for the estimation of Opipramol dihydrochloride in bulk and pharmaceutical dosage form. The determination was made at 256 nm for Opipramol dihydrochloride over the concentration range of 5-30 µg/ml with mean recovery of 99.85%.The linearity was found to be $R^2$= 0.999. The LOD and LOQ were found to be 0.24µg/ml and 0.74µg/ml respectively. Methanol was used as solvent. Chromatographic elution has been carried out on Thermo C18 (250 × 4.6 mm, 5 µm) column by using the mobile phase Potassium dihydrogen phosphate buffer (10mM) : Acetonitrile (60:40 v/v, pH 2.5). The flow rate was 1.0 ml/min. Detection was monitored at 256 nm using UV detector. The retention times of Opipramol dihydrochloride was found to be 3.5±0.2. The linearity was observed ($R^2$ = 0.999) in the concentration range of 5-30 µg/ml for Opipramol dihydrochloride. The limit of detection and limit of quantification for Opipramol dihydrochloride was found to be 0.09 and 0.3 respectively. The precision (intra-day, interday, repeatability) of methods were found within limits (RSD <2%). Accuracy was determined by recovery studies and it is found to be 99.75-100.54%. Validation of Proposed methods was carried out according to ICH guidelines.

## INTRODUCTION:

Opipramol dihydrochloride is an anxiolytic and antidepressant which is used throughout Europe. Although it is a member of the tricyclic antidepressants (TCAs), opipramol is atypical among TCAs and its primary mechanism of action is much different in comparison. Most TCAs act as monoamine reuptake Inhibitors, but opipramol does not, and instead acts primarily as a sigma receptor agonist. pipramol dihydrochloride is a well-tolerated drug and is said to produce fewer side effects than selective serotonin reuptake inhibitors (SSRIs) and serotonin–norepinephrine reuptake inhibitor (SNRIs).

Opipramol dihydro chloride is rapidly and completely absorbed by GIT.

Metabolism occurs through the CYP2D6 isoenzyme. Its terminal half-life in plasma is 6–11 hours.[1] About 70% is eliminated in urine with 10% unaltered. The remaining portion is eliminated through faeces.




**Structure of opipramol dihydrochloride**

The objective of this work was to develop an analytical UV and HPLC procedure, which would serve as stability indicating method for Opipramol dihydrochloride. A thorough literature survey revealed that the no method has been reported for stability indicating method for Opipramol dihydrochloride.

## MATERIALS AND METHODS

### For UV-Spectrophotometric

**Materials:** Methanol (Aventor), Opipramol dihydrochloride API was procured from R L Fine chemicals, Tablet Formulation (OPIPROL 50MG) was procured from Bela Drug Centre.

**Apparatus:** Double beam UV-visible spectrophotometer (Shimadzu UV-1800), Analytical weighing balance (Wensar)

### FOR RP-HPLC

**Materials:** HPLC grade water (Astron Chemical India), HPLC grade methanol (Fischer Scientific, Ahmedabad), HPLC grade Acetonitrile (Fischer Scientific, Ahmedabad), Ortho-phosphoric acid (AR Grade- Krishna Chemical Industry), Dipotassium hydrogen orthophosphate

- Opipramol dihydrochloride API was procured from R L Fine chemicals
- Tablet Formulation (OPIPROL 50MG) was Procured from Bela Drug Centre.

**Apparatus**

- HPLC: LC-2010-CHT, (Software-Lab Solutions)
- Column: Thermo C18 (250 X 4.6 mm, 5µm)
- Digital Analytical Balance: Wensar DA13-220, India
- pH meter: Thermo Electron Crop, Pune, India
- Sonicator: Equitron, India

## METHODOLOGY

### Chromatographic conditions

- Column: Thermo C18 (250 x 4.6mm, 5µ)
- Mobile Phase: Phosphate Buffer: Acetonitrile (60:40v/v, pH: 2.5 adjusted with orthophosphoric acid)
- Flow Rate: 1 ml/min
- Detection Wavelength: 256nm
- Run time: 10 min
- Injection Volume: 10 µl
- Diluent: Mobile phase

**Preparation of mobile phase:** A mixture of phosphate buffer and acetonitrile in the ratio of (60:40) was mixed properly & pH 2.5 adjusted with ortho-phosphoric acid. It was filtered through 0.45µ membrane filter & degassed by sonication.

**Preparation of standard stock solution of Opipramol dihydrochloride:** Accurately weighed quantity of Opipramol dihydrochloride 50mg was transferred to 50ml volumetric flask, and then makes up the volume up to the mark with mobile phase to give a stock solution having strength of 1000µg/ml.

**Preparation working standard solution of Opipramol dihydrochloride:** 100 µg/ml of Opipramol dihydrochloride solution was prepared by diluting 10 ml of above standard stock solution with mobile

phase in 100 ml volumetric flask up to the mark.

**Preparation of working solution:** From working standard solution 1ml is pipette out in 10ml of volumetric flask and made up the volume upto the mark with methanol and mobile phase for UV-Spectrophotometric and RP-HPLC respectively.

**FORCE DEGRADATION STUDY**

**Acid hydrolysis:** 10 ml from the standard stock solution of 1000 µg/ml was taken, and transferred it into 100 ml volumetric flask. Than made up the volume with the 0.5N HCl upto the mark. And it refluxed for 8hr at 40 $^{O}$c on water bath. The acidic degradation performed under dark condition to exclude the possible photolytic degradation. The degradation sample was cooled at room temperature and neutralized the sample with same strength of 0.5N NaOH. 1ml of solution was pipette out from resultant degradation sample to make 10µg/ml and made up the volume with the Methanol and mobile phase for UV and HPLC respectively.

**Basic hydrolysis:** 10 ml from the standard stock solution of 1000 µg/ml was taken, and transferred it into 100 ml volumetric flask. Than made up the volume with the 0.5N NaOH up to the mark. And it refluxed for 8hr at 40 $^{O}$c on water bath. The basic degradation performed under dark condition to exclude the possible photolytic degradation. The degradation sample was cooled at room temperature and neutralized the sample with same strength of 0.5N HCl. 1ml of solution was pipette out from resultant degradation sample to make 10µg/ml and made up the volume with the Methanol and mobile phase for UV and HPLC respectively.

**Oxidative condition:** Take 10 ml from the standard stock solution of 1000 µg/ml, and transferred it into100 ml volumetric flask. Than made up the volume with the 3% $H_2O_2$ up to the mark. And it refluxed for 8hr at 40 $^{O}$c on water bath. The oxidative degradation performed under dark condition to exclude the possible photolytic degradation. The degradation sample was cooled at room temperature. 1ml of solution was pipette out from resultant degradation sample to make 10µg/ml and made up the volume with the Methanol and mobile phase for UV and HPLC respectively.

**Thermal condition:** For dry heat degradation the sample were placed in the oven at 80°C for 24hrs under the dark condition and then cooled at room temperature. 1ml of degraded solution was pipette out from resultant degradation sample to make 10µg/ml and made up the volume with the Methanol and mobile phase for UV and HPLC respectively.

**Photolytic condition:** For photolytic degradation the sample were placed in the UV chamber for 24hrs. 1ml of degraded solution was pipette out from resultant degradation sample to make 10µg/ml and made up the volume with the Methanol and mobile phase for UV and HPLC respectively.

**METHOD VALIDATION: Linearity & Range (n=6):** The linearity of Opipramol dihydrochloride was found to be in the range of 5-30 µg/ml. Linearity of drug was checked in term of slope, intercept and correlation coefficient.

**Preparation of Calibration curve** : Aliquots of stock solution of Opipramol dihydrochloride (100 µg/ml) 0.5, 1, 1.5, 2, 2.5 and 3 ml was pipetted out in same six different 10 ml volumetric flasks and made up the volume with mobile phase to obtain the concentration of about 5, 10, 15, 20, 25 and 30 µg/ml for Opipramol dihydrochloride. Calibration curve was obtained by plotting respective peak area Vs Concentration in µg/ml and regression equation was obtained.

**Precision:** The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from

multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: Intermediate (Intraday) precision, Reproducibility (Interday precision), Repeatability.

**Intraday Precision (n=3):** Solutions containing 5, 10 and 15 µg/ml of Opipramol dihydrochloride was analyzed three times on the same day and %R.S.D was calculated.

**Interday Precision (n=3):** Solutions containing 5, 10 and 15 µg/ml of Opipramol dihydrochloride was analyzed on three different successive days and %R.S.D was calculated.

**Repeatability (n=6):** Solutions containing 10 µg/ml of Opipramol dihydrochloride was analyzed for six times and %R.S.D. was calculated.

**Limit of Detection (LOD):** Limit of detection can be calculated using following equation as per ICH guidelines.

$$\mathbf{LOD = 3.3 \times (\sigma / S)}$$

Where, σ = standard deviation of the Y intercept of calibration curve S = Mean slope of the corresponding calibration curve.

**Limit of Quantification (LOQ):** Limit of quantification can be calculated using following equation as per ICH guidelines.

$$\mathbf{LOQ = 10 \times (\sigma / S)}$$

Where, σ = standard deviation of the Y intercept of calibration curve, S = Mean slope of the corresponding calibration curve.

**Accuracy (n=3):** The accuracy of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. Accuracy of the developed method was confirmed by doing recovery study as per ICH guideline at three different concentration levels 50%, 100%, 150% and the values were measured at 256 nm of Opipramol dihydrochloride. The amount of Opipramol dihydrochloride was calculated at each level and % recovery was calculated by measuring the peak area and fitting the values in equation.

**Robustness:** The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage. It should show the reliability of an analysis with respect to deliberate variation in method parameter. In case of liquid chromatography, examples of typical variations are:

- Influence of variations of pH in mobile phase;
- Influence of variations in mobile phase composition;
- Flow rate

**System Suitability Tests:** A system suitability test is an integral part of liquid chromatography. They are used to verify that resolution and reproducibility of chromatography system are adequate for the analysis to be done. The test includes the Resolution, Column efficiency, tailing factor and Theoretical plates.

**Assay:**

**Preparation of solution:** For analysis of Opipramol dihydrochloride in tablet, 20 tablets (Opiprol 50 mg) was accurately weighed and average weight was calculated. Tablet was finely powdered. Powder weight equivalent to 10 mg of drug containing Opipramol dihydrochloride was dissolved in to a 100 ml volumetric flask made up the volume with Methanol up to the mark.

## RESULT AND DISCUSSION:

**UV-Spectrophotometery: Force degradation study: Acid hydrolysis:** Opipramol dihydrochloride degradation study with 0.5 N HCl at 40$^{O}$c for 8hr observed at **256** nm.

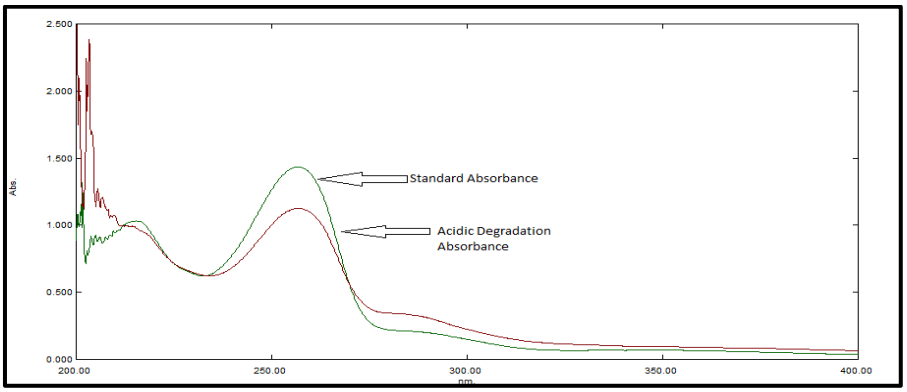



**Figure 1: UV Spectra of acidic degradation by 0.5 N Hcl**

**Basic hydrolysis:** Opipramol dihydrochloride degradation study with 0.5 N NaOH at 40$^{O}$c for 8hr observed at 279nm

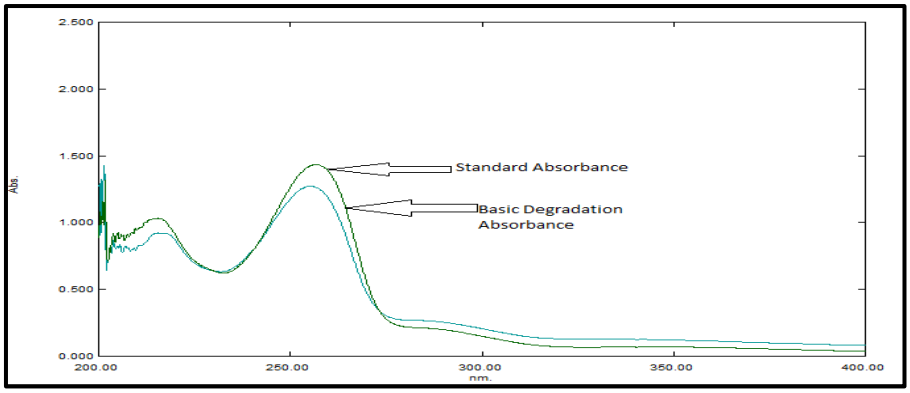



**Figure 2: UV Spectra of basic degradation BY 0.5N NaOH**

**Oxidative condition:** Opipramol dihydrochloride degradation study with 3% $H_2O_2$ at 40$^{O}$c for 8hr observed at 256nm.

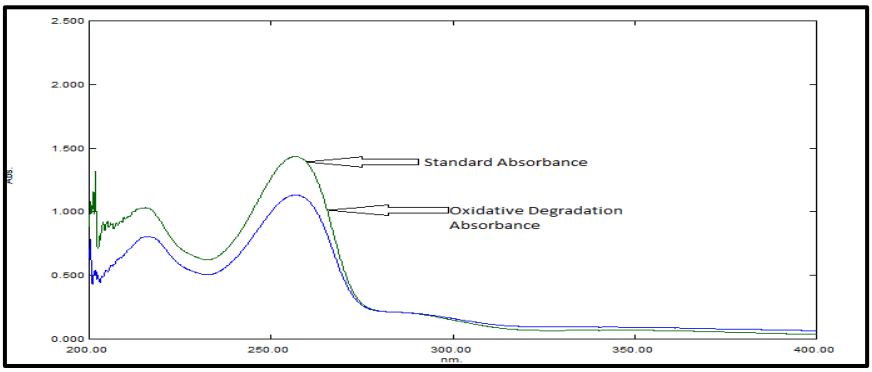



**Figure 3: UV Spectra of oxidative degradation BY 3% $H_2O_2$**

**Thermal condition:** Opipramol dihydrochloride degradation study in oven at 80$^{O}$C for 24hrs observed at 256nm.

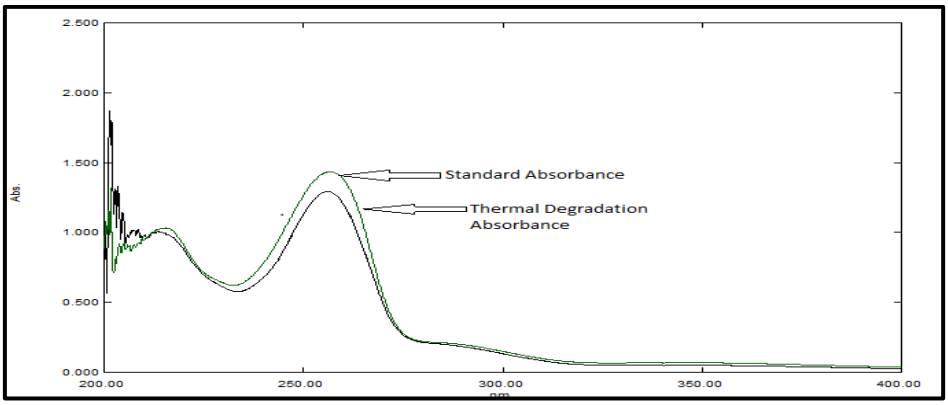



**Figure 4: UV Spectra of thermal degradation**

**Photolytic condition:** Degradation study for Opipramol dihydrochloride was observed at 256 nm.

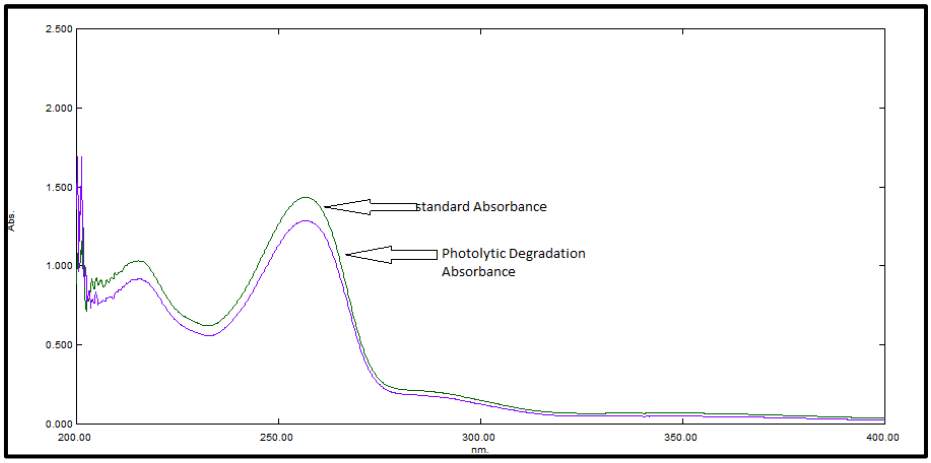



**Figure 5: UV Spectra of photolytic degradation**

**Stability of the drug under stress condition:**

**Table 1: Summary of stress study of opipramol dihydrochloride**

| Parameter | Condition | Absorbance at 256nm | % Drug degradation |
|---|---|---|---|
| Normal | Normal | 1.434 | - |
| 0.5N HCl | 8hrs for 40°C | 1.105 | 22.95 |
| 0.5N NaOH | 8hrs for 40°C | 1.272 | 11.3 |
| 3% $H_2O_2$ | 8hrs for 40°C | 1.132 | 21.06 |
| Thermal | 80°C for 24hrs | 1.311 | 8.58 |
| Photolytic | UV chamber for 24hrs | 1.356 | 5.44 |

**METHOD VALIDATION**

**Linearity:** The linearity range for Opipramol dihydrochloride was found to be in the range of 5-30µg/ml. linearity data for Opipramol dihydrochloride at 256 nm are depicted in table.

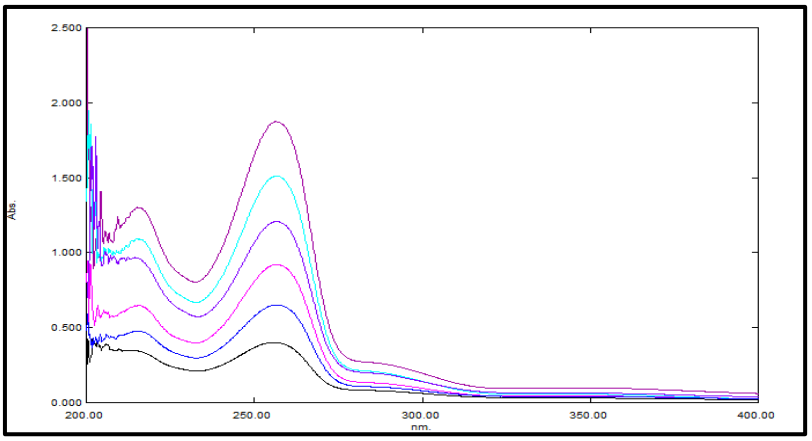



**Figure 6: Overlay spectra of opipramol dihydrochloride**

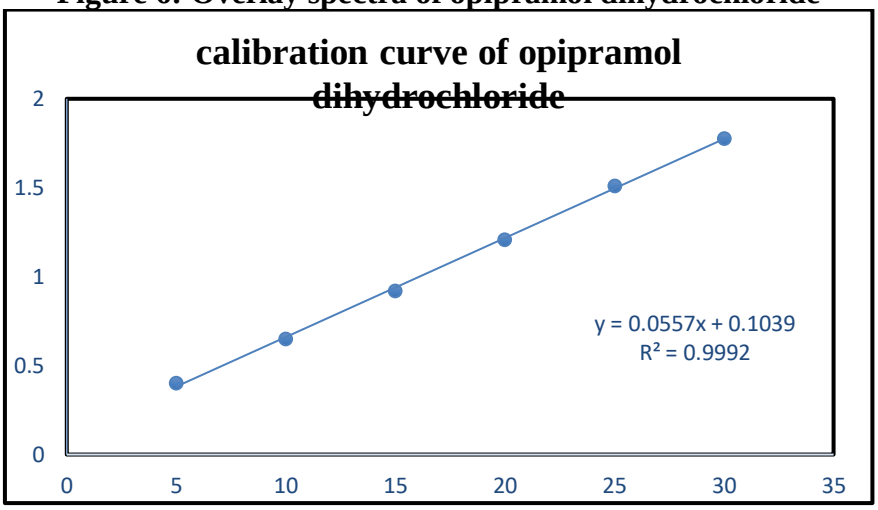



**Figure 7: Calibration curve of opipramol dihydrochloride**

**Table 2: Linearity of opipramol dihydrochloride**

| CONC. (µg/ml) | MEAN±SD | %RSD |
|---|---|---|
| 5 | 0.4025±0.00325 | 0.80825 |
| 10 | 0.65267±0.00287 | 0.43934 |
| 15 | 0.923±0.003 | 0.32503 |
| 20 | 1.206±0.00265 | 0.21938 |
| 25 | 1.5135±0.00171 | 0.11284 |
| 30 | 1.775±0.00277 | 0.15599 |

**Accuracy: Table 3: Recovery data of opipramol dihydrochlorifde:**

| % Level | Amount of Opipramol dihydrochloride in sample (µg/ml) | Amount of standard Opipramol dihydrochloride added (µg/ml) | Total Amount (µg/ml) | Amount of OPI found (µg/ml) | %Recovery | Mean±SD | %RSD |
|---|---|---|---|---|---|---|---|
| 50 | 10 | 5 | 15 | 14.86 | 99.06 | 0.928 ± 0.065 | 0.064 |
| 100 | 10 | 10 | 20 | 19.93 | 99.67 | 1.213 ± 0.102 | 0.150 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 150 | 10 | 15 | 25 | 25.23 | 100.92 | 1.513 ± 0.032 | 0.031 |

**Precision: Repeatability:** The data for repeatability for Opipramol dihydrochloride20µg/ml at 256nm is shown in the table

**Table 4: Repeatability of opipramol dihydrochloride**

| Sr no. | Conc.(µg/ml) | Absorbance |
|---|---|---|
| 1 | 10 | 0.655 |
| 2 | 10 | 0.652 |
| 3 | 10 | 0.657 |
| 4 | 10 | 0.653 |
| 5 | 10 | 0.652 |
| 6 | 10 | 0.655 |
| Mean | 10 | 0.654 |
| SD | 0.002 | |
| %RSD | 0.305 | |

**2. Intraday precision & Interday precision:** The data for intraday precision & Interday precision for Opipramol dihydrochloride at 256nm is shown in the table.

**Table 5: Precision data for opipramol dihydrochloride**

| Conc. | Intraday precision | | Interday precision | |
|---|---|---|---|---|
| (µg/ml) | Mean ± S.D. (n=3) | %RSD | Mean ± S.D. (n=3) | %RSD |
| 5 | 0.406±0.0026 | 0.65 | 0.406±0.0031 | 0.77 |
| 10 | 0.656±0.0028 | 0.43 | 0.654±0.0032 | 0.50 |
| 15 | 0.925±0.0026 | 0.28 | 0.925±0.0029 | 0.31 |

**Assay:** The data for assay of Opipramol dihydrochloride at 256nm is shown in the table:

**Table 6: Assay of dosage form**

| **Brand** | **Label claim(mg)** | **Recovered conc.** | **%Mean recovery ± SD (n=3)** |
|---|---|---|---|
| OPIPROL | Opipramol dihydrochloride (50mg) | 0.658 | 99.47±0.204 |

**LOD & LOQ: Table 7: LOD & LOQ for opipramol dihydrochloride**

| Sr. no. | Parameter | Mean Slope | SD | Result (µg/ml) |
|---|---|---|---|---|
| 1 | LOD | 0.55583 | 0.00417 | 0.024 |
| 2 | LOQ | 0.55583 | 0.00417 | 0.074 |

**Summary of validation parameter:**

**Table 8: Summary of validation**

| Parameter | Opipramol dihydrochloride |
|---|---|
| Linearity (µg/ml) | 5-30 |
| Correlation co-efficient | 0.999 |
| Slope | 0.55583 |
| Intercept | 0.00417 |
| Limit of detection(µg/ml) | 0.024 |
| Limit of quantitation(µg/ml) | 0.074 |
| Repeatability | 0.654 |
| Interday | 0.31-0.77 |
| Intraday | 0.28-0.65 |
| Accuracy (%) | 99.06-100.92 |

**Stability indicating RP-HPLC Method:**

**Force degradation study:**

**Acid hydrolysis:** Opipramol dihydrochloride degradation study with 0.5 N HCl at 40$^{O}$c for 8hrs.

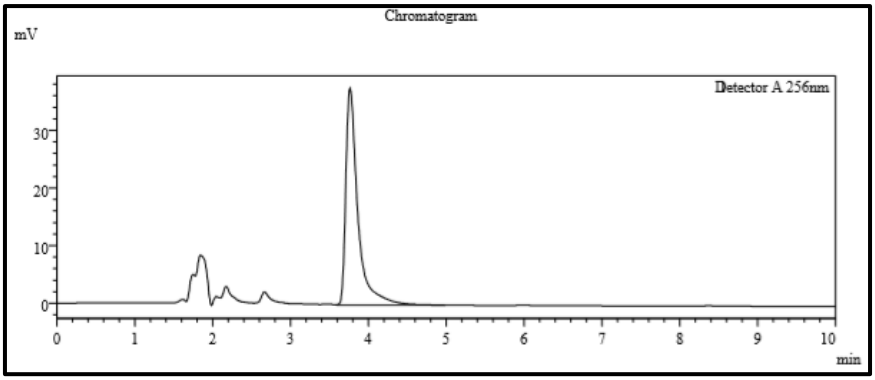



**Figure 7: Acidic degradation with 0.5N HCl**

**Basic hydrolysis:** Opipramol dihydrochloride degradation study with 0.5 N HCl at 40$^{O}$c for 8hrs.

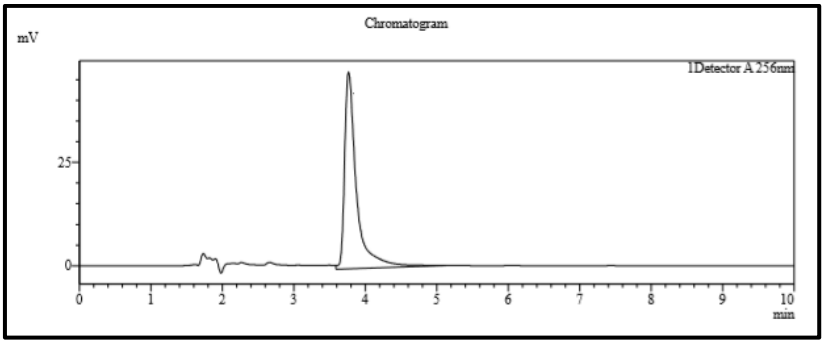



**Figure 8: Basic degradation with 0.5N NaOH**

**Oxidative condition:** Opipramol dihydrochloride degradation study with 3% $H_2O_2$ at 40$^{O}$c for 8hrs.

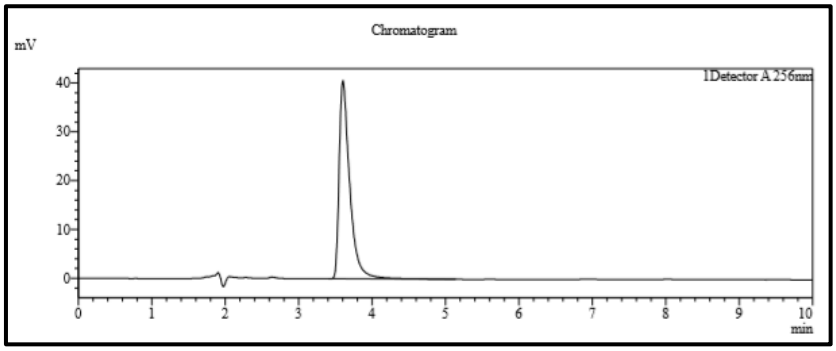



**Figure 9: Oxidative degradation with 3% $H_2O_2$**

**THERMAL CONDITION:** Opipramol dihydrochloride degradation study in oven at 80$^{O}$C for 24hr.

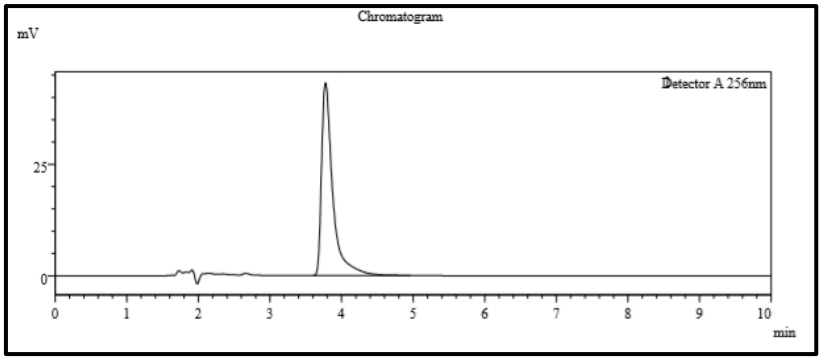



**Figure 10: Thermal degradation**

**Photolytic condition:** Opipramol dihydrochloride degradation study in UV chamber for 24hrs.

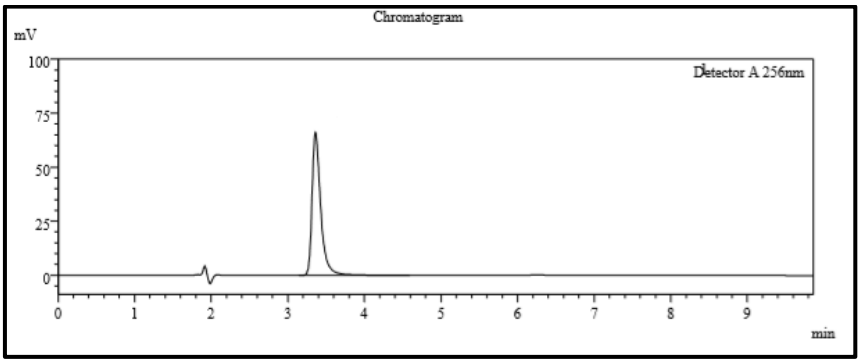



**Figure 11: Photolytic degradation in UV chamber**

**Stability of the drug under stress condition:**

**Table 9: Summary of stress study of opipramol dihydrochloride**

| Parameter | Condition | Area | %Drug degradation |
|---|---|---|---|
| Normal | Normal | 538840 | - |
| 0.5N HCl | 8hrs for 40ºC | 407266 | 24.42 |
| 0.5N NaOH | 8hrs for 40ºC | 452431 | 16.16 |
| 3% $H_2O_2$ | 8hrs for 40ºC | 407394 | 24.4 |
| Thermal | 80ºC for 24hrs | 492520 | 8.6 |
| Photolytic | Sunlight | 532147 | 1.25 |

**METHOD VALIDATION:**

**Specificity:** Specificity of an analytical method was assessed by, defining its ability to measure accurately and specifically the analyte of interest without interference from blank**.** It was prove by comparing the chromatogram of mobile phase, test preparation solution to show that there was no interference of mobile phase and excipients peaks with peak of Opipramol dihydrochloride.

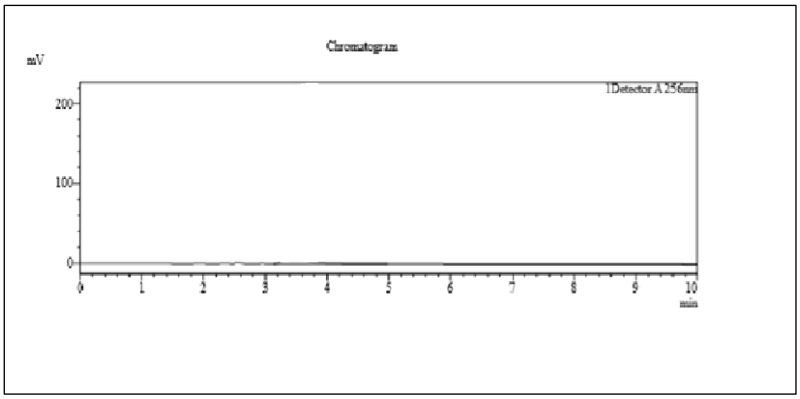



**Figure 12: Blank Chromatogram**

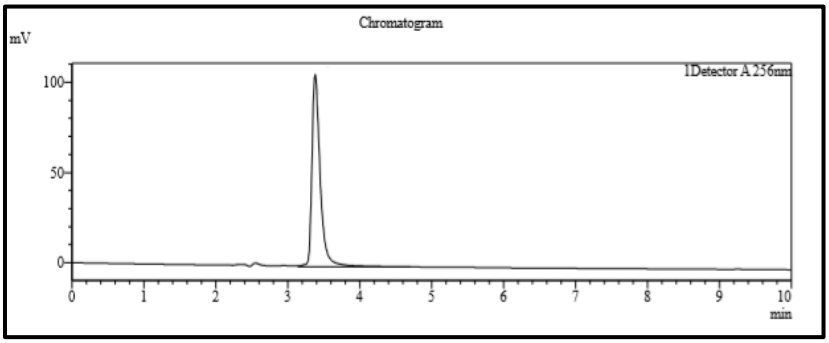



**Figure 13: Chromatogram of opipramol dihydrochloride**

**LINEARITY:** Calibration curve for Opipramol dihydrochloride consist of different concentration of standard Opipramol dihydrochloride solution ranging from 5-30 µg/ml. peak area of each solution was measured and calibration curve was plotted.

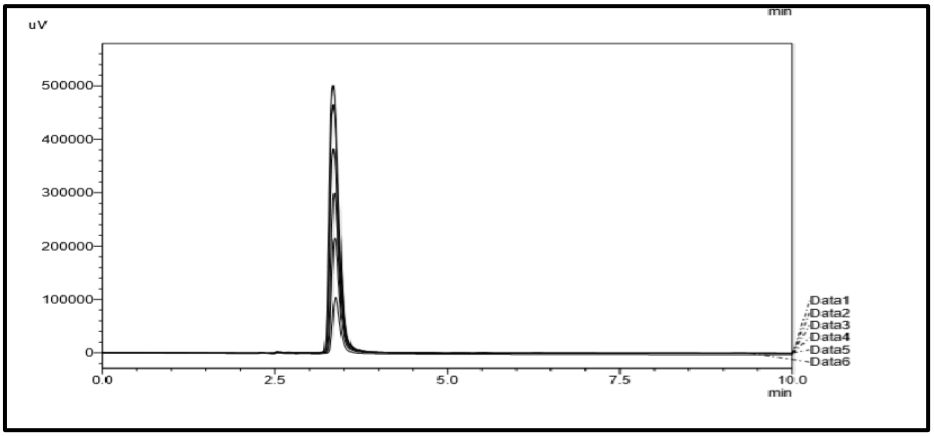



**Figure 14: Linearity of opipramol dihydrochloride**

Table 10: Linearity data of opipramol dihydrochloride:

| CONC (µg/ml) | MEAN±SD | %RSD |
|---|---|---|
| 5 | 855614±4251.79 | 0.49 |
| 10 | 1781030±6640.56 | 0.37 |
| 15 | 2578471±8585.59 | 0.33 |
| 20 | 3512369±10877.6 | 0.30 |
| 25 | 43206040±7769.08 | 0.17 |
| 30 | 5078654±4889 | 0.09 |

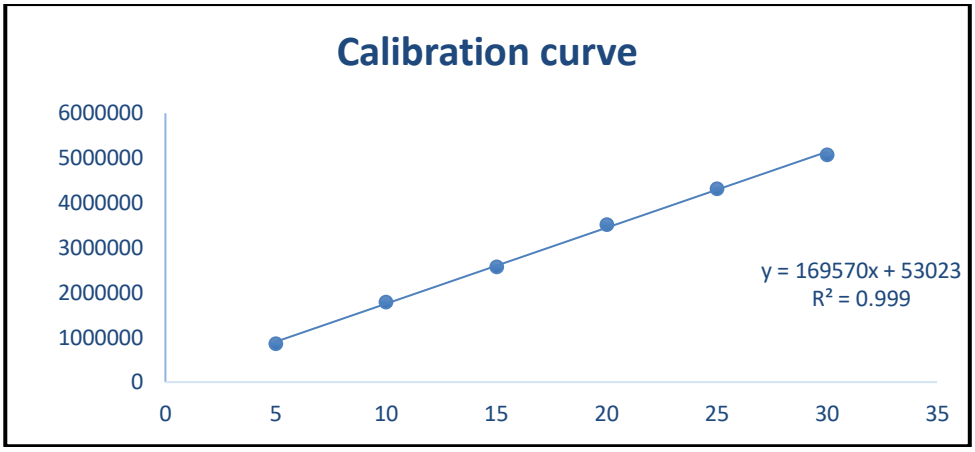



**Figure 15: calibration curve of opipramol dihydrochloride**

PRECISION: Repeatability:

The data for repeatability for Opipramol dihydrochloride 10µg/ml at 256nm is shown in the table.

Table 11: Repeatability of opipramol dihydrochloride

| Sr no. | Conc.(µg/ml) | Area |
|---|---|---|
| 1 | 10 | 1778523 |
| 2 | 10 | 1785214 |
| 3 | 10 | 1778344 |
| 4 | 10 | 1789664 |
| 5 | 10 | 1789546 |
| 6 | 10 | 1778965 |
| Mean | 10 | 1783376 |
| SD | 4988.58 | |
| %RSD | 0.27 | |

Intraday and Interday Precision: The data for intraday precision & Interday precision for Opipramol dihydrochloride at 256nm is shown in the table.

Table 12: Precision data for opipramol dihydrochloride

| Conc. | Intraday precision | | Interday precision | |
|---|---|---|---|---|
| (µg/ml) | Mean ± S.D (n=3) | %RSD | Mean ± S.D. (n=3) | %RSD |
| 5 | 855024±2591.19 | 0.30 | 854705±3286.45 | 0.38 |
| 10 | 1778452±3914 | 0.22 | 1775812±4123.04 | 0.23 |
| 15 | 2566850±3457.5 | 0.13 | 2566050±4122.3 | 0.16 |

Accuracy: The % recovery for Opipramol dihydrochloride was found to be 99-101%.

**Table 12: Accuracy study data for opipramol dihydrochloride**

| Name of Drug | % Level of recovery | Amount of drug Sample (µg/ml) | Spiked Amount Taken (µg/ml) | Total amount found (µg/ml) | % Recovery ± S.D. (n=3) |
|---|---|---|---|---|---|
| Canagliflozin | 50 | 10 | 5 | 14.96 | 99.75±0.34 |
| | 100 | 10 | 10 | 20.05 | 100.26±0.42 |
| | 150 | 10 | 15 | 25.13 | 100.54±0.26 |

ASSAY: The data for assay of Opipramol dihydrochloride at 256nm is shown in the table:

**Table 13: Assay of dosage form**

| Brand | Label claim(mg) | Recovered | %Mean recovery ± SD |
|---|---|---|---|
| | | Conc (µg/ml) | (n=3) |
| OPIPROL | Opipramol dihydrochloride (50mg) | 9.97 | 99.7±0.195 |

LOD AND LOQ: Table 14 : LOD & LOQ For opipramol dihydrochloride

| Parameter | Mean Slope | SD of intercept | Result (µg/ml) |
|---|---|---|---|
| LOD | 169603.16 | 5117.24 | 0.09 |
| LOQ | 169603.16 | 5117.24 | 0.30 |

**SYSTEM SUITABILITY PARAMETER:** The system suitability parameter for Opipramol dihydrochloride was found to be:

**Table 15: System syitability parameter**

| **Sr. No** | **System suitability parameter** | **Mean ± S.D.(n=3)** | **%RSD** |
|---|---|---|---|
| 1 | Retention time | 3.57 ± 0.00737 | 0.20 |
| 2 | Theoretical Plates | 27862.3 ± 36.074 | 0.12 |
| 3 | Tailing Factors | 1.761 ± 0.00265 | 0.15 |

**Summary of validation parameter:**

**Table 16: Summary of validation**

| Parameter | Opipramol dihydrochloride |
|---|---|
| Linearity(µg/ml) | 5-30 |
| Correlation co-efficient($r^2$) | 0.999 |
| Slope | 169603.16 |
| Intercept | 5117.24 |
| Limit of detection (µg/ml) | 0.09 |
| Limit of quantitation (µg/ml) | 0.30 |
| Repeatability (%RSD) | 0.27 |
| Interday (%RSD) | 0.16-0.38 |
| Intraday (%RSD) | 0.13-0.30 |
| Accuracy (% recovery) | 99.75-100.84 |
| Assay | 100.42 ± 0.195 |

## CONCLUSION

A simple, rapid, sensitive, accurate and precise stability indicating UV-Spectrophotometric and RP-HPLC methods has been developed and validated for routine analysis of Opipramol dihydrochloride. The stability indicating UV-Spectrophotometric and RP-HPLC methods is suitable for estimation of Opipramol dihydrochloride. The developed method was successfully applied in marketed tablet dosage form. The proposed method can be utilized for the routine analysis of Opipramol dihydrochloride in pharmaceutical dosage form. They are validated according to ICH guidelines.

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