Development and Validation of Tramadol Hydrochloride in Bulk and Pharmaceutical Dosage form by Ultraviolet Spectroscopy

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ABSTRACT
A simple, rapid, accurate, precise and economic spectrophotometric technique for estimation of tramadol hydrochloride in 0.1N HCl have been developed. Tramadol Hydrochloride exhibit absorbance most 270nm when 0.1N HCl used as solvent proportion, so absorbance was once measured at the identical wavelengths for the determination of Tramadol Hydrochloride obeys Beer Lambert’s law in the concentration range of 20-180µg/ml. The present study describes development and validation of simple and economic UV spectrophotometric method for the estimation of Tramadol Hydrochloride in bulk and injection dosage form using absorbance maxima method. Solubility studies indicated that a Tramadol Hydrochloride shows better solubility in proposed diluents i.e., 0.1N HCl solution the λmax of Tramadol Hydrochloride was found to be 270nm. Because of cost effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries as compared to other reported methods.

Keywords: Validation, Tramadol Hydrochloride, injection, 0.1N HCl, UV spectrophotometric.

MATERIALS AND METHODS

Materials
Tramadol Active Pharmaceutical Ingredient was provided as gift tester by Windlass Biotech Dehradun Uttarakhand. Tramadol (Marketed formulation) is manufactured by Consen Pharma limited.

Instruments
The Ultra Violet-Spectroscopy were conceded out with a Cary 60Single Beam UV spectrometer manufacturer by Agilent Tech, Digital Weight Balance: TX323L, Shimadzu was used.

Preparation of Standard Stock Solution of Tramadol
Accurately weigh about 50mg of the drug and transferred to 50ml of volumetric flask and dissolved it in 50ml of 0.1N HCl. Then volume was made up to the mark with 0.1N HCl. The 10ml of previously set solution was diluted with 50ml of HCl. This standard solution contained 100µg of drug per ml.

Determination of wavelength of maximum absorbance (λ max)
1ml of standard stock solution was pipette out and transferred to a 10ml of volumetric flask. The volume was made up to the mark with 0.1N HCl. The solution contained 100µg/ml of the drug. Then 1ml of the solution is taken in a 10ml volumetric flask was added to it then volume was made up to the mark with 0.1N HCl. This solution contain 10µg/ml of the drug. The absorbance of this solution was scanned in the range of 200-400nm against 0.1N HCl as a blank.
The absorbance of the Tramadol Hydrochloride in 0.1 N HCl by UV Spectrophotometric method.

Preparation of calibration curve for Tramadol at 270nm

1,2,3,4,5,6,7 and 8ml standard stock solution (200μg/ml) were pipette out into a series of 10ml volumetric flask. Then the volumes were made up to the mark with 0.1N HCl and mixed to obtain the solutions in the concentration range of 20, 40, 60, 80, 100, 120, 140, 160μg/ml of drug.

The absorbance of these resultant solutions were measured at 270nm against 0.1N HCl as a blank and graph was plotted between absorbance obtained and the concentration of the solution. (Table 1).

Table 1: Linearity, Range, E 1% 1CM, Absorptivity (L gm⁻¹ cm⁻¹), and Molar Absorptivity (L mol⁻¹ cm⁻¹)

| Concentration (μg/ml) | Absorption | Mean | E1%  | Absorptivity | Molar Absorptivity |
|-----------------------|------------|------|------|--------------|-------------------|
|                       | A1         | A2   | A3   |              |                   |
| 0                     | 0          | 0    | 0    | 0            |                   |
| 20                    | 0.1152     | 0.1151 | 0.1151 | 0.1151      | 57.55             | 5.755             | 1515.867         |
| 40                    | 0.2340     | 0.2340 | 0.2362 | 0.2340      | 58.5              | 5.85              | 1540.89          |
| 60                    | 0.3545     | 0.3546 | 0.3548 | 0.3546      | 59.1              | 5.91              | 1556.694         |
| 80                    | 0.4718     | 0.4718 | 0.4716 | 0.4718      | 58.97             | 5.897             | 1553.2698        |
| 100                   | 0.5862     | 0.5861 | 0.5863 | 0.5861      | 58.61             | 5.86              | 1543.7874        |
| 120                   | 0.7036     | 0.7038 | 0.7028 | 0.7032      | 58.6              | 5.86              | 1543.524         |
| 140                   | 0.8081     | 0.8074 | 0.8076 | 0.8077      | 57.69             | 5.769             | 1519.5546        |
| 160                   | 0.9241     | 0.9246 | 0.9254 | 0.9247      | 57.79             | 5.779             | 1522.1886        |
| 180                   | 1.0299     | 1.0298 | 1.0296 | 1.0297      | 57.42             | 5.742             | 1512.4428        |

Repeatability

Pipetted out 1ml of standard solution shifted into a series of nine 10ml analytical flask and diluted with 0.1N HCl to get the concentration of 20μg/ml. Optical density of the resultant solutions was dignified at 270nm 0.1N HCl used as a blank and graph was plotted between absorbance obtained and the concentration of the solution. (Table 2).

Table 2: Study of Repeatability

| Nominal Con μg/ml | Absorbance | Observed Con(μg/ml) | Mean Con μg/ml | SD          | %RSD        |
|-------------------|------------|---------------------|----------------|-------------|-------------|
| 20                | 0.1111     | 17.2                | 17.2           | 0.00293     | 0.01704     |
| 20                | 0.1157     | 18.1                | 17.2           | 0.00293     | 0.01704     |
| 20                | 0.1096     | 17.0                | 17.2           | 0.00293     | 0.01704     |
| 20                | 0.1115     | 17.2                | 17.2           | 0.00293     | 0.01704     |
| 20                | 0.1067     | 16.4                | 17.2           | 0.00293     | 0.01704     |
| 20                | 0.1113     | 17.2                | 17.2           | 0.00293     | 0.01704     |
Accuracy
The accuracy was assessed by the standard addition method of three replicate determinations of three different solutions containing 80,100,120 µg/ml of Tramadol Hydrochloride. The average % recoveries for three different concentrations was found to be 99.79 using proposed UV spectrophotometric method. The higher values indicated that the proposed UV spectrophotometric method was accurate for the determination of Tramadol Hydrochloride in pharmaceutical dosage form. Results of recovery studies are summarized in (Table 3).

| Recovery | Nominal Conc. (µg/ml) | Absorbance | Observed conc. (µg/ml) | % Recovery |
|----------|-----------------------|------------|------------------------|------------|
| 80%      | 90=50+40              | 0.5043     | 89.9                   | 99.89      |
| 80%      | 90=50+40              | 0.5203     | 89.9                   | 99.89      |
| 80%      | 90=50+40              | 0.5248     | 90.0                   | 100.00     |
| 100%     | 100=50+50             | 0.6096     | 99.8                   | 99.80      |
| 100%     | 100=50+50             | 0.5866     | 99.9                   | 99.90      |
| 100%     | 100=50+50             | 0.5868     | 99.9                   | 99.90      |
| 120%     | 110=50+60             | 0.6450     | 109.4                  | 99.45      |
| 120%     | 110=50+60             | 0.6523     | 109.6                  | 99.64      |
| 120%     | 110=50+60             | 0.6449     | 109.9                  | 99.91      |
| Mean     |                       |            |                        | 99.82      |

Table 3: Accuracy

Specificity
Specificity study was carried out by observing any interference in absorbance of drug in the existence of conjoint excipients like Starch, Talc, Lactose, Magnesium Stearate etc. Absorbance of 100 µg/ml drug solution with and without excipients was measured at 270nm. The results obtained were summarized in the (Table 4).

| Nominal con(µg/ml) | Without Excipients | With Excipients | % Interference |
|--------------------|--------------------|-----------------|----------------|
|                    | Absorbance         | Observed Conc. (µg/ml) | Absorbance | Observed Conc. (µg/ml) | % Interference |
| 100                | 0.5856             | 101.1           | 0.5567       | 96.2 | 0.95 |
| 100                | 0.5822             | 100.5           | 0.5795       | 100.2 | 1.00 |
| 100                | 0.5814             | 100.6           | 0.5721       | 98.7 | 0.98 |
| 100                | 0.5601             | 96.6            | 0.5563       | 96.1 | 0.99 |
| 100                | 0.5613             | 96.8            | 0.5716       | 98.6 | 1.02 |
| Mean               |                    |                 |              | 0.987811 |

% Assay of Tramadol injection two different brands
The injection were in liquid and amount of liquid containing 2ml of Tramadol was transferred into 100ml of volumetric flasks and make up the volume up to the mark with 0.1N HCl. The absorbance of this resultant solution was estimated at 270nm.

| Sr. No | Absorbance | Conc.(µg/ml) | Dil. Factor | Content (ml) | Label claim(ml) | %Assay |
|--------|------------|--------------|-------------|--------------|-----------------|--------|
| 1      | 0.6059     | 104.8        | 100         | 97.9         | 100             | 97.9   |
| 2      | 0.6053     | 103.6        | 100         | 98.7         | 100             | 98.7   |
| 3      | 0.6062     | 105.7        | 100         | 97.9         | 100             | 97.9   |
| Mean   |            |              |             |              |                 | 98.16  |
Table 6: Brand B (Supridol IV) Neon laboratories LTD

| Sr. No | Absorbance | Conc. (µg/ml) | Dil. Factor | Content (ml) | Label claim (ml) | % Assay |
|--------|------------|---------------|-------------|--------------|------------------|---------|
| 1      | 0.5470     | 94.4          | 100         | 101.10       | 100              | 101.1   |
| 2      | 0.5466     | 94.6          | 100         | 101.90       | 100              | 101.9   |
| 3      | 0.5479     | 94.5          | 100         | 102.60       | 100              | 102.6   |
| Mean   |             |               |             |              |                  | 101.86  |

CONCLUSION

A simple UV spectrophotometric method have been developed and validated for the determination of Tramadol Hydrochloride in bulk, tablet and injection dosage form. The results of the validation parameters show that the UV spectrophotometric methods were found to be accurate, precise and sensitive. Because of cost-effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the quantitative analysis of Tramadol Hydrochloride in pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy.

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