IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Hptlc Determination Of Terazosin In Tablet Formulation

Omkar Shripatrao Ghatge[1], Anil. A. Danane, Sanjana S. Chavan.

B pharm, Asst. Professor, B pharm

Appasaheb Birnale collage of Pharmacy, Sangli

Abstract

The calibration curve, constructed at a wavelength of 250 nm, exhibited a linear relationship for Terazosin Hydrochloride Dihydrate concentrations ranging from 50 to 150 g/ml. Terazosin Hydrochloride Dihydrate's limit of detection (LOD) and limit of quantitation (LOQ) were determined to be 0.3983 g/ml and 1.207 g/ml, respectively. These numbers show the analytical method's sensitivity.The proposed chromatographic technique for determining Terazosin Hydrochloride Dihydrate has been shown to be accurate, exact, and efficient. The suggested chromatographic approach was validated in terms of linearity, accuracy, and precision. The percentage of Relative Standard Deviation (% RSD) for all parameters was determined to be less than two, showing that the newly established procedure has been verified and the findings produced using this approach are accurate.

Keyword- Method development, Method validation, Accuracy, Linearity, Method precision, Terazosin Hydrochloride Dihydrate.

Introduction

HPTLC is the High-Performance version of Thin Layer Chromatography and a state-of-the art technique for plant analysis. It features significantly shorter developing times, lower solvent consumptions and improved resolution. Highly reproducible results and traceable records are achieved through a standardized methodology and the use of suitable instruments (typically controlled by software) for all steps of the analysis. A system suitability test is used to qualify results.

	HPTLC	TLC
Sorbent Layer	100µm	250µm
Efficiency	High because low particle size generated	Low
Separation	3-5 cm	10-15 cm
Time for analysis	shorter migration distance and significantly faster analysis	Slow
Solid support	Numerous stationary phases are available, like Silica gel, C8 or C18.	Silica gel, Aluminium and Kiesulguhr
Chamber Development	New varieties that need less mobile phase	More amount
Spotting of sample	Automatic	Manual

There are several steps in HPTLC.

1. Choosing HPTLC plates and sorbent

2. Cleaning the sample if necessary and pre-chromatographic derivatization are all parts of sample preparation.

3. Utilizing the example

4. Growth on the chopping block (separation)

5. Spot detection, such as post-chromatographic derivatization

6. Quantitation

Terazosin is an alpha-1 adrenergic antagonist used in the treatment of symptomatic benign prostatic hyperplasia and management of hypertension. Terazosin is a quinazoline derivative alpha-1-selective adrenergic blocking agent indicated for benign prostatic hyperplasia and hypertensionLabel1. Terazosin blocks adrenaline's action on alpha-1 adrenergic receptors, causing relaxation of smooth muscle in blood vessels and the prostate2.

Terazosin is selective for alpha-1-adrenoceptors but not their individual subtypes3,4. Inhibition of these alpha-1-adrenoceptors results in relaxation of smooth muscle in blood vessels and the prostate, lowering blood pressure and improving urinary flow1,2,3,4. Smooth muscle cells accounts for roughly 40% of the volume of the prostate and so their relaxation reduces pressure on the urethra2.

It has also been shown that catecholamines induce factors responsible for mitogenesis and alpha-1-adrenergic receptor blockers inhibit this effect2.

A final long term mechanism of terazosin and other alpha-1-adrenergic receptor blockers is the induction of apoptosis of prostate cells2. Treatment with terazosin enhances the expression of transforming growth factor beta-1 (TGF-beta1), which upregulates p27kip1, and the caspase cascade2,5.

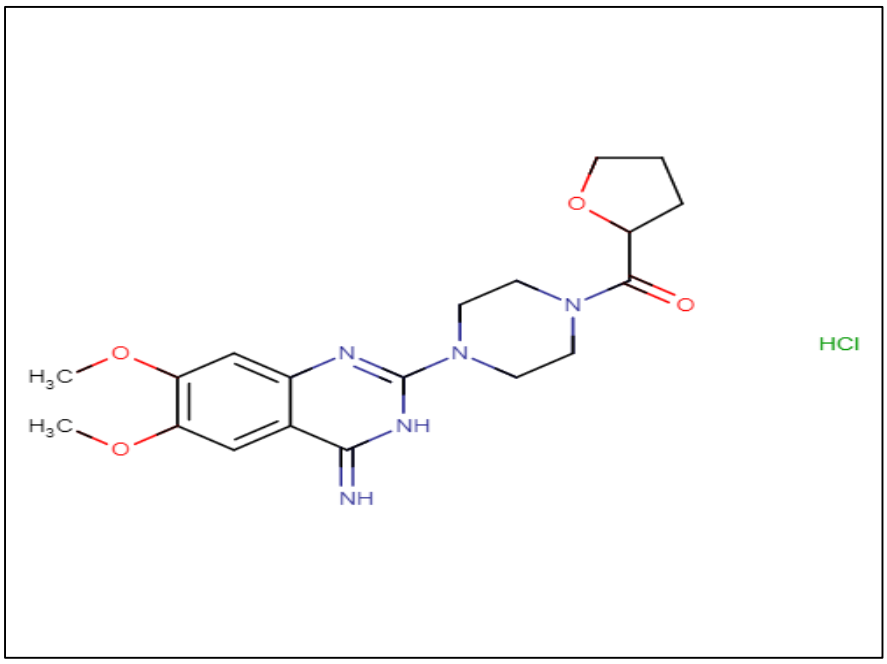


Figure 1. Chemical structure of terazosin

2.0 Material and Method

Terazosin was provided by CTX Lifesciences , Gujrat and all the solvents provided by Appasaheb Birnale College of Pharmacy , Sangli & Central Pharma,Sangli and used such.

The samples were spotted in the form of bands of width 6mm with syringe on Merck, HPTLC Silica gel 60 F_{254} Plates Which are 200mm x 100mm with 250µm thickness Both test and standard samples (5µL each) were applied onto the HPTLC plate by spray-on technique along with nitrogen gas supply for simultaneous drying of bands.Wavelength selected was 250nm.

2.1 Preparation of Standard Stock Solution

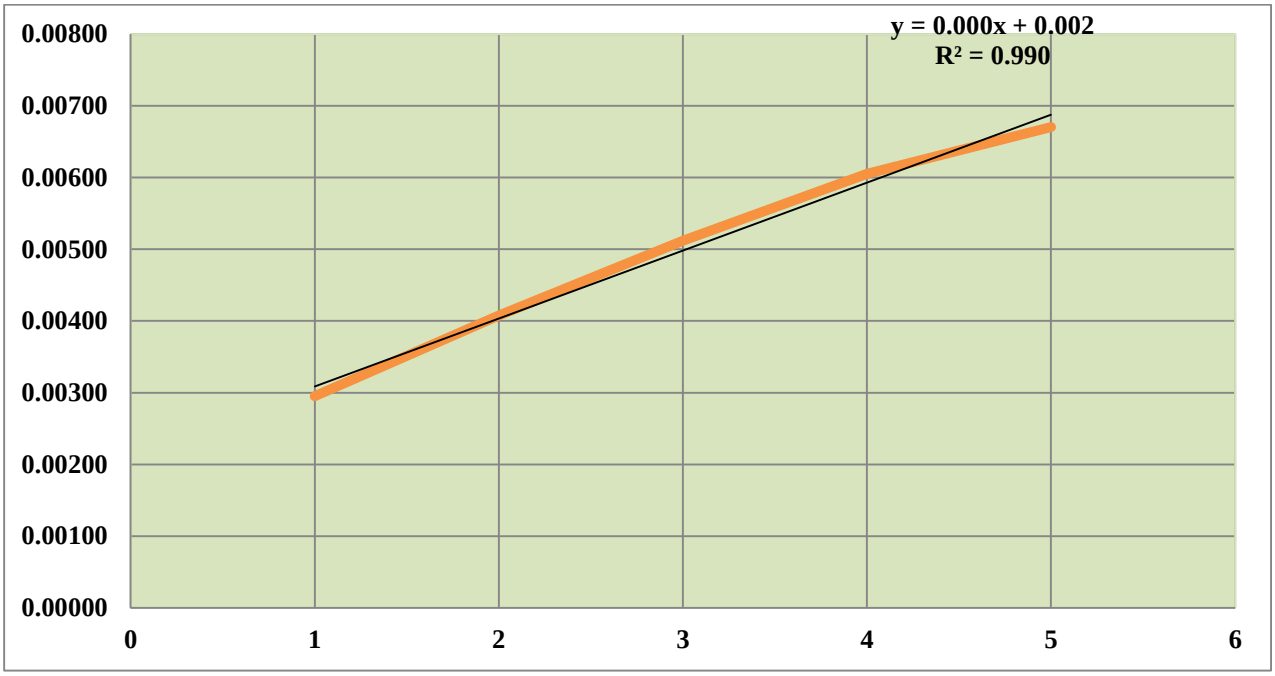
5mg of Drug API in 5 mL of wat er sonicate for 5min and final volume makeup to 10mL with methanol. and t he taken 1.0mL of Stock solution and make up final volume up to 10mL (1 : 1 / Methanol : Water).,(Final Conc Of Standard = 50PPM)

2.2 Preparation of Sample Solution

5 Tab in 5mL water sonicate for 5 min and volume makeup to 10mL with methanol and then taken 1.0 mL of above solution and make up final volume up to 10mL (1 : 1 / Met hanol : Water)(Final Conc Of Sample = 50PPM)

2.3 Preparation of Calibration Curve

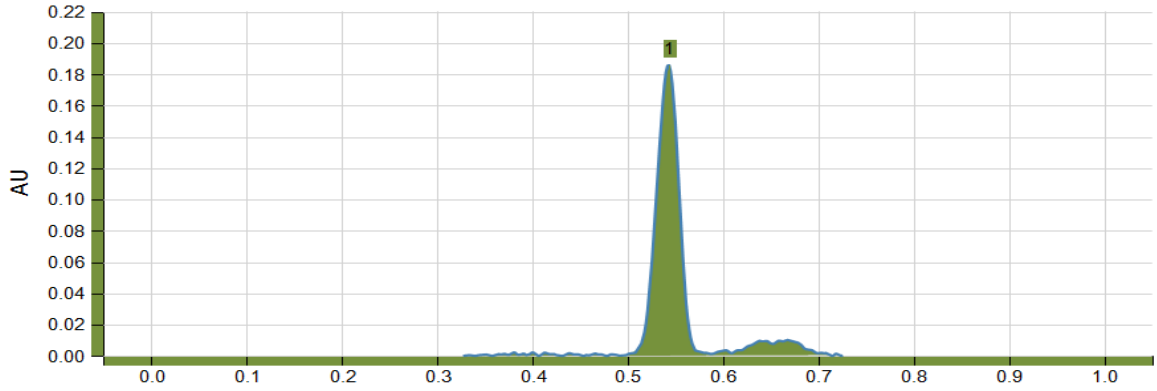
The adequate solution from stock solution diluted to obtain concentration of 100-2500 µg/ml. The solution of (20µl) was spotted into plate with the help of syringe.Measurements repeated thrice and calibration curves of Concentration Vs Area under curve and recorded.



3. Results and Discussion

3.1 Optimization of mobile phase

Optimization of mobile phase was carried out by changing proportions of methanol, toluene and chloroform. It was observed that composition used Chloroform:Toluene:MeOH (5:3:2) gave sharp peak at Rf ≈ 8. Chromatogram of optimized chromatographic condition is given under Figure

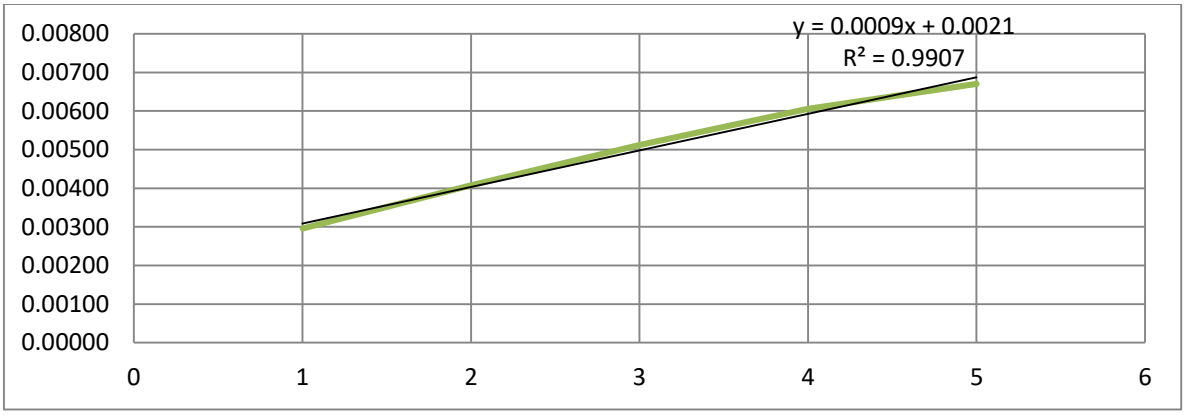


3.2. Validation

3.2.1. Linearity

Correlation coefficient of 0.999 shows perfect linearity. By observing calibration curve this is clear that all of the points are closed to regression line also proves linearity of the method.

Level	Standard Area of Terazosin HCL	Mean Standard Area of Terazosin HCL
50% level	0.00297	0.00295
	0.00293	
	0.00296	
75% level	0.00406	0.00408
	0.00407	
	0.00410	
100% level	0.00512	0.00512
	0.00514	
	0.00510	
125% level	0.00600	0.00605
	0.00607	
	0.00609	
150% level	0.00667	0.00670
	0.00670	
	0.00674	



3.2.2. Precision

Repeatability was assessed by running six times 500µg/ml solution at a time.

Sr No.	Sample Area of Terazosin HCL STD	Assay of Terazosin HCL STD
1	0.00428	101.52
2	0.00424	100.57
3	0.00425	100.81
4	0.00428	101.52
5	0.00426	101.04
6	0.00427	101.28
Mean	0.00426	101.12
SD	0.00002	0.39
% RSD	**0.38**	**0.38**

Repeatability RSD was found to be 0.38. Values (RSD) found was less than 1, shows method is precise in nature.

3.2.3. Accuracy

Accuracy studies were performed on Hytrin tablets. Results are presented under Table

Sr. No.	Spike level	Ammount added (mg) of Terazosin HCL STD	Area of Terazosin HCL STD in Sample	Mean Area of Terazosin HCL STD in Sample	Ammount Found (mg) of Terazosin HCL STD in Sample	% Recovery of Terazosin HCL STD in Sample	Mean % Recovery of Terazosin HCL STD in Sample	RSD %
1	100 % Base Level	0	0.00509	0.0051	0.00	100.07	99.54	1.27
2	100 % Base Level		0.00511			100.46		
3	100 % Base Level		0.00499			98.10		
4	10% Spike	0.5	0.00552	0.0055	0.542	108.52	108.32	0.18
5	10% Spike		0.00550			108.13		
6	10% Spike		0.00551			108.32		
7	20% Spike	1	0.00605	0.0061	1.191	118.94	119.13	0.17
8	20% Spike		0.00607			119.33		
9	20% Spike		0.00606			119.13		
10	30% Spike	1.5	0.00653	0.0066	1.933	128.37	128.83	0.49
11	30% Spike		0.00654			128.57		
12	30% Spike		0.00659			129.55		

Percentage recovery found was between 108.32-128.83% (as per increment in concentration) proves method to be accurate.

3.2.4. Robustness

Robustness studies were performed under different conditions as presented in below tables.

a) Chamber Saturation = + 5 min (30 min)

Sr No.	Standard Area of Terazosin HCL STD	Rf of Terazosin HCL STD
1	0.00531	0.497
2	0.00529	0.479
3	0.00529	0.492
4	0.00508	0.503
5	0.00517	0.497
Mean	0.00523	0.494
SD	0.00010	0.009
% RSD	**1.91**	**1.83**

b) Chamber Saturation = - 5 min (25min)

Sr No.	Standard Area of Terazosin HCL STD	Rf of Terazosin HCL STD
1	0.00501	0.515
2	0.00509	0.529
3	0.00505	0.516
4	0.00517	0.513
5	0.00520	0.511
Mean	0.00510	0.517
SD	0.00008	0.007
% RSD	**1.56**	**1.37**

c) Mobile Phase Composition = + 10% (Chloroform : Toluene : Methanol / 4.8 : 3.0 : 2.2 v/v/v)

Sr No.	Standard Area of Terazosin HCL STD	Rf of Terazosin HCL STD
1	0.00420	0.542
2	0.00416	0.547
3	0.00420	0.542
4	0.00434	0.550
5	0.00430	0.540
Mean	0.00424	0.544
SD	0.00008	0.004
% RSD	**1.80**	**0.76**

d) Mobile Phase Composition = - 10% (Chloroform : Toluene : Methanol / 5.2 : 3.0 : 1.8 v/v/v)

Sr No.	Standard Area of Terazosin HCL STD	Rf of Terazosin HCL STD
1	0.00525	0.426
2	0.00542	0.427
3	0.00546	0.418
4	0.00545	0.424
5	0.00548	0.424
Mean	0.00541	0.424
SD	0.00009	0.003
% RSD	**1.72**	**0.82**

4. Conclusion

HPTLC is one of the mostly used methods for analysis in pharmaceutical industries, clinical chemistry, forensic chemistry, biochemistry, cosmetology, food and drug analysis, environmental analysis and other areas. This has been attributed to its multiple advantages such as it being the only chromatographic method that offers presentation results as an image. Thus simple and economical HPTLC method development was attempted here.

Method was optimized by using mobile phase chloroform:Toluene:MeOH in ratio 5:3:2.
Linearity was assessed by analyzing correlation coefficient, visualizing calibration curve
The proposed method can be used for the determination of terazosin in pharmaceutical preparations even in the presence of potential degradants due to environmental conditions.