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## Original Research Article

## Development and validation of dissolution test method for determination of cyclobenzaprine hydrochloride from its formulation using HPLC

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## ABSTRACT

**Aim:** The aim of present study was to develop and validate a dissolution test method for Cyclobenzaprine HCL in its formulation using RP-HPLC method.**Design:** Optimization of chromatographic parameters, development of the dissolution test method using RP-HPLC and to validate the developed methods as per ICH guidelines.**Materials and Methods:** The optimized dissolution parameters includes USP apparatus II at a paddle rotation rate of 50 rpm and 900 ml of 1.2 pH 0.1N HCL buffer at 37°C±0.5°C. Under these conditions, the in vitro release profiles of cyclobenzaprine HCL showed good results. The drug release was estimated by RP-HPLC using column Shodex C<sub>18</sub>-4E (250×4.6mm×5μm), detection wavelength 289.4 nm having the flow rate 1.0 mL/min using Acetonitrile : phosphate buffer (3.0 pH) in the proportion of 65:35% v/v.**Results:** The percent drug amount released estimated by proposed method was found to be 99.04%. The method was found to be linear with correlation coefficient was found to be 0.9991 in the concentration range was 2-10 μg/mL. The mean % recovery of Cyclobenzaprine was found to be 100.04. Precision values observed less than 2. All the validation parameters were within the acceptance range.**Conclusion:** The results obtained by proposed dissolution method for tablet formulation containing Cyclobenzaprine HCL are reliable, precise and accurate. Hence it was routinely adopted for dissolution analysis of the said drugs in the formulation.© This is an open access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>) which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

## 1. Introduction

Cyclobenzaprine Hydrochloride (CBZ) chemically known as 3-(5H-Dibenzo[a,d]annulen-5-ylidene)-N,N-dimethyl-1-propanamine hydrochloride.<sup>2</sup> (Figure 1) The molecular formula & molecular weight of Cyclobenzaprine is C<sub>20</sub>H<sub>21</sub>N and 275.4g/mol. Cyclobenzaprine is a off-white crystalline tricyclic amine salt that is freely soluble in water and alcohol, slightly soluble in chloroform and methylene chloride, practically insoluble in hydrocarbons. Cyclobenzaprine is a centrally acting skeletal muscle relaxant with antidepressant activity.<sup>3,4</sup> The exact mechanism of action of cyclobenzaprine has not been fully determined, but this drug seems to primarily act

at the brain stem to reduce tonic somatic motor activity, influencing both gamma and alpha motor neurons leading to a reduction in muscle spasms. cyclobenzaprine is used short-term to treat muscle spasms associated with acute, painful musculoskeletal conditions. It is usually used along with rest and physical therapy. It works by helping to relax the muscles.<sup>5,6</sup>

Literature survey revealed that many analytical methods like UV, HPLC, HPTLC DSC, FT-IR and LC-MS for the determination of cyclobenzaprine in pure drug, pharmaceutical dosage forms and in biological samples have been reported.<sup>7,8</sup> But no method have been reported for dissolution study of cyclobenzaprine hcl in solid dosage forms, So, the aim of the existing work to development of dissolution test method using RP-HPLC method for analysis of cyclobenzaprine HCL in Tablets and to validate

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dissolution method accordance with ICH guidelines for, precision, linearity and range, accuracy, ruggedness and robustness study.

## 2. Materials and Methods

### 2.1. Chemicals and reagents

Cyclobenzaprine HCL was kindly obtained as a gift sample from Zim Laboratories Ltd. (Nagpur). Commercial tablets containing cyclobenzaprine hydrochloride 5mg was procured from the local chemist shop manufactured by Macleods Pharmaceuticals Ltd. Acetonitrile and Methanol used was of HPLC grade. Double distilled water was used for preparing dissolution media and HPLC mobile phase. 0.1 N HCl and Phosphate Buffer pH 6.8 was prepared as per the pharmacopoeia. Other chemicals include potassium dihydrogen phosphate; ortho phosphoric acid and hydrochloric acid of GR grade were used. 0.1 N HCl, acetate buffer pH 4.0, Phosphate Buffer pH 6.8 was prepared as per the pharmacopoeia.

### 2.2. Instrumentation

Uv-Spectrophotometer: Jasco-V-630, HPLC: Analytical Technology Limited, Analytical HPLC isocratic system consisted of Shodex C<sub>18</sub>-4E (5 $\mu$ m) 250 $\times$ 4.6mm, Uv-3000 detector and P-3000 Pump, Rheodyne injector with 20 $\mu$ L capacity, Dissolution Apparatus: Electrolab Tablet Dissolution tester-TDT-06P, Weighing balance: Shimadzu AUX 220, pH-meter: Digital pH Meter (model 111E), Sonicator: PCI Mumbai 3.5L100H.

### 2.3. Determination of working wavelength

The standard solutions cyclobenzaprine HCl was prepared in Methanol having concentration 10  $\mu$ g/ml and subjected to U.V. spectrophotometric study to determine  $\lambda$  max of drug over the wavelength range 200-400 against Methanol as blank solution. Cyclobenzaprine shows maximum absorption at 223.6 and 289.4nm, the wavelength selected was 289.4 nm. The spectrum recorded is shown in Figure 2.

### 2.4. Preparation of phosphate buffer (pH 3.0)

Dissolve 1.36 g of potassium dihydrogen orthophosphate and 2 mL of triethylamine in 800 mL of water, Adjusted pH to 3.0 with orthophosphoric acid and add sufficient water to produce 1000 mL.

### 2.5. Preparation of mobile phase

A mixture of Acetonitrile and Phosphate Buffer (pH 3.0) in the ratio of 65:35v/v was prepared. The mobile phase was sonicated for 15 min and filtered through nylon membrane filter (0.45 $\mu$ m).

### 2.6. Preparation of standard stock solution

A standard stock solution having concentration 1000  $\mu$ g/mL of CBZ was prepared in mobile phase.

### 2.7. Preparation of working standard solution

A 1.0 mL of the above standard solution was diluted upto 10.0 mL to prepare a solution having concentration 100  $\mu$ g/mL of CBZ, from this solution further 2.0 mL was pipetted and diluted upto 10.0 mL to get working standard solution having concentration 20  $\mu$ g/mL of CBZ.

### 2.8. Chromatographic conditions

Chromatography was achieved on a Shodex C<sub>18</sub>-4E column(250 x 4.6 mm). The mobile phase was a mixture of ACN: Phosphate buffer in the proportion of 65:35 % v/v and adjusted pH to 3.0 with orthophosphoric acid which was filtered (0.45 $\mu$ m) and degassed before use. All analysis was performed at room temperature at a flow rate of 1 mL/min. Detection was made at 289.4 nm. A 20  $\mu$ L volume injection were utilized for analysis.

### 2.9. System suitability parameters

The system suitability study was carried out using six replicates injections of standard solution containing 20 $\mu$ g/mL of CBZ was prepared in mobile phase. A 20 $\mu$ L of solution were injected through manual injector and analyzing the chromatograms for peak area, theoretical plates, % RSD and tailing factor. Results are shown in Table 1.

### 2.10. Dissolution Test Conditions

Drug dissolution tests were carried out with USP apparatus II (paddle type) at 50 rpm with dissolution volume of 900mL. Thermostatic bath was used to maintain the temperature of the cell at 37 $\pm$ 0.5 $^{\circ}$ C. Various dissolution media's were tried out of which 0.1 N HCL (1.2 pH) was selected. Weighed and dropped 1 tablet in each of the six dissolution vessel containing 0.1 N HCL (pH 1.2) for the drug under analysis. Aliquots of 5.0 mL were withdrawn at 5, 10, 20, 30, 40, 50 and 60 min time interval, used as sample and replaced with an equal volume of the fresh medium to maintain a constant total volume. After the end of each time point, sample aliquots were filtered and chromatographed. The percentage drug release was estimated by validated HPLC method at each time point.

### 2.11. Dissolution method parameter optimization for CBZ

Various dissolutions were performed to optimize the parameters like dissolution media, dissolution media volume, apparatus and rpm, using the optimized

**Table 1:** Results of system suitability parameters

S.No.	Wt. of Std. drug Taken (mg)	Area (mV)
1.		1437084
2.		1402044
3.		1447609
4.	~10 mg	1434069
5.		1446993
6.		1404021
Mean		1428636.66
± SD		20546.88
% RSD		1.438
Retention time		3.665
Tailing factor		1.59
Theoretical Plates		3359.66

**Table 2:** Results showing effect of change in USP apparatus on CBZ

TimePoints Mins	0.1N HCL (pH 1.2) Dissolution Media							
	Apparatus: USP-I (Basket)		Dissolution Volume 900mL					
			Apparatus USP:II (Paddle)		% Release at RPM			
	50		75		50		75	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
5	67.51	0.95	71.53	1.17	75.80	0.45	84.27	0.91
10	81.45	0.99	80.69	0.61	89.25	0.81	91.58	0.12
15	88.08	0.73	88.40	0.43	99.64	0.54	97.64	0.35
20	87.98	1.03	87.01	0.94	99.34	0.81	96.83	0.78
25	86.90	1.09	87.13	0.82	98.10	0.94	97.42	0.46
30	85.60	0.96	86.87	0.96	98.13	0.96	95.65	0.88
45	83.82	0.61	86.13	0.23	96.56	0.53	95.50	0.93
60	82.95	1.12	85.31	1.12	97.04	0.45	94.24	1.10

**Table 3:** Results showing effect of change in volume of dissolution media on CBZ

TimePoints Mins	0.1N HCL (pH1.2) Dissolution Media							
	500 mL		Apparatus USP Type II					
			900mL		% Release at RPM			
	50		75		50		75	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
5	33.04	0.67	41.85	0.98	72.79	0.49	79.81	0.38
10	42.60	0.26	48.04	0.67	82.99	0.56	90.58	0.32
15	50.31	0.14	55.13	0.98	98.67	0.32	98.01	0.88
20	49.01	0.23	54.06	0.26	98.40	0.48	97.04	0.93
25	47.69	0.33	52.99	0.55	97.75	0.57	96.74	0.16
30	47.52	0.56	52.19	0.59	96.96	0.32	96.70	0.53
45	47.37	0.25	51.18	0.50	97.58	1.20	96.60	1.02
60	46.72	0.31	50.70	0.47	96.27	0.71	95.24	0.46

**Table 4:** Results showing effect of change in dissolution media (buffer) on CBZ

TimePoints Mins	0.1N HCL (pH1.2) Dissolution Media Apparatus USP Type II							
	0.1N HCL (pH 1.2)				Phosphate buffer (pH 6.8)			
	50		75		50		75	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
5	65.94	0.40	87.85	0.81	49.63	0.85	70.12	1.13
10	91.09	0.46	93.04	0.25	68.28	0.53	78.73	1.08
15	99.84	0.93	97.72	0.93	82.67	0.92	86.17	1.20
20	98.18	0.11	97.44	0.20	80.06	0.92	85.80	1.66
25	98.03	0.52	97.21	0.90	80.98	1.25	83.75	1.59
30	96.68	0.96	96.03	0.44	78.58	0.94	83.62	1.64
45	97.34	0.46	95.40	0.88	79.03	1.09	83.62	1.09
60	95.13	0.96	95.18	0.96	76.33	1.21	81.49	1.22

**Table 5:** Final dissolution method parameters for the drug

Drug	Dissolution media	Media volume	USP Apparatus	RPM
Cyclobenzaprine	0.1N HCL	900mL	Type-II (Paddle)	50

**Table 6:** % Release of drug under final selected chromatographic condition

Sample	Test point(min)	Retention time	A.U.C. (mV)	% Drug release	Tailing Factor	Theoretical plate
Standard (10µg/mL)	-	3.316	1190971	-	1.62	3460
	5	3.571	500216	75.60		3390
	10	3.483	585064	88.42		3405
	15	3.598	655188	99.02		3362
Test sample	20	3.421	651090	98.40	1.63	3394
	25	3.587	644785	97.45		3386
	30	3.563	641967	97.02		3353
	45	3.448	642821	97.15		3352
	60	3.451	639076	96.58		3313

**Table 7:** Observation of linearity response of CBZ

S.No.	Concentration (µg/ml)	A.U.C (mV)
1	2	284272
2	4	463967
3	6	637275
4	8	793641
5	10	987361
Correlation coefficient R <sup>2</sup>		0.9991

chromatographic conditions and the solubility data of the drugs to select a set of parameter that will give maximum % release of the drug.

### 2.12. Study of change in USP apparatus type

To study the effect of change in USP apparatus, 0.1 N HCL (pH 1.2) was selected as dissolution media. A media volume of 900 mL and thermostatic bath temperature was kept constant and the dissolution was performed on two different USP apparatus. The results were evaluated for cyclobenzaprine. The % drug release for two apparatus

types were calculated.

### 2.13. Change in the volume of dissolution media

The dissolution media used in the above study was kept constant, 0.1 N HCL (pH 1.2) whereas dissolution media volume was varied from 500 mL and 900 mL, performed using USP apparatus type II. The % drug release was calculated.

**Table 8:** Observations and result of recovery for CBZ

SpikeConc. Level (%)	Amt of drug added (mg)	Total Amt. of Drug Estimated (mg)	Amt Recovered	% recovery
80%	4.07	9.066	4.066	99.91
		9.082	4.082	100.29
		9.080	4.080	100.25
		9.921	4.947	99.22
100%	4.96	9.927	4.927	99.35
		9.931	4.931	99.43
		11.273	6.273	100.53
		11.275	6.275	100.57
120%	6.24	11.293	6.293	100.86
Mean				100.04
±SD				0.595
%RSD				0.59

**Table 9:** Results of repeatability precision study

Sample	% Dissolution of CBZ at 15 min
1	100.55
2	99.04
3	99.85
4	100.53
5	99.16
6	99.29
Mean	99.74
%RSD	0.68

**Table 10:** Results of intra-day precision study

Time interval (h)	A.U.C(mV)	% Dissoution
1	590412	100.54
	582496	99.20
2	584712	99.57
	593214	101.02
3	573122	97.60
	571004	97.24
Overall mean		98.83
%RSD		1.25

**Table 11:** Results of inter-day precision study

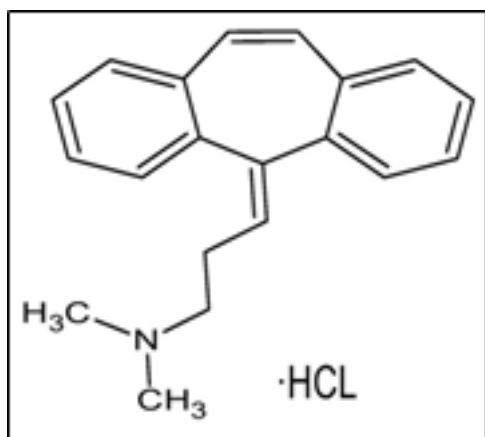
Time interval	A.U.C(mV)	% Dissoution
1 <sup>st</sup> day	574522	97.84
	574414	97.78
2 <sup>nd</sup> day	571026	97.24
	563201	95.91
3 <sup>rd</sup> day	572287	95.75
	561057	95.55
Overall mean		96.41
%RSD		0.95

**Table 12:** Results of ruggedness study

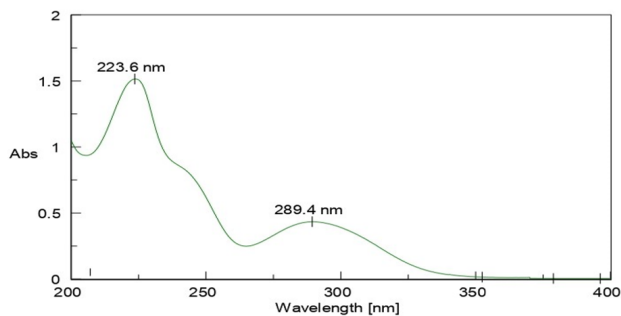
Analysts	% Dissolution	Overall Mean	%RSD
Analyst-I	100.83	100.07	1.08
Analyst-II	99.31		

**Table 13:** Results for robustness study

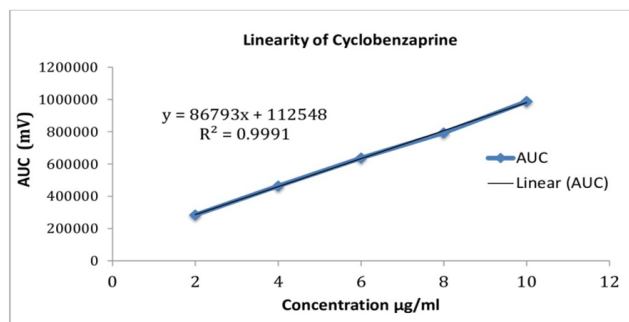
S. No.	Parameters	Retention time	Theoretical Plate	Tailing factor
1	Standard condition	3.458	3452	1.65
2	Flow rate at 0.8mL/min	5.563	3626	1.62
3	Flow rate at 1.2mL/min	2.871	3695	1.61
4	Wavelength at 284.4	3.563	3527	1.61
5	Wavelength at 294.4	3.068	3561	1.61
6	pH at 2.5	3.163	3145	1.63
7	pH at 3.5	3.614	3524	1.63
	Mean			1.621
	±SD			0.015
	%RSD			0.93



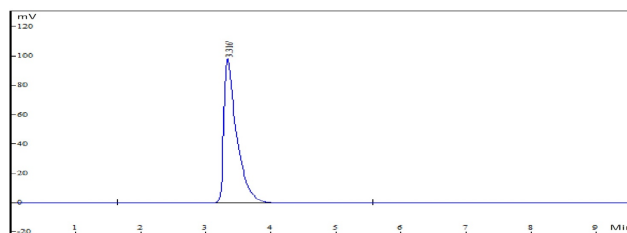
**Fig. 1:** Chemical structure of Cyclobenzaprine HCL



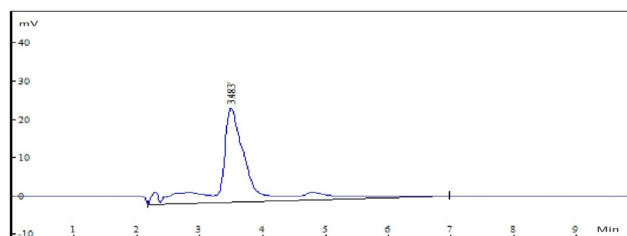
**Fig. 2:** UV spectrum of cyclobenzaprine HCL



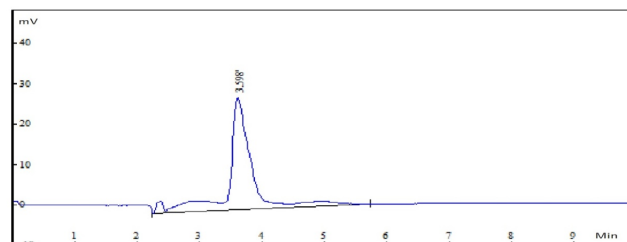
**Fig. 3:** Graph showing linearity of CBZ at different concentration



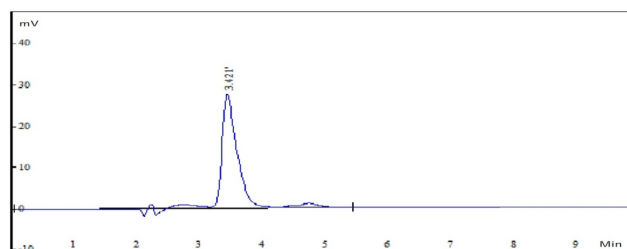
**Fig. 4:** Chromatogram of standard under optimized condition



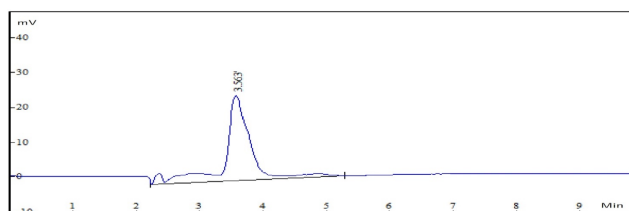
**Fig. 5:** Chromatogram for Test sample at 10 min



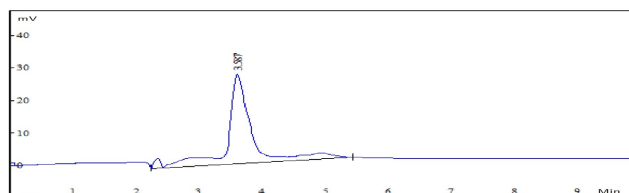
**Fig. 6:** Chromatogram for Test sample at 15 min



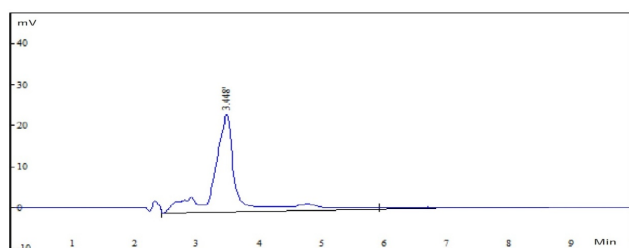
**Fig. 7:** Chromatogram for Test sample at 20 min



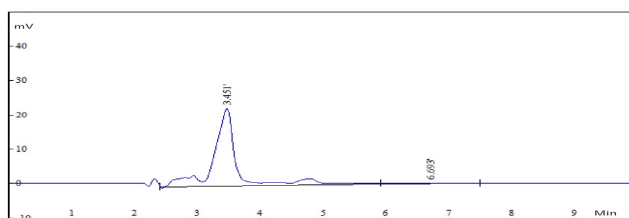
**Fig. 8:** Chromatogram for Test sample at 25 min



**Fig. 9:** Chromatogram for Test sample at 30 min



**Fig. 10:** Chromatogram for Test sample at 45 min



**Fig. 11:** Chromatogram for Test sample at 60 min

#### 2.14. Change in dissolution media (Buffer)

Phosphate buffer (pH 6.8) and 0.1 N HCL (pH 1.2) were used as dissolution media, with a media volume of 900 mL was selected. The % drug release was calculated.

### 3. Method validation

The dissolution test method was validated to through the determination of linearity, precision, accuracy, solution stability. Prior to injecting sample solutions, the column was equilibrated for at least 30 min with the mobile phase flowing through the system.

#### 3.1.

##### 3.1.1. Linearity

The linearity for CBZ with respect to concentration was demonstrated by considering the label claim of the CBZ as 100% target concentration. Linearity was studied by analyzing five standard solutions covering the range of 2-10 $\mu$ g/ml. From the working standard solution (100  $\mu$ g/ml) 0.2ml, 0.4ml, 0.6ml, 0.8ml and 1.0ml of aliquots were pipetted out into a series of 10 mL volumetric flasks and volume made up to the mark with the mobile phase to get concentrations in the range of 2 $\mu$ g/ml-10 $\mu$ g/ml respectively. Calibration curve of peak area versus % target concentration was plotted by injecting the above prepared solutions and calibration curve is shown in Figure 3.

##### 3.1.2. Accuracy

The accuracy of the proposed method was evaluated by spiking method i.e. adding known amount of CBZ standard drug (80%-120%) to that of target dissolution concentration as per the labeled claim of 5 mg CBZ formulation respectively. Accordingly pure drug was added at the selected levels along with 5.0 mg tablet. Dissolution of the drug was performed using optimized dissolution parameters. Aliquots of 1.0 mL were withdrawn and filtered through whattman filter paper and analyzed by chromatographic method at spiked concentration levels of 80%, 100 and 120%, respectively. Each concentration was analyzed in triplicate. The system was allowed to equilibrate for 30 minutes by passing mobile phase through chromatographic column at a flow rate of 1.0 mL/min. After equilibration, triplicate injections of test solution of different concentration having a volume of 20 $\mu$ L were injected. Total amount of drug estimated and recovered was calculated.

##### 3.1.3. Precision

The precision of the method was evaluated by measuring the precision expressed as % RSD. Tablet samples were subjected to dissolution test condition 900 mL of dissolution medium (0.1 N HCL buffer) pre-heated at 37°C $\pm$ 0.5°C, paddle with stirring rate of 50 rpm). The test sample were obtained by performing the dissolution of the drug under analysis using optimized dissolution parameters and were chromatographed by using finalised chromatographic parameters. The study was performed with 3 consecutive studies i.e. Repeatability precision study, Intraday Precision study and Inter-day precision study. The obtained test samples were injected at 1<sup>st</sup> h, 2<sup>nd</sup> h and 3<sup>rd</sup> h. Chromatograms were recorded for Intra-day precision study. Similarly, the same sample solution was injected on 1st, 2nd, and 3rd day for Inter-day precision study. The chromatograms so recorded and result were calculated.

### 3.1.4. Range

Range of the Analytical procedure is the interval between the upper and the lower concentration (amounts) of analyze in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and Linearity.

### 3.1.5. Ruggedness

The ruggedness of an analytical method is the degree of reproducibility of test results obtained by the analysis of the samples under a variety of conditions. The method was studied for ruggedness by analysing sample and standard preparation by two different analyst.

### 3.1.6. Robustness

The robustness of an analytical procedure is a measure of its ability to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage. The robustness of test method was carried out for following parameters:

- a) Change in flow rate, b) Change in pH of mobile phase, c) Change in detection wavelength

## 4. Results and Discussion

### 4.1. HPLC Method development and dissolution method validation

The optimized chromatographic condition mentioned below was kept constant throughout the experimentation and mobile phase was allowed to equilibrate with stationary phase which was indicated by a steady line.

**System:** Analytical HPLC

**Stationary Phase:** Shodex C18-4E (250 x 4.6mm, 5 $\mu$ m)

**Mobile phase:** ACN: Phosphate buffer (pH 3.0) (65:35 % v/v)

**Detection wavelength:** 289.4nm

**Column temperature:** 25°C-30°C

**Flow rate:** 1.0 mL/min

**pH:** 3.0

**Injection volume:** 20  $\mu$ L

**Run time:** 9 min

A 20  $\mu$ L solution of above mix standard was injected through manual injector and chromatogram was recorded. A standard chromatogram for cyclobenzaprine HCl is shown in Figure 4.

### 4.2. Optimization of dissolution method parameters for estimation of cyclobenzaprine

Various dissolutions were performed to optimize the parameters like dissolution media, dissolution media volume, apparatus and rpm, using the optimized chromatographic conditions and the solubility data of the drugs to select a set of parameter that will give

maximum % release of the drug. The chromatograms of dissolution analysis of formulation under study at selected intervals recorded under optimized chromatographic parameters are shown in Figures 5, 6, 7, 8, 9, 10 and 11.

### 4.3. Change in USP apparatus

The result of % release of drug is shown in Table 2. From the table, it was observed that the release of drug in USP I was slow as compared to USP II. Also the release of drug at 50 rpm was found to be optimum as compared to other rpm conditions; therefore USP II and 50 rpm were selected as one of the optimized dissolution parameter and were further used in the experimentation.

### 4.4. Change in the volume of dissolution media

The result of % release of drug is shown in Table 3. From the table, it can be observed that the percent drug release in a media volume using 500 mL was found to be less as compared to a media volume of 900 mL. Hence media volume of 900 mL was selected as one of the optimized dissolution parameter and was further used in the experimentation.

### 4.5. Change in dissolution media (Buffer)

The result of % release of drug is shown in Table 4. From the Table, it was observed that the release rate of the drug obtained was less in Phosphate Buffer (pH 6.8) as compared to 0.1 N HCl at Q point 15 min therefore, 0.1N HCl was selected as optimized dissolution media and further used in the experimentation. The finalized dissolution parameter selected for the dissolution test method of cyclobenzaprine are shown in Table 5 and percent release of drug under final chromatographic and final dissolution parameters are shown in Table 6 for cyclobenzaprine.

### 4.6. Validation parameters

The peak area of linearity solutions noted was plotted against the corresponding concentrations to obtain the calibration graph. The correlation coefficient were found to be 0.9991 and the calibration data is presented in Table 7. The proposed method gives linear results with wide range of concentration of drug.

The results of accuracy data at different spike level are shown in Table 8. From the accuracy studies the mean % recovery of drugs at each accuracy level was found to be 100.04%, Which is found to be in the acceptance range of 95%-105%. It was proved that method is accurate.

The Precision of the dissolution study carried out as repeatability, intra-day and inter-day variations. The % release was found to be in acceptance level and % RSD of drugs from repeatability study was found to be 1.68, the % RSD for Intra-day study was found to be 1.25 and the %



RSD for Inter-day study was found to be 0.95 respectively ascertaining the precision of method. The observation and the result of precision study for drug is summarized in the Tables 9, 10 and 11.

The observation and the result of ruggedness study for drug is summarized in the Table 12. Ruggedness of the method is evaluated by analysis of aliquots from homogenous slot by two different analyst. The RSD between two different analysts should not be more than 2.0%. The proposed method was found to be rugged.

The robustness of the method was evaluated by injection of the sample at deliberately varying the chromatographic conditions i.e change in flow rate by 0.2mL/min, change in wavelength and pH by  $\pm 5$ . The method was found to be robust. The results obtained by robustness study are given in Table 13.

## 5. Conclusion

The results obtained by RP-HPLC method for dissolution test of tablet formulation containing cyclobenzaprine HCL are reliable, precise and accurate. Hence, it can be routinely adopted as a quality control test for dissolution analysis of cyclobenzaprine HCL in its formulation.

## 6. Source of Funding

None.

## 7. Conflict of Interest

The authors declare no conflict of interest.

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