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# Bioanalytical Method Development and Validation of Dapoxetine Hydrochloride in Human Plasma by RP-HPLC

**Pranit. B. Kale[1*], Santosh A. Waghmare[1], Arun. M. Kashid[2] and S. B. Wankhede[3]**

*[1] SWGP's Loknete Shri Dadapatil Pharate College of Pharmacy, Mandavgan Pharata, Pune, Maharashtra- 412211, India*
*[2]Sinhgad Institute of Pharmacy, Narhe, Pune-411 041, India*
*[3]JSPM's Charak College of Pharmacy and Research, Wagholi, Pune-412 207, India*

**Corresponding author*

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**A B S T R A C T**

A simple, accurate and rapid Bioanalytical reverse phase high performance liquid chromatography (RPHPLC) method for determination of Dapoxetin hydrochloride in human plasma was validated as per ICH guideline. Dapoxetin hydrochloride is significantly superior in premature ejaculation and more active against serotonin transport inhibitor than any other drug in class. The total analysis was carried out on using stationary phase symmetry C1 (4.6mm X 250mm, 5µm) with Mobile Phase Acetonitrile: Buffer (60:40) pH adjusted to3.5 flow rate was 1.0 ml/min, injection volume of 10 ppm and detection wavelength was 293nm at ambient temperature with total run time of 10 minutes. Retention time of spiked plasma and dapoxetine hydrochloride were found to be 2.153 min and 4.442 min, r2 value were 0.995 and 0.999 and linearity range was 5ppm to 25ppm for both. The method was developed for accuracy, linearity, precision, recovery and stability in complies and stability in complies with CDER and ICH guideline.

## Introduction

Dapoxetine is chemically (S)-N,N-dimetyl-3-(naphtalen-1-yloxy)-1-phenylpropan-1-amine. Dapoxetine works by inhibiting the serotonin transporter, increasing serotonin's action at the post synaptic cleft, and as a consequence promoting ejaculatory delay. It is a medication used for the treatment of premature ejaculation (PE) in men 18–64 years old (1, 2, 3_.

Dapoxetine is a selective serotonin reuptake inhibitor currently undergoing trials through Alza (under license from GenuPro, a

collaboration between Eli Lilly and PPD). Dapoxetine is a short-acting SSRI drug currently being considered for approval by the Food and Drug Administration (FDA) for the treatment of premature ejaculation in men, which would make it the first drug approved for such treatment. Despite two clinical trials finished in 2006, experts doubt it will be approved by the FDA soon because SSRIs come with undesirable side-effects after long-term use, such as psychiatric problems, dermatological reactions, increase in body weight, lower sex-drive, nausea, headache, upset stomach and weakness, thus not significantly outweighing the benefit of premature ejaculation medication versus the risks (3, 4, 5, 6). By contrast with SSRIs approved for depression, which take 2 weeks or longer to reach steady-state concentration, dapoxetine has a unique pharmacokinetic profile, with a short time to maximum serum concentration (about 1 h) and rapid elimination (initial half-life of 1-2 h). (Figure 1 Represent the Structure of Dapoxetine Hydrochloride).

## Materials and Methods

Acetonitrile (HPLC Grade), Orthophosphoric acid (AR Grade), Potassium dihydrogen orthophosphate (Merck, AR Grade), Water for HPLC, Methanol (HPLC Grade) etc.

## Preliminary Analysis of dapoxetine HCl

Preliminary analysis of dapoxetine HCl such as description, solubility, and UV confirms the identification of dapoxetine HCl as per available literature.

## Solubility study

Solubility of the drug was carried out with the different solvents such as methanol, acetonitrile, ethanol, 0.1 N hydrochloric acid, water and UV analysis was carried out to confirm the detection wavelength. The solution which shows the maximum absorbance was selected. Acetonitrile showed the maximum absorption at 292 nm wavelength.

## Selection of analytical wave length

Name of drug : Dapoxetine HCl

Concentration : 10 µg/ml

Solvents : Buffer : Acetonitrile

Scanned range : 200-400 nm

Max Absorbance : 292.3 nm

The maximum UV absorbance of dapoxetine HCl was found at 292.3 nm. It was also observed that maximum absorption is occurs between 200-216 nm but at these wavelength sample matrix also absorbs significantly in this region.

## Analytical Method Development

The analytical method has been developed after several permutations and combinations of mobile phase with stationary phase.

Table 1 represents the summary of several mobile phase compositions tried to optimize appropriate mobile phase composition for study. Various combinations showed peak asymmetry, theoretical plate less than 2000 and less retention time. Mobile phase consisting, acetonitrile: ammonium formate buffer pH-3.5 in the ratio of 6:4 v/v was selected as optimized mobile phase as it gave appropriate peak symmetry, theoretical plates and retention time.

## Optimized chromatographic conditions

Summary of chromatographic parameters selected

Column : Symmetry C18, 3.5µm, 250 mm x 4.6 mm

Mobile phase : Acetonitrile: Ammonium formate (6:4 v/v)

Flow rate : 1 ml/min

Detection wavelength : 292 nm

Sample injector : 20 µl loop

Temperature : Ambient

Run time : 10 Min

## Bioanalytical Method validation

## System suitability parameters

## Results and Discussion

It was found that the all system suitability parameters are within the acceptance criteria and method is suitable for determination of dapoxetine HCl from human plasma sample (Table 2.).

## Selectivity

For selectivity, the blank samples of the plasma were obtained from six different persons. Each blank sample was tested for interference in dapoxetine peak.

The plasma and dapoxetine peak were well resolved. Typical chromatogram of blank human plasma and spiked in human plasma are shown in Fig. 5 and 6. It was found that peak from blank plasma does not interfere with peak of dapoxetine. Hence developed method is selective and peak obtained at 4.4 is only because of dapoxetine.

## Linearity and Range

Linearity range of dapoxetine was observed at 5, 10, 15, 20 and 25µg/ml. The equation of linearity for dapoxetine was y = 21742x + 69256. For all curves the correlation coefficient ($r^2$) is more than 0.999. (Figure 7) The linearity range was observed in between 25-150µg/ml. (Table 3). For spiked human plasma Linearity range of dapoxetine was observed at 5, 10, 15, 20 and 25µg/ml. (Figure 8) The equation of linearity for dapoxetine was y = 13601x + 77162. For all curves the correlation coefficient ($r^2$) was 0.995 (Table 4).

## Accuracy

It can observe that all the obtained results of accuracy were satisfactory. The % mean accuracy lies between 88.00 – 106.00 %. Hence a good accuracy was observed by this method (Table 5, 6, 7).

## Precision

It was found that the precision results were found satisfactory with respect to percent coefficient of variation (%CV) for all levels which were within the limit. The % coefficient of variation (%CV) of LQC sample is 1.31 % and t he % CV of MQC and HQC samples are 1.18 and 0.70% respectively. The developed method was précised for estimation of dapoxetine from human plasma. [Table 8 (Interday precision result of dapoxetine) and table 9 (Intraday precision results of dapoxetine)].

**Table.1** Different trial for selection of the mobile phase

| Mobile phase | Composition Ratio | pH | Retention Time |
|---|---|---|---|
| **Phosphate buffer: ACN** | 50:50 | 3.5 | 8min |
| **Phosphate buffer: ACN** | 40:60 | 3.5 | 6.5 min |
| **Phosphate buffer: ACN** | 30:70 | 3.5 | 5.8 min |
| **Ammonium formate: ACN** | 40:60 | 3.5 | 4.4 min |
| **Ammonium formate: ACN** | 30:70 | 3.5 | 4.1 min |
| **Ammonium formate: ACN** | 20:80 | 3.5 | 3.9 min |
| **Water: ACN** | 40:60 | 3.5 | 10 min |
| **Water: ACN** | 30:70 | 3.5 | 8 min |

**Table.2** System suitability parameters

| Sr.No. | Parameters | Dapoxetine | Limit |
|---|---|---|---|
| **1** | Resolution | 4.4 | > 2 |
| **2** | Column efficiency | 6960 | > 2000 |
| **3** | Symmetry factor | 1.54 | < 2 |
| **4** | Capacity factor | 6.3 | > 2 |

**Table.3** Linearity of dapoxetine (API)

| Sr.No. | Standard concentration(µg/ml) | Mean Area |
|---|---|---|
| **1** | 5 | 183047 |
| **2** | 10 | 283509 |
| **3** | 15 | 391946 |
| **4** | 20 | 500193 |
| **5** | 25 | 618266 |

**Table.4** Linearity for dapoxetine HCl spiked in human plasma

| Sr.No. | Concentration (µg/ml) | Peak Area |
|---|---|---|
| **1** | 5 | 149500 |
| **2** | 10 | 214593 |
| **3** | 15 | 268979 |
| **4** | 20 | 352025 |
| **5** | 25 | 420820 |

**Table.5** Accuracy result of dapoxetine (8 µg/ml) (LQC)

| Sr.No. | Conc.(µg/ml) | Area | % recovery | Recovered concentration (µg/ml) |
|---|---|---|---|---|
| **1** | 8 | 194336 | 99.14 | 7.93 |
| **2** | 8 | 185138 | 90.5 | 8.52 |
| **3** | 8 | 202234 | 106.53 | 8.52 |
| | Mean | | | 7.89 |
| | SD | | | 0.64 |
| | % CV | | | 8.10 |
| | % Accuracy | | | 98.73 |

**Table.6** Accuracy result of dapoxetine (16 µg/ml) (MQC)

| Sr. No. | Concentration (µg/ml) | Area | % recovery | Recovered concentration (µg/ml) |
|---|---|---|---|---|
| **1** | 16 | 301600 | 99.74 | 15.95 |
| **2** | 16 | 293857 | 96.12 | 15.38 |
| **3** | 16 | 309416 | 103.4 | 16.54 |
| | Mean | | | 15.96 |
| | SD | | | 0.5822 |
| | % CV | | | 3.64 |
| | % Accuracy | | | 99.75 |

**Table.7** Accuracy result of dapoxetine (24 µg/ml) (HQC)

| Sr. No. | Concentration (µg/ml) | Area | % recovery | Recovered concentration (µg/ml) |
|---|---|---|---|---|
| **1** | 24 | 401806 | 97.74 | 23.45 |
| **2** | 24 | 413976 | 101.54 | 24.37 |
| **3** | 24 | 401980 | 94.11 | 22.58 |
| **Mean** | | | | 23.47 |
| **SD** | | | | 0.8913 |
| **% CV** | | | | 3.79 |
| **% Accuracy** | | | | 97.80 |

**Table.8** Interday precision result of dapoxetine

| A | DAY 1 | DAY 2 | DAY 3 |
|---|---|---|---|
| | **Concentration 8 µg/mL (LQC)** | | |
| **1** | 194536 | 187807 | 189987 |
| **2** | 189145 | 190987 | 184928 |
| **3** | 192245 | 189234 | 183025 |
| **4** | 186087 | 188086 | 192851 |
| **5** | 179987 | 179987 | 190167 |
| **6** | 187895 | 185453 | 188042 |
| **Mean** | **188282** | **186925** | **188166** |
| **SD** | **5037.3** | **3853** | **363.65** |
| **% CV** | **2.675** | **2.061** | **1.9337** |
| **B** | **Concentration 16 µg/mL(MQC)** | | |
| **1** | 301600 | 301587 | 298754 |
| **2** | 294876 | 295776 | 294536 |
| **3** | 298987 | 300123 | 294536 |
| **4** | 293334 | 298347 | 294332 |
| **5** | 295112 | 294434 | 301165 |
| **6** | 293223 | 295334 | 293564 |
| **Mean** | **296188** | **297600** | **297392** |
| **SD** | **3374** | **2874** | **3728** |
| **% CV** | **1.139** | **0.965** | **1.25** |
| **C** | **Concentration 24 µg/mL (HQC)** | | |
| **1** | 403112 | 401587 | 398754 |
| **2** | 405876 | 410276 | 404536 |
| **3** | 403223 | 409123 | 404332 |
| **4** | 408987 | 408347 | 401165 |
| **5** | 402334 | 404434 | 405422 |
| **6** | 409112 | 406516 | 403564 |
| **Mean** | **405440** | **405334** | **402962** |
| **SD** | **3040** | **3295** | **2581** |
| **% CV** | **0.75** | **0.810** | **0.62** |

**Table.9** Intraday precision results of dapoxetine

| A | 1st reading | 2nd reading | 3rd reading |
|---|---|---|---|
| | **Concentration 8 µg/mL (LQC)** | | |
| **1** | 194536 | 189452 | 187807 |
| **2** | 189145 | 183816 | 190987 |
| **3** | 192245 | 183259 | 189234 |
| **4** | 186087 | 192851 | 188086 |
| **5** | 179987 | 190579 | 179987 |
| **6** | 187895 | 188042 | 185453 |
| **Mean** | **188282** | **187999** | **186925** |
| **SD** | **5037.3** | **363.65** | **3853** |
| **% CV** | **2.801** | **1.631** | **2.061** |
| **B** | **Concentration 16 µg/mL(MQC)** | | |
| **1** | 301600 | 298025 | 301587 |
| **2** | 294876 | 2940391 | 295776 |
| **3** | 298987 | 294805 | 300123 |
| **4** | 293334 | 294279 | 298347 |
| **5** | 295112 | 301851 | 294434 |
| **6** | 293223 | 293489 | 295334 |
| **Mean** | **296188** | **296801** | **297600** |
| **SD** | **3374** | **3728** | **2874** |
| **% CV** | **1.537** | **1.35** | **1.28** |
| **C** | **Concentration 24 µg/mL (HQC)** | | |
| **1** | 403112 | 398754 | 401587 |
| **2** | 405876 | 404536 | 410276 |
| **3** | 403223 | 404332 | 409123 |
| **4** | 408987 | 401165 | 408347 |
| **5** | 402334 | 405422 | 404434 |
| **6** | 409112 | 403564 | 406516 |
| **Mean** | **405440** | **402962** | **405334** |
| **SD** | **3040** | **2581** | **3295** |
| **% CV** | **0.91** | **0.71** | **0.85** |

**Table.10** Recovery results of dapoxetine (8 µg/ml) (LQC)

| Replicate | Peak Area of Standard drug | Peak area of drug Spiked in plasma |
|---|---|---|
| **1** | 243509 | 194336 |
| **2** | 250012 | 204136 |
| **3** | 249221 | 195554 |
| **Mean** | 247580 | 198008 |
| **SD** | 3548 | 5341 |
| **% CV** | 1.43 | 2.69 |
| **% Mean Recovery** | 97.97 | |

**Table.11** Recovery results of dapoxetine (16 µg/ml) (MQC)

| Replicate | Peak Area of Standard drug | Peak area of drug Spiked in plasma |
|---|---|---|
| **1** | 421946 | 301600 |
| **2** | 419963 | 298895 |
| **3** | 422015 | 301945 |
| **Mean** | 421308 | 300813 |
| **SD** | 1165 | 1670 |
| **% CV** | 0.27 | 0.55 |
| **% Mean Recovery** | 99.39 | |

**Table.12** Recovery results of dapoxetine (24 µg/ml) (HQC)

| Replicate | Peak Area of Standard drug | Peak Area of spiked plasma drug |
|---|---|---|
| **1** | 598222 | 401806 |
| **2** | 594256 | 405345 |
| **3** | 589996 | 399321 |
| **Mean** | 594158 | 402157 |
| **SD** | 4113 | 3027 |
| **% CV** | 6.92 | 0.75 |
| **% Mean Recovery** | 98.68 | |

**Table.13** Freeze and thaw stability result of dapoxetine (8 µg/ml) (LQC)

| Replicate | Peak Area of Standard Sample | Peak Area of Stability Sample |
|---|---|---|
| **1** | 7.89 | 7.01 |
| **2** | 8.06 | 7.6 |
| **3** | 8.1 | 7.4 |
| **Mean** | 8.01 | 7.33 |
| **SD** | 0.11 | 0.30 |
| **% CV** | 1.35 | 1.26 |
| **% Mean Stability** | 91.57% | |

**Table.14** Freeze and thaw stability result of dapoxetine (24µg/ml) (HQC)

| Replicate | Peak Area of standard sample | Peak Area of stability sample |
|---|---|---|
| **1** | 24.18 | 23.2 |
| **2** | 24.64 | 23.01 |
| **3** | 23.52 | 22.5 |
| **Mean** | 24.11 | 22.90 |
| **SD** | 0.562 | 0.361 |
| **% CV** | 2.33 | 1.57 |
| **% Mean Stability** | 94.98% | |

**Table.15** Short-term stability results of dapoxetine (8 µg/ml) (LQC)

| Replicate | Peak Area of Standard sample | Peak Area of Stability sample |
|---|---|---|
| **1** | 8.23 | 7.8 |
| **2** | 8.06 | 7.4 |
| **3** | 8.1 | 7.2 |
| **Mean** | 8.13 | 7.46 |
| **SD** | 0.08 | 0.30 |
| **% CV** | 1.08 | 1.30 |
| **% Mean Stability** | 91.75% | |

**Table.16** Short-term stability result of dapoxetine (24 µg/ml) (HQC)

| Replicate | Peak Area of Standard sample | Peak Area of Stability sample |
|---|---|---|
| **1** | 24.01 | 22.01 |
| **2** | 24.23 | 22.98 |
| **3** | 23.96 | 22.45 |
| **Mean** | 24.06 | 22.48 |
| **SD** | 0.143 | 0.48 |
| **% CV** | 0.59 | 2.13 |
| **% Mean Stability** | 93.66% | |

**Table.17** Long-term stability result of dapoxetine (8 µg/ml) (LQC)

| Replicate | Peak area of standard sample | Peak area of Stability sample |
|---|---|---|
| **1** | 7.98 | 6.85 |
| **2** | 8.1 | 6.99 |
| **3** | 8.2 | 7.02 |
| **Mean** | 8.09 | 6.95 |
| **SD** | 0.11 | 0.09 |
| **% CV** | 1.35 | 1.29 |
| **% Mean Stability** | 85.9% | |

**Table.18** Long-term stability result of dapoxetine (24 µg/ml) (HQC)

| Replicate | Peak Area of standard sample | Peak area of Stability sample |
|---|---|---|
| **1** | 24.02 | 21.04 |
| **2** | 24.12 | 21.2 |
| **3** | 24.2 | 21.5 |
| **Mean** | 24.11 | 21.14 |
| **SD** | 0.090 | 0.092 |
| **% CV** | 0.37 | 0.42 |
| **%Mean Stability** | 88.79% | |

**Table.19** Stock solution stability result of dapoxetine (8 µg/ml) (LQC)

| Replicate | Peak area of standard sample | Peak area of stability sample |
|---|---|---|
| **1** | 8.12 | 7.24 |
| **2** | 8.1 | 7.12 |
| **3** | 7.86 | 7.01 |
| **Mean** | 8.02 | 7.12 |
| **SD** | 0.144 | 0.11 |
| **% CV** | 1.80 | 1.61 |
| **% Mean Stability** | 88.74% | |

**Table.20** Stock solution stability result of dapoxetine (24 µg/ml) (HQC)

| Replicate | Peak area of standard sample | Peak area of stability sample |
|---|---|---|
| **1** | 24.2 | 21.56 |
| **2** | 23.54 | 21.01 |
| **3** | 23.98 | 21.4 |
| **Mean** | 23.76 | 21.32 |
| **SD** | 0.38 | 0.282 |
| **% CV** | 1.60 | 1.326 |
| **% Mean Stability** | 89.74% | |

**Table.21** Summary of all validation parameter results

| Sr. No | Validation Parameters | Result |
|---|---|---|
| **1** | Linearity range (µg/ml) | 5-25 |
| **2** | Retention time (min) | 4.4 |
| **3** | Correlation coefficient (r2) | 0.995 |
| **4** | Intraday Precision (mean %CV) | 7.327 |
| **5** | Inter day Precision (mean %CV) | 6.26 |
| **6** | Mean Recovery (%) | 73.01 |
| **7** | Freeze and Thaw stability % Mean stability | 93.27 |
| **8** | Short-term temperature stability % Mean stability | 92.70 |
| **9** | Long-term stability % Mean stability | 87.34 |
| **10** | Stock solution stability % Mean stability | 89.24 |

**Fig.1** Structure of Dapoxetine

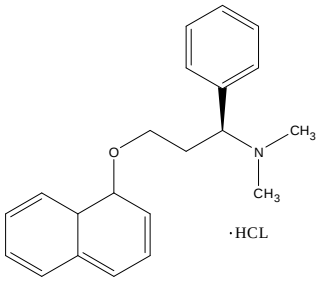


**Fig.2** UV spectrum of dapoxetine HCL

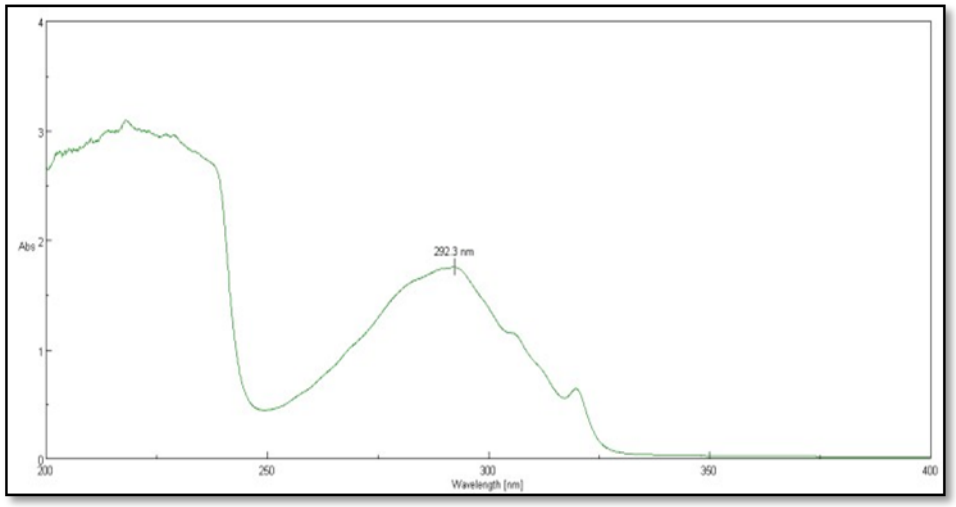



**Fig.3** HPLC Chromatogram of Dapoxetine HCL (15µg/ml)

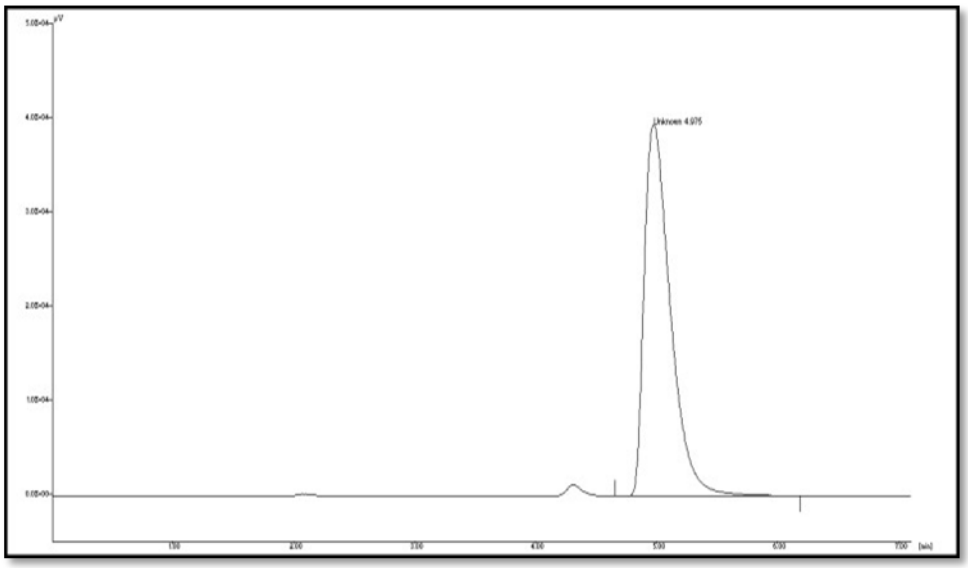


**Fig.4** Chromatogram of Dapoxetine HCL Spiked in Human Plasma (10µg/ml)

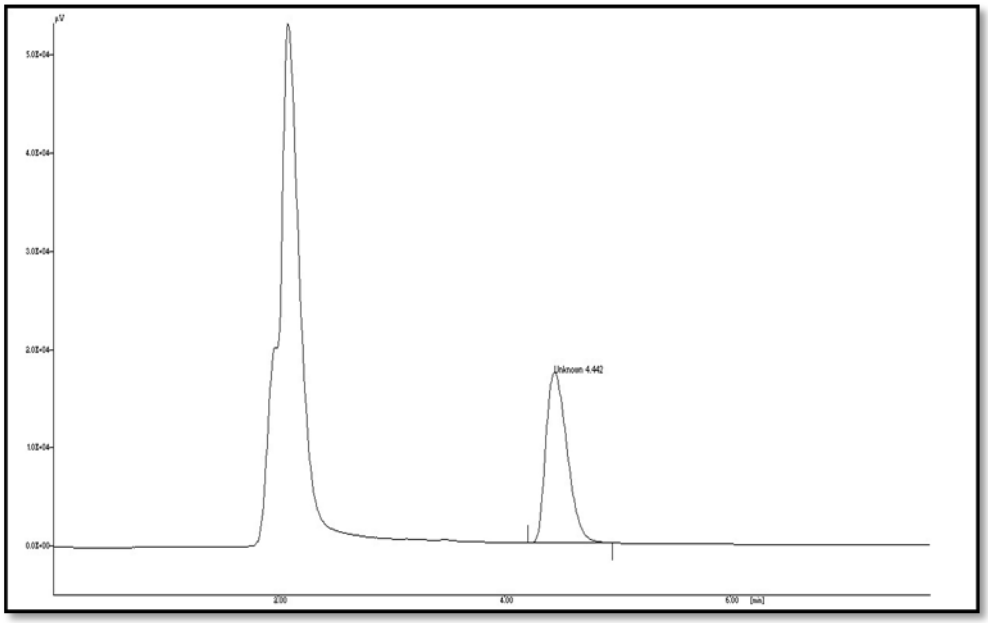



**Fig.5** A Typical Chromatogram of Blank Human Plasma

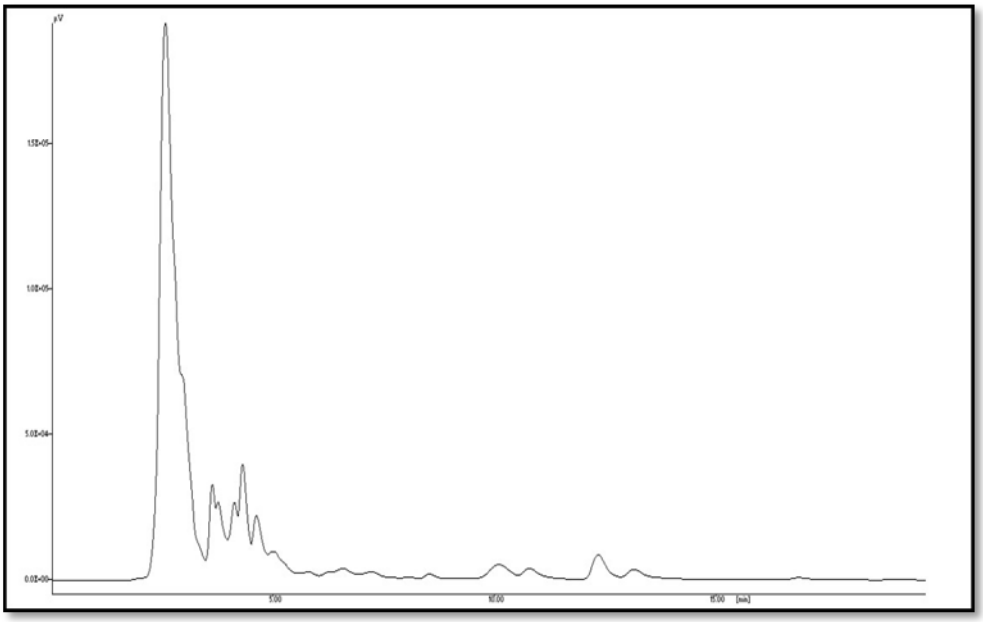


**Fig.6** Typical Chromatogram of Dapoxetine

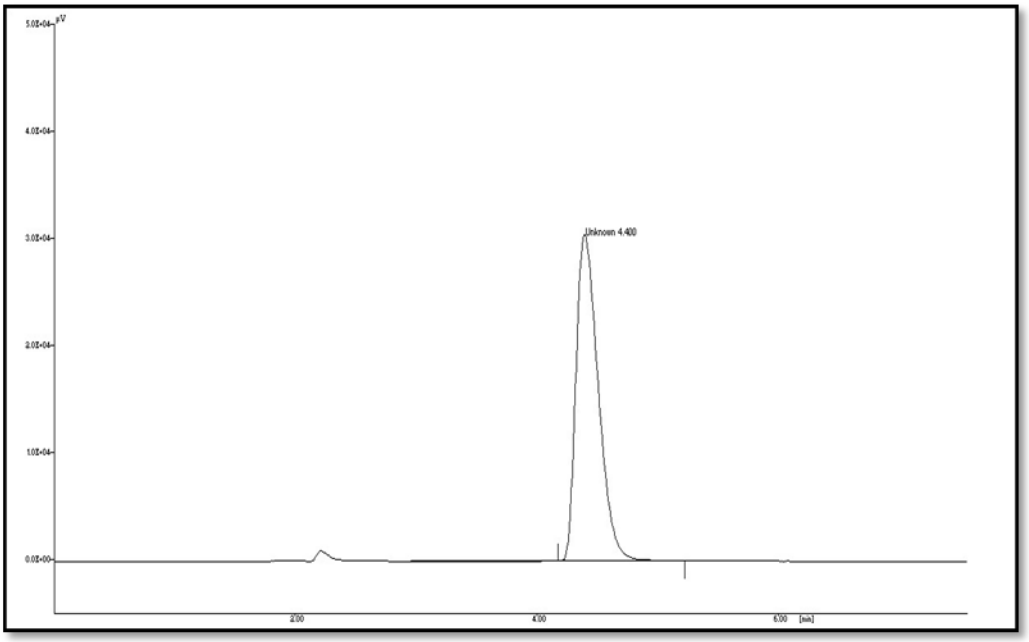



**Fig.7** Calibration Curve for Dapoxetine (API)

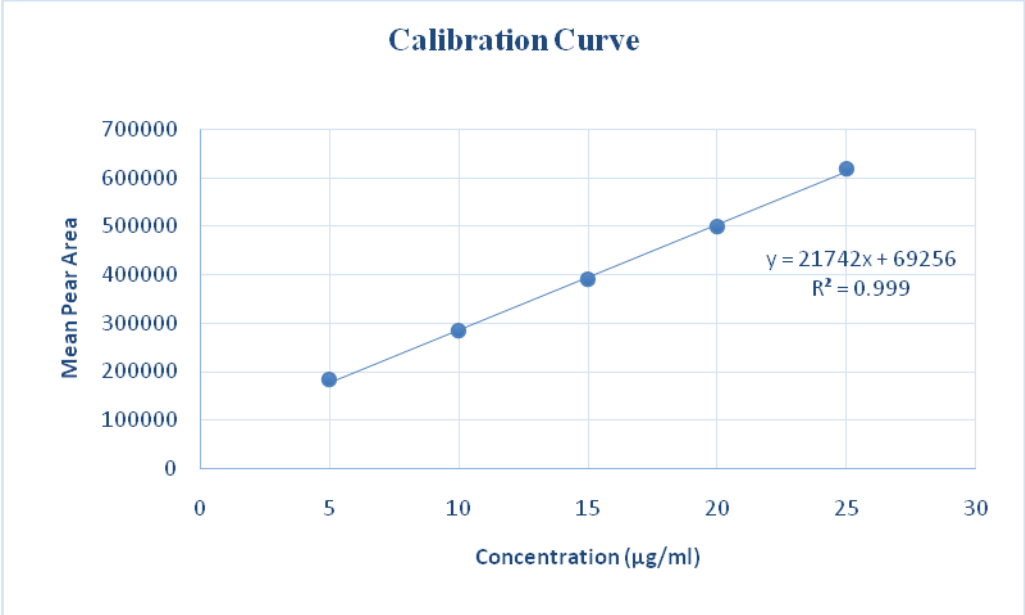
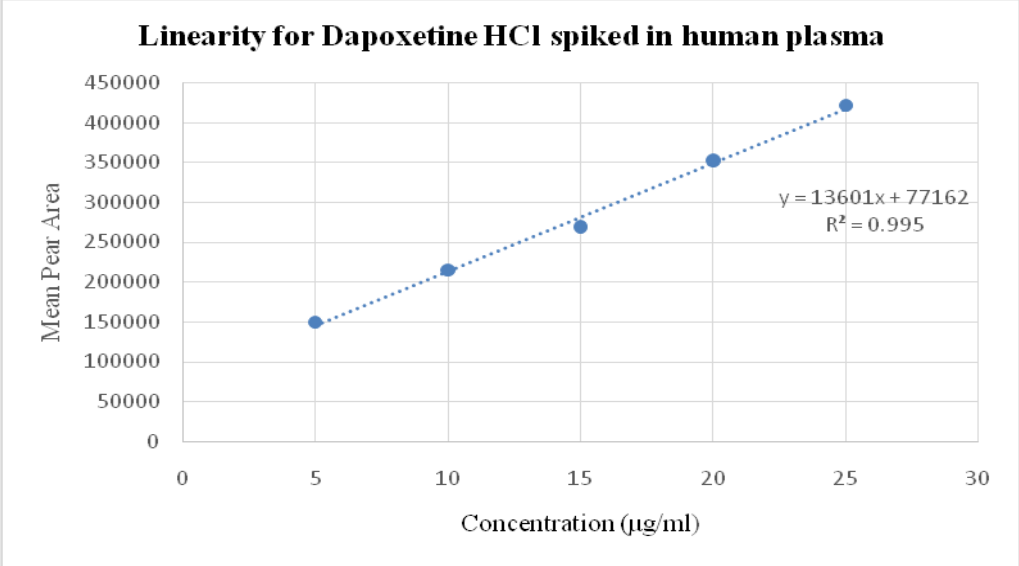


**Fig.8** Calibration Curve of Dapoxetine Spiked in Human Plasma




## Recovery

The percent recovery of dapoxetine from human plasma was found to be 97.97, 99.39, 98.68 for LQC, MQC and HQC level. The recovery of dapoxetine ease consistent, precise and reproducible (Table 10, 11 and 12).

## Stability

## Freeze and Thawstability

Dapoxetine did not show significant alteration in its concentration even after three cycles of freeze and thaw (Table 13 and 14).

## Short-term temperature stability

According to observed results the concentration of dapoxetine in the biological sample did not show significant alteration in its concentration. Samples are stable up to 6 hrs (Table 15 and 16).

## Long-term stability

The percent mean long-term temperature stability of dapoxetine in the biological sample did not show significant alteration in its concentration even after 7 days. After 21 days the concentration of dapoxetine decreased up to 30% within the time period under the indicated storage conditions, however the days (Table 17 and 18).

## Stock solution stability

Dapoxetine when stored at room temperature did not show significant alteration in its concentration; hence the standard stock solution can be stored upto 6 hrs after its preparation. Sample did not show significant alteration in its concentration after 6 hrs (Table 19 and 20).

## Summary of all validation parameter results

All the parameters of validation were found within the acceptance criteria as per USFDA guidelines. Thus, we conclude the developed bioanalytical method was suitable for determination of dapoxetine from human plasma and can be further applied in of pharmacokinetic study of dapoxetine (Table 21).

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