

**A REVIEW ARTICLE ON LITERATURE REVIEW OF CHROMATOGRAPHIC, SPECTROPHOTOMETRIC AND OTHER METHODS FOR QUANTITATIVE ESTIMATION OF TERAZOSIN HYDROCHLORIDE AND TOLTERODINE TARTRATE IN PURE AND COMBINATION WITH OTHER DRUGS.****\*Pragati J. Vanavi, J. S. Shah<sup>1</sup> and D. G. Maheshwari<sup>2</sup>**\*M. Pharm (QA), <sup>1</sup>Associate Professor, <sup>2</sup>Associate Professor (HOD).<sup>1,2</sup>Department of Quality Assurance, L. J. Institute of Pharmacy, Ahmedabad-380021, India.**\*Corresponding Author: Dr. J. S. Shah**

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**ABSTRACT**

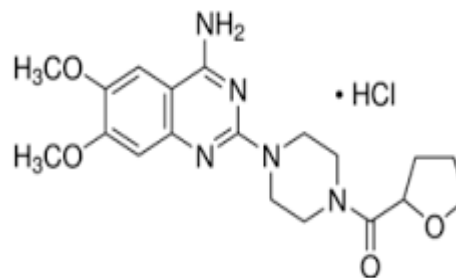
Vanavi, Shah and Maheshwari: Review literature of Terazosin Hydrochloride and Tolterodine Tartrate This Article enlightens area in which the works already have been done for Terazosin Hydrochloride, a selective  $\alpha_1$  receptor antagonist and Tolterodine Tartrate, antimuscarinic drug. Terazosin have effective approach towards symptoms and conditions of benign prostatic hyperplasia, for quantitative determination of Terazosin, Spectroscopic methods (UV, Visible) Chromatographic method (HPLC, HPTLC) and other methods (LC/MS/MS) were performed and successfully quantified. Similarly Tolterodine have effective approach for symptoms of benign prostatic hyperplasia such as urinary urgency.

**KEYWORDS:** Terazosin Hydrochloride, Tolterodine Tartrate, Literature Review, Analytical methods, Spectrophotometric method, Chromatographic methods, HPLC.

**INTRODUCTION**

Terazosin belongs to selective alpha –antagonist with Mol.mass:459.92g/mol, It is effectively works in treatment of symptoms of benign prostatic hyperplasia. It can be indicated for patient with hypertension and prostate enlargement because it lowers blood pressure. It blocks the action of adrenaline on smooth muscle of the bladder and the blood vessel walls. Alpha 1 Receptors leads contraction and hypertrophic growth of smooth muscle cells. It Works by Alpha1 receptors are coupled with G proteins. Three alpha 1 receptors subtype have been identified: they are alpha 1 A, alpha 1 B, alpha 1 D. Terazosin is first to show selectivity for alpha 1 A receptor. All alpha receptors maintain vascular tone. The  $\alpha_{1A}$ -receptor manages basal vascular tone; the  $\alpha_{1B}$ -receptor mediates the vasoconstrictory effects of exogenous  $\alpha_1$ -agonists. Activation of  $\alpha_1$ -receptors activates  $G_q$ -proteins, which results in intracellular stimulation of phospholipases C,  $A_2$ , and D. This results in mobilization of  $Ca^{2+}$  from intracellular stores, activation of mitogen-activated kinase and  $PI_3$  kinase pathways and subsequent vasoconstriction. Pharmacological effect of Terazosin is inhibition of  $\alpha_1A$  receptor activation. Thus it will produce vasculature and

prostate muscle relaxation, decreased blood pressure and improved urinary outflow in symptomatic benign prostatic hyperplasia.

**LITERATURE REVIEW OF TERAZOSIN HYDROCHLORIDE.**

**Figure: 1 Chemical Structure of Terazosin Hydrochloride.**

**1.1 Official methods for estimation of Terazosin Hydrochloride**

Terazosin hydrochloride is official in United State pharmacopoeia (USP29 NF24, 2005) and Indian Pharmacopoeia-2014.

**TABLE 1.1: OFFICIAL METHODS FOR ESTIMATION OF TERAZOSIN<sup>(1-2)</sup>**

Sr. No.	DRUG	METHOD	DESCRIPTION	Ref. No.
1	Terazosin Hydrochloride (USP29)	Liquid chromatography	<b>Detection Wavelength:</b> 254nm <b>Mobile Phase:</b> Citrate Buffer: Acetonitrile ( 1685:315 v/v) <b>Stationary Phase:</b> Stainless Steel Column 4.6×25mm packed to porous silica <b>Flow Rate:</b> 1.0 ml/min	[1]
2	Terazosin hydrochloride (IP 2014)	Potentiometric method	<b>Titrate:</b> 0.3 gm of mixture+ 5ml of 0.01MHCl+50ml methanol <b>Titrate with :</b> 0.1 M NAOH	[2]

**1.2 Reported methods for estimation of Terazosin Hydrochloride****TABLE 1.2 REPORTED SPECTROPHOTOMETRIC METHOD<sup>[3-12]</sup>**

Sr. No.	DRUG	METHOD	DESCRIPTION	Ref. No.
1	Terazosin Hydrochloride in Bulk and formulation.	Spectrometric Method	<b>Wavelength:</b> 250 nm <b>Solvent:</b> Methanol <b>Linearity Range:</b> 2-14 µg/ml <b>Correlation Coefficient (R<sup>2</sup>):</b> <b>LOD:</b> 1.5971 <b>LOQ:</b> 15.97137	[3]
2	Terazosin Tablet	Diazotization with 1% sodium nitrite and HCL followed by coupling with β naphthol in 4% NAOH	<b>Wavelength :</b> 560nm <b>Linear Range:</b> 1-10µg/ml <b>LOD-</b> - <b>LOQ-1</b> µG/ml	[6]
3	Terazosin Tablet	Fluorimetric: Dilution in methanolic 0.1N H <sub>2</sub> SO <sub>4</sub>	<b>Wavelength:</b> 246 and 382 nm <b>Linearity Range:</b> 25-150ng/ml <b>LOD:</b> - <b>LOQ:</b> 25ng/ml	[7]
4	Terazosin in Urine and Plasma	Fluorimetric: pre-concentrating Terazosin by microextraction solvent	<b>Detection Wavelength:</b> 376 and 330 nm <b>Linearity Range:</b> 0.1-115µg/L <b>LOD:</b> 0.027µg/ml <b>LOQ:</b> -	[8]
5	Terazosin and Bovine serum albumin interactions.	Spectrofluorimetric.	<b>Wavelength:</b> 280/413 nm <b>Linearity Range:</b> 0-9×10 <sup>-6</sup> /mol <b>LOD:</b> 0.21mg/l <b>LOQ:</b> -	[9]
6	Terazosin Tablet Terazosin Tablets and urine samples.	Spectrofluorimetric Slit width 1.5nm slit width 5nm	<b>Wavelength:</b> ex -332 and em-382 nm <b>Linearity Range:</b> 1×10 <sup>-5</sup> to 7 µg/ml <b>LOD:</b> 3.04×10 <sup>-4</sup> µg/ml <b>LOQ:</b> 1×10 <sup>-3</sup> µg/ml <b>LOD:</b> 1.11×10 <sup>-5</sup> µg/ml <b>LOQ:</b> 3.7×10 <sup>-5</sup> µg/ml	[10]
7	Terazosin Determination in presence of degradation product.	A. First and second derivative spectra study. B. Reaction with cloranyl. C. Reaction of drug with mercurochrome D. iron-pair salt of drug and bromocresol purple. E. Fluorimetric.	<b>a. Wavelength:</b> 340 and 345 nm <b>Linearity Range:</b> 4-18µg/ml <b>b. Wavelength:</b> 340 nm <b>Linearity Range:</b> 24-45µg/ml <b>c. Wavelength:</b> 543 nm <b>Linearity Range:</b> 4-12µg/ml <b>d. Wavelength:</b> 412nm <b>Linearity Range:</b> 4-20µg/ml <b>e. Wavelength:</b> λ <sub>ex</sub> 390/ λ <sub>em</sub> 382nm <b>Linearity Range:</b> 0.025-0.1µg/ml	[11]
8	Terazosin pure and tablet.	Ion pair complex	<b>Detection Wavelength:</b> 419,415,425,428 nm <b>Linearity Range:</b> 2-14, 1-12,1-10,5-130µg/ml	[12]
9	Terazosin hydrochloride in drug substance	Potentiometric and Fluorimetric method	<b>Potentiometric method</b> <b>Electrodes:</b> 2 Carbon paste ion selective <b>Titration:</b> Phosphomolybdic acid and	[5]

and tablet formulation		Phosphotungestic acid. <b>Response:</b> In Conc. Range of $1 \times 10^{-6}$ - $1 \times 10^{-2}$ mol L <sup>-1</sup> , $2 \times 10^{-6}$ - $1 \times 10^{-2}$ mol L <sup>-1</sup> <b>Slope:</b> 58.4±0.35(By PMA), 57.3±0.23 mV Decade <sup>-1</sup> (By PTA) <b>pH Range:</b> 2-6 <b>Low detection limit:</b> $8 \times 10^{-7}$ , $6 \times 10^{-7}$ mol L <sup>-1</sup> <b>Fluorimetric method</b> <b>Method 1</b> <b>Measurement of native fluorescence</b> <b>Conc. Range:</b> 10-1000ng mol <sup>-1</sup> <b>correlation coefficient:</b> r <sup>2</sup> -0.9982 <b>LOD:</b> 3.87ng/ml <b>LOQ:</b> 10.5ng/ml <b>Method 2</b> <b>By binary complex formation</b> <b>Conc. Range:</b> 0.5-12ng/ml <b>correlation coefficient:</b> r <sup>2</sup> -0.9987 <b>LOD:</b> 0.198ng/ml <b>LOQ:</b> 0.6ng/ml	
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### 1.3 Summary of chromatographic method

Table 1.3 SUMMARY OF CHROMATOGRAPHIC METHOD [4,13-17]

Sr NO.	Drug	Method	Description	Ref. No
1	Terazosin Tablet	Stability indicating HPTLC	<b>Stationary Phase:</b> Silica gel precoated aluminum plate <b>Mobile Phase:</b> Chloroform:Toluene:Methanol(9:1:6) <b>Detection:</b> 254nm <b>Linear Range:</b> 50-2500µg/ml <b>LOD:</b> 18.06µg/ml <b>LOQ:</b> 54.72µg/ml	[4]
2	Simultaneous determination with Prazosin, Alfuzosin and Doxazosin	HPTLC	<b>Stationary Phase:</b> Silica Gel Precoated Aluminum Plate. <b>Mobile Phase:</b> Chloroform:Methanol(9.5:0.5) <b>Detection:</b> 254nm <b>Linearity Range:</b> 0.8-1.2mg/ml <b>LOD:</b> 0.013mg/ml <b>LOQ:</b> 0.041mg/ml	[13]
3	Pharmacokinetic study	HPLC with fluorescence	<b>Stationary phase:</b> Column packed with Spherical Silica gel particles Chemically bonded with Octadecyl group <b>Mobile Phase:</b> 0.01M disodium hydrogen phosphate:acetonitrile:tetrahydrofuran(76:22:2 v/v) <b>Fluorescence Detection:</b> $\lambda_{ex}$ 250nm $\lambda_{em}$ 370nm <b>Linearity Range:</b> 0.25-100ng/ml <b>LOQ:</b> 0.25ng/ml	[14]
4	Enantioselective Determination	HPLC with fluorescence	<b>Stationary Phase:</b> Chiral stationary phase chiralpak AD 100 <b>Mobile Phase:</b> Hexane+2-Propranolol(0.05%):Diethyl Amine 0.9% (65:35) <b>Detection :</b> $\lambda_{ex}$ 238nm $\lambda_{em}$ 370nm <b>Linearity Range:</b> -	[15]
5	Terazosin Tablet	HPLC with fluorescence	<b>Stationary Phase:</b> Shimpak column VP-ODS <b>Mobile Phase:</b> disodium hydrogen phosphate:acetonitrile:tetrahydrofuran(76:22:2)v/v <b>Detection :</b> $\lambda_{ex}$ 250nm $\lambda_{em}$ 370nm <b>Linearity Range:</b> 20,180,320 ng/ml <b>LOD :</b> 0.1308ng/ml	[16]

6	Pharmacokinetic studies of Terazosin	HPLC-UV	<b>Stationary Phase:</b> RP C18 column <b>Mobile Phase:</b> Acetonitrile: THF: potassium dihydrogen phosphate(15:5:80) <b>Detection:</b> 254nm <b>Linearity Range:</b> 10-400ng/ml <b>LOQ:</b> 10ng/ml	[17]
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#### 1.4 Reported literature of Terazosin in combination with other drugs

Table 1.4 REPORTED LITERATURE OF TERAZOSIN IN COMBINATION WITH OTHER DRUGS.<sup>[18-20]</sup>

Sr No	Drug	Method	Description	Ref no
1	Terazosin+ Prazosin+ Doxazosin in Formulation	HPLC-UV	<b>Stationary Phase:</b> Kromacil c18 Column <b>Mobile Phase:</b> ACNdiethyle amine: Methanol: Ammonium acetate(60:20:20:0) <b>Linearity Range:</b> 2-500µg/ml <b>LOD:</b> 0.065 µg/ml <b>LOQ:</b> 0.197 µg/ml	[18]
2	Terazosin+ Alfuzosin +Prazosin+ Doxazosin+ Tamsulosin Formulation	HPLC-UV	<b>Stationary Phase:</b> c18 column <b>Mobile Phase:</b> ACNdiethylamine: Methanol: ammonium acetate: water <b>λ:</b> 230nm <b>Linearity Range:</b> 4-16 µg/ml <b>LOD:</b> 0.08 µg/ml <b>LOQ:</b> 0.264 µg/ml	[19]
3	Terazosin+ Prazosin in Formulation	HPLC-UV	<b>Stationary Phase:</b> Kromacil C18 Column <b>Mobile Phase:</b> Methanol <b>Flow Rate:</b> 1.1 ml/min <b>Linearity Range:</b> 10-60 µg/ml <b>LOD:</b> 0.514 µg/ml <b>LOQ:</b> 1.557 µg/ml	[20]

## 2. REVIEW LITERATURE OF TOLTERODINE TARTRATE.

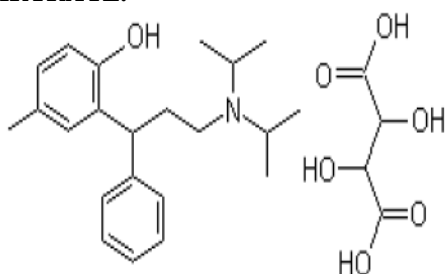


Fig 2.1: Chemical structure of Tolterodine tartrate.

Tolterodine is an antimuscarinic which is used to treat overactive bladder and to relieve urinary difficulties like frequent urination and inability to control urination. The chemical name of Tolterodine tartrate is (+)-(R)-2-[1-[2[(Diisopropylamino) ethyl] benzyl]-p-cresol L-tartrate (1:1) salt. It Works by at postganglionic muscarinic receptor, Tolterodine tartrate produce competitive antagonist effect for acetylcholine. Cholinergic muscarinic receptors are responsible for Urinary bladder contraction and salivation.

### 2.1 Official Method

TABLE 2.1: OFFICIAL METHODS OF TOLTERODINE TARTRATE<sup>[2]</sup>

Sr. No	Drug	Method	Description	Ref. No
1	Tolterodine Tartrate	Liquid Chromatography	<b>Stationary Phase:</b> Stainless still 25×4.6mm packed with octadecylsilane bonded with porous silica 5µm <b>Mobile Phase:</b> A.0.05M Potassium Dihydrogen orthophosphate pH 3.5 with Ortho phosphoric acid <b>B.</b> Acetonitrile Initial (65:35) <b>Method:</b> Gradient <b>Detection:</b> 215nm	[2]

## 2.2 Reported Chromatographic methods

TABLE 2.2 REPORTED CHROMATOGRAPHIC METHODS<sup>[21-33]</sup>

Sr No	Drug	Method	Description	Ref No
1	Tolterodine in bulk drug and Pharmaceutical dosage form	RP-HPLC	<b>Stationary Phase:</b> Hypersil c18 column <b>Mobile Phase:</b> Acetonitrile:10mM Ammonium acetate(80:20v/v) <b>Detection:</b> 283nm <b>Linearity Range:</b> 20-100µg/ml <b>Mean Recovery:</b> 99.39%	[21]
2	Tolterodine in Pharmaceutical dosage form	RP-HPLC	<b>Stationary Phase:</b> Hypersil BDS C18 Column. <b>Mobile Phase:</b> Potassium Phosphate pH 4.5:Acetonitrile(Mixed by low pressure gradient program) <b>Detection:</b> 205nm <b>Linearity Range:</b> 10-60 µg/ml <b>LOD:</b> 0.6 µg/ml <b>LOQ:</b> 10 µg/ml <b>Tailing Factor:</b> 1.00	[22]
3	Tolterodine Stability indicating Determination in Pharmaceutical dosage form	RP-HPLC	<b>Stationary Phase:</b> Reversed Phase C18 column. <b>Mobile Phase:</b> Buffer solution of ammonium dihydrogen phosphate: methanol (40:60) <b>Detection:</b> 220nm <b>Flow rate:</b> 1.5 mL/min. <b>Linearity Range:</b> 200.60-601.80 µg/ml <b>Retention time:</b> 6.49 min.	[23]
4	Tolterodine Tartrate in bulk and in Pharmaceutical dosage formulation.	RP-HPLC	<b>Stationary Phase:</b> Kromacil Symmetry C18 column. <b>Mobile Phase:</b> Phosphate buffer pH 3.0: Acetonitrile. <b>Detection:</b> 282nm <b>Flow Rate:</b> 0.8ml/min <b>Linearity Range:</b> 20-100 µg/ml <b>% Recovery:</b> 98.1%-100.2% <b>LOD:</b> 0.108 µg/ml <b>LOQ:</b> 0.36 µg/ml	[24]
5	Tolterodine Tartrate in Capsule formation.	RP-HPLC	<b>Stationary Phase:</b> Reversed Phase C18 column. <b>Mobile Phase:</b> Methanol: phosphate buffer(40:60)v/v <b>Detection:</b> 220nm <b>Retention time:</b> 10 min.	[26]
6	Tolterodine tartrate in Tablet formulation.	HPLC	<b>Stationary Phase:</b> Kromacil C18 column. <b>Mobile Phase:</b> Acetonitrile:Methanol:Ammoniumacetatre pH3 (30:30:40) <b>Detection:</b> 281 nm <b>Retention time:</b> 4.99 min. <b>Mean % Recovery:</b> 102.65% <b>Linearity Range:</b> 10-30 µg/ml	[27]
8	Tolterodine Tartrate stability indicating assay and impurities profiling.	RP-HPLC	<b>Stationary Phase:</b> C18 column <b>Mobile Phase:</b> Water: Acetonitrile <b>Detection:</b> 285 nm <b>Retention time:</b> 4.7 min	[25]
9	Tolterodine Tartrate	HPTLC	<b>Stationary Phase:</b> Aluminum plate precoated with silica gel G 60 <b>Mobile Phase:</b> Acetonitrile:Water:Formic acid(50:50:3) <b>Detection:</b> Densitometric absorbance mode at 281nm <b>Drug Found:</b> 99.1% <b>Linearity Range:</b> 10-30 µg/ml <b>LOD:</b> 21ng <b>LOQ:</b> 53ng	[28]
10	Tolterodine tartrate in tablet	HPLC	<b>Stationary Phase:</b> - <b>Mobile Phase:</b> Phosphate acetate 0.1M pH 2.5:acetonitrile: (50:50 v/v)	[29]

			<b>Flow rate:</b> 1.2 ml/min <b>Detection:</b> 285 nm <b>LOD:</b> 5µg/ml <b>LOQ:</b> 10 µg/ml <b>Linearity Range:</b> 10-100 µg/ml	
11	Tolterodine Tartrate Stability indicating and assay method.	HPLC	<b>Stationary Phase:</b> Water X-Teraa MS C18 column. <b>Mobile Phase:</b> 0.05% TFA+ water: 0.05%+ Acetonitrile(Binary Gradient mode) <b>Detection:</b> 220nm <b>LOD:</b> 66ng/ml <b>LOQ:</b> 200ng/ml	[30]
12	Simultaneous estimation of Tolterodine and Tamsulosin in bulk and pharmaceutical dosage form.	RP-HPLC	<b>Stationary Phase:</b> Hypersil BDS <b>Mobile Phase:</b> Phosphate Buffer: Acetonitrile (65:35v/v) <b>Flow rate:</b> 1 ml/min <b>Detection:</b> 220nm <b>Retention time:</b> Tamsulosin: 2.285min Tolterodine: 4.334min <b>Linearity range:</b> Tamsulosin: 1-6 µg/ml Tolterodine 10-60 µg/ml	[31]
13	Simultaneous estimation of Tolterodine tartrate and Tamsulosin HCL assay method from combination capsule form.	HPTLC	<b>Stationary Phase:</b> Silica gel 60F254 <b>Mobile Phase:</b> methanol: ethyl acetate : triethylamine (5;5;0.3 v/v/v) <b>LOD:</b> Tamsulosin 13.26 ng/band Tolterodine 22.44ng/ml <b>LOQ:</b> Tamsulosin 44.34 ng/band Tolterodine 74.85 ng/band <b>Detection:</b> Densitometric signal at 220 nm	[32]
14	Simultaneous determination of Tartaric acid and Tolterodine in Tolterodine Tartrate.	HPLC	<b>Stationary Phase:</b> Acclaim Trinity P1 <b>Mobile Phase:</b> A: 5% 0.2 M NH <sub>4</sub> OAc, pH 4/ 52% water/ 43% CH <sub>3</sub> CN B: 80% 0.2 M NH <sub>4</sub> OAc ,pH 4/ 20% CH <sub>3</sub> CN <b>Flow rate:</b> 0.8 mL/min <b>Detection:</b> Corona <i>ultra</i> Charged Aerosol Detector	[33]

### 2.3 Summary of literature of spectrophotometric method for Tolterodine tartrate

TABLE 2.3 SUMMARY OF LITERATURE OF SPECTROSCOPIC METHOD FOR TOLTERODINE TARTRATE<sup>[37-44]</sup>

Sr No	Drug	Method	Description	Ref No
1	Tolterodine Tartrate in bulk and pharmaceutical formulation.	UV	<b>Solvent:</b> Water <b>Detection:</b> <b>Zero order :</b> 281.5nm <b>First order:</b> 274nm <b>AUC:</b> 276-286nm <b>Linearity Range:</b> 30-180 µg/ml	[37]
2	Tolterodine in bulk drug and formulation	Visible spectrophotometric	<b>Complex:</b> Charge Transfer colored complex of Tolterodine tartrate with N-Bromo succinimide, complexes with chloramines -T and Phosphomolybdic acid. <b>Detection:</b> 520nm,540nm,840nm <b>Linearity range:</b> 5-35ppm, 2-14ppm, 10-60ppm <b>LOD:</b> 0.03 µg/ml <b>LOQ:</b> 0.6 µg/ml	[38]
3	Tolterodine Tartrate in bulk and pharmaceutical dosage form.	UV spectrophotometric.	<b>Solvent:</b> 0.1N NAOH <b>Linearity Range:</b> 10-80 µg/ml <b>Detection:</b> 280nm <b>LOD:</b> 0.715 µg/ml <b>LOQ:</b> 2.167 µg/ml	[39]
4	Tolterodine Tartrate in bulk in pharmaceutical	Extractive colorimetric method using tropaeolin ooo-	<b>Solvent and Complex:</b> A Chloroform extractable orange red complex formed between the acid dye, tropaeolin OOO-1 and Tolterodine in acid media.	[40]



	dosage form.	1	<b>Detection:</b> 503nm <b>Linearity Range:</b> 1-30 µg/ml <b>LOD:</b> 0.08 µg/ml <b>LOQ:</b> 1 µg/ml	
5	Tolterodine Tartrate in pure and Pharmaceutical forms.	Extractive visible method.	<b>Complex:</b> 1:1 ion pair complex of the drug with 3 acid dyes Bromophenolblue, bromocresol green, bromocresol purple dyes. <b>Detection:</b> 416,419,404nm <b>LOD:</b> 0.288,0.231,0.242 µg/ml	[41]
6	Tolterodine Tartrate in bulk and tablet dosage form.	UV Spectrophotometric.	<b>Detection:</b> 283nm <b>Linearity Range:</b> 10-50 µg/ml <b>LOD:</b> 0.1865 µg/ml <b>LOQ:</b> 0.5621 µg/ml	[42]
7	Tolterodine Tartrate in pure and formulations.	UV Spectro photometric.	<b>Detection:</b> 282nm <b>Linearity Range:</b> 60-120 µg/ml <b>% Recovery:</b> 99.93-100.37 <b>LOD:</b> 4.08 µg/ml <b>LOQ:</b> 13.61 µg/ml	[43]
8	Tolterodine Tartrate in pure form and pharmaceutical preparation.	Spectro fluorimetric.	<b>Solvent:</b> Phosphate buffer pH 6 <b>Detection:</b> Native fluorescence in Methanol at 313nm After excitation at 285nm <b>LOD:</b> 0.090 µg/ml <b>LOQ:</b> 0.273 µg/ml	[44]

## 2.4 Summaries of other methods

TABLE 2.4 SUMMARIES OF OTHER METHODS [34-37]

Sr No	Drug	Method	Description	Ref No
1	Tolterodine and its metabolite in rat plasma and pharmacokinetic study.	LC-MS/MS method.	<b>Stationary Phase:</b> Ascentis Express RP amide column <b>Mobile phase:</b> 10mM ammonium acetate: Acetonitrile(20:80 v/v) <b>Flow rate:</b> 0.5mL/min <b>Linearity Range:</b> 20-5000pg/mL	[35]
2	Tolterodine Tartrate in human plasma and urine samples.	UPLC Assay method.	<b>Detection:</b> 220nm <b>Stationary Phase:</b> BEH C18 Sub-2- µm <b>Mobile Phase:</b> Trifluoroacetic acid: Acetonitrile <b>LOD:</b> 0,05 µg/ml <b>LOQ:</b> 0.15 µg/ml <b>Retention time:</b> 2.4min	[36]
3	Tolterodine Tartrate and its metabolite in human plasma and pharmacokinetic study.	UHPLC-ESI-MS/MS	<b>Mobile Phase:</b> Ethyl acetate: n-hexane(70:30v/v) <b>Stationary Phase:</b> Agilent Zorbax XDB-phenyl column. <b>Detection:</b> Electro spray ionization <b>LOQ:</b> 5.0pg/ml	[34]

## CONCLUSION

This review depicts the reported Spectrophotometric and Chromatographic methods; developed and validated for estimation of Terazosin Hydrochloride and Tolterodine tartrate. According to this review it was concluded that for Terazosin Hydrochloride and Tolterodine Tartrate different Spectroscopic & Chromatographic methods are available for Single component as well as for combination and also it was found that the Mobile phase containing Phosphate buffer, Methanol and Acetonitrile were common for most of the chromatographic method to provide more resolution. For Chromatographic method flow rate was observed in the range of 0.8-1.5 ml/min to get good retention time. For most of the Spectroscopic methods common solvent was Methanol. This all

methods were found to be simple, accurate, economic, precise and reproducible in nature.

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## REFERENCE

1. United State Pharmacopeia, USP 29 NF 24, 2005, USP Convention INC, Rockville, Asian Edition, 2005; 3: 2678-2679.
2. Indian Pharmacopeia 2014, Ghaziabad; gov. of India ministry of health and family welfare, the controller of publication Indian Pharmacopoeia commission, 2014; 3: 2840-2841,2892-2894.
3. Prakash s Sarsambhi, S. Appala Raju, "Spectrophotometric determination of Terazosin hydrochloride", *Asian journal of chemistry*, 2001; 13(2): 760-762.
4. Shrivastava, Alankar, Abhishek PATEL and Vipin B. GUPTA, "Stability Indicating HPTLC Determination of Terazosin in Tablet Formulation." *World Journal of Analytical Chemistry*, 2013; 1(3): 31-36.
5. Nahla S. Ismail and Taghreed A. Mohamed, Potentiometric and Fluorimetric Methods for the Determination of Terazosin HCl in Drug Substance and Dosage Forms, *National Organization for Drug Control and Research*, Giza, Cairo, Egypt, *Int. J. Electrochem. Sci.*, 2014; 9: 7394 – 7413.
6. Sankar, V, Raghuraman, S, Sivanand, V, Ravichandran, V, "Spectrophotometric method for the estimation of Terazosin in Tablets." *Ind J Pharm Sci*, 2000; 61(6): 463- 464.
7. Prasad, C.V.N, Gautham, A, Bhardwaj, V, Praimoo, P. "Quantitative determination of Terazosin HCl in tablet preparation by Fluorimetric". *Ind J Pharm Sci.*, 1998; 60(3): 167.
8. Zeeb, M, Sadeghi, M, "Sensitive Determination of Terazosin in Pharmaceutical Formulations and Biological Samples by Ionic-Liquid Micro extraction Prior to Spectrofluorimetric." *Inter J Anal Chem.*, 2012; 1-7.
9. Jiang, C.J, Gao, M.X He, J.X, "Study of the interaction between Terazosin and serum albumin synchronous fluorescence determination of Terazosin." *Anal Chim Act.* 2002; 452: 185-189.
10. Wang, C.C, Luconi, M.O, Masi, A.N., Fernandez, L., "Determination of Terazosin by cloud point extraction-Fluorimetric combined methodology." *Talanta*, 2007; 72(5): 1779-85.
11. Abdine, H.H, El-Yazbi, F.A, Blaih, S.M, Shaalan, R.A., "Spectrophotometric and Spectrofluorimetric methods for the determination of Terazosin in dosage forms." *Spectrosc Lett: Int J Rapid Communication*, 1998; 31(5): 969-980.
12. El Sheikh, R, Esmail, N.S, Gouda, A.A, Basset, W.A, "Extractive spectrophotometric determination of some  $\alpha$ -adrenergic antagonists in pure forms and in pharmaceutical formulations." *CI & CEQ*, 2012; 18(2): 179-191.
13. Shrivastava A., Gupta V.B, "validated HPLC and HPTLC Methods for simultaneous determination of some  $\alpha$ 1-Adrenoreceptor Blockers" *Lat Am J Pharm*, 2012; 31(2): 279-86.
14. Cheah P Y, Yuena K H, Liong M L, "Improved high performance liquid chromatography analysis of Terazosin in human plasma", *J Chromatogr BI*, 2000; 749: 439-443.
15. Zavitanos, A.P, Alebic-Kolbah, T, "Enantioselective determination of Terazosin in human plasma by normal phase HPLC-Electro spray mass spectrometry", *J Chromatogr A*, 1998; 794: 45-56.
16. Zou, H.Y., Wu et al,"Flourescent Quantification of Terazosin content in human plasma and tablet using second order calibration based on both parallel factor analysis and alternating penalty tri linear decomposition", *Analytical chim acta*, 2009; 650: 143-149.
17. Bakshi, M, Ojha, T, Singh, S, "Validated specific HPLC methods for determination of Prazosin, Terazosin and Doxazosin in the presence of degradation products formed under ICH-recommended stress condition", *J Pharm biomed Anal.*, 2004; 34: 19-2.
18. Shrivastav A., Gupta V.B., "Stability indicating reverse phase HPLC method for the simultaneous determination of Prazosin, Terazosin and Doxazosin in Pharmaceutical formulations" *Sci pharm*, 2012; 80: 619-631.
19. Shrivastava A, Gupta V.B, "Validated HPLC and HPTLC Methods for simultaneous Determination of some  $\alpha$ 1 Adrenoreceptor Blockers", *lat Am J Pharm.*, 2012; 31(2): 279-86.
20. Shrivastava, A., Gupta, V.B.," Simultaneous Determination of two  $\alpha$ 1 Adrenoreceptor Blockers Terazosin and Prazosin using Tamsulosin as Internal Standard." *Inter J Pharma sci.*, 2012; 4(3): 752-756.
21. Sathis kumar Shetty, S Arpan, "Development and validation of Tolterodine by RP-HPLC method in Bulk Drug and Pharmaceutical Dosage forms", *International journal of pharmatech Research.*, 2011; 3(2): 1083-1087.
22. P. Rihana, Srinivas babu P, B.R. Challa., "Analytical method development and validation of Tolterodine in pharmaceutical dosage forms by RP-HPLC", *Scholar research library*, 2014; 6(3): 246-254.
23. S Vinay, Z Zaheer, M Farooqui, " Stability indicating HPLC Determination of Tolterodine Tartrate in Pharmaceutical dosage form", *Indian journal of chemical techmology*, 2006; 13: 242-246.
24. S. Ashutosh Kumar, M. Debnath, V. L. N. Seshagiri Rao," Method development and validation of Tolterodine Tartrate in bulk as well as in pharmaceutical formulation by using RP-HPLC", *international journal of pharmacy and pharmaceutical sciences*, 2013; 5(3).
25. "Stability indicating assay method and impurity profiling of Tolterodine Tartrate", 2006; 172-207.
26. C. Bala kumar, B Lakshmi Narayan, M. Chandrasekar, "Development and Validation of RP-HPLC Method for the quantitative estimation of Tolterodine Tartrate in Capsule formulation", *RGUHS J Pharm Sci*, 2013; 3(3): 57-64.
27. S Radha Krishna, B M Rao, N Someswara Rao, " A Validated Stability indicating HPLC method for the



- determination of related substances and assay of Tolterodine tartrate”, *RASAYAN J. Chem*, 2009; 2(1): 144-150.
28. N. Ramathilagam., M. Meeradevi, P. Solairaj, S C Rajesh., “ Development and Validation Of HPLC method for the estimation of Tolterodine Tartrate In tablets”, *International journal of pharmacy and Biological science*, 2012; 2(4): 332-337.
29. M. Shaiba, R. Maheshwari, Rahul Chakraborty, P Sai Praveen, V jagathi, “High Performance thin layer chromatography estimation of Tolterodine tartrate”, *Research journal of pharmaceutical, biological and chemical sciences*, 2011; 2(1): 6-11.
30. Hossein Danafar, “Comparative in vitro assessment of Tolterodine tartrate tablets by high performance liquid chromatography”, *Pharmaceutical and Biomedical research*, 2016; 2(2): 39-49.
31. B. Sidartha, DR.I. Sudheer Babu, ch. Ravindra Gupta, C. Parthiban,”Analytical method development and validation for simultaneous estimation of Tamsulosin and Tolterodine Tartrate in bulk and pharmaceutical dosage form by RP-HPLC method”, *Asian journal of pharmaceutical and clinical research*, 2014; 7(2): 156-160.
32. Madhavi patel, Batuk dabhi, Hetal Jabaliaya, Bhawani singh, Anamik shah,” Simultaneous estimation of Tolterodine Tartarte and Tamsulosin HCL by validated HPTLC Assay method from combination capsule form”, *Journal of chemical and pharmaceutical research*, 2015; 7(5): 81-88.
33. Chanita Chantarasukon, Supareak tukkeeree, jefferey roher, “ Simultaneous determination of Tartaric Acid amd Tolterodine in Tolterodine tartrate”, [online] [www.dionex.com/en-us/webdocs/113488-AN 1002,2012](http://www.dionex.com/en-us/webdocs/113488-AN 1002,2012).
34. L. M. Pallapothu, R.K.Pigli, K. Bhaskar, S.V Rudraraju,” A flexible and high sensitive validated UHPLC-ESI-MS/MS method for the estimation of Tolterodine Tartrate and its metabolite 5-OH methyl Tolterodine in human plasma by using simple liquid-liquid extraction method and application to pharmacokinetic study”, *Aizant drug research solutions pvt.ltd*.
35. Rihana Parveen Shaik, Srinivas Babu Puttagunta, Chandrasekhar Bannoth Kothapali, Bahlul Zayed Sh. Awen, B.R, Challa,” A validated LC-MS/MS method for the determination of Tolterodine tartrate and its metabolite in rat plasma and application to pharmacokinetic study” *Journal of pharmaceutical analysis*, 2013; 3(6): 489-499.
36. Ramesh Yanamandra, Chandra Sekhar vadla, Umamaheshwar Puppala, Balaram Patro, Yellajyosula. L.N Murthy, Parimi atchuta ramaiah, “A new rapid and sensitive stability indicating UPLC assay method for Tolterodine tartrate: application in pharmaceuticals, human plasma and urine samples”, *Scientia Pharmaceutica*, 2012; 80: 101-114.
37. S. K. Shetty, A. Shah, “new spectrophotometric method for estimation of Tolterodine in bulk and pharmaceutical formulation”, *international journal of pharmaceutical sciences and research*, 2011; 2(6): 1456-1458.
38. S. Vanilatha, M. Mary Theresa, N. Prasanna, D. Shantha kumara, B. Harika, P.Sirisha, M. Archana,” new method development and validation of Tolterodine using Visible Spectrophotometer”, *International journal of science innovations and discoveries*, 2011; 1(2): 288-293.
39. B. Siddartha, Dr. I. Sudheer Babu, A. Krupalini, Prathyusha V. “Devlopment and validation of UV-Spectrophotometric Method of Tolterodine in Bulk and Pharmaceutical Dosage Form”, *Asian J Pharm. Ana*, 2013; 3(3): 102-104.
40. Mani Ganesh, Pushpraj Hemalatha, Mei Mei Peng, Rajangam Vinodh, Kalaimani Saktimanigandan, Hyun Tae Jang, “ Determination of Tolterodine Tartrate in bulk and formulation by extractive colorimetric method using Tropaeolin OOO-1”, *Tropical journal of Pharmaceutical research*, 2014; 13(10): 1667-1673.
41. Safvan M. Fraihat, Munjed Ibrahim, “ Extractive Spectrophotometric Determination Of Tolterodine Tartrate In pure and pharmaceutical Forms:”, *4<sup>th</sup> international conference on environment science and engineering*, 2014; 68(9): 45-50.
42. Amruta B. Loni, Anita Hosmani, Apurva Gote, Pooja A. Guled, Sandhya C. Jeurkar, Smita T. Kumbhar, “ Spectrophotometric Estimation of Tolterodine Tartrate in Bulk and Tablet Dosage form”, *American journal of pharmatech research*, 2013; 3(6): 161-167.
43. Siva Shankar Rao G, P.S. Sarat, Ramachandran D,” UV-spectrophotometric Assay Method for the assay of Tolterodine in pure and formulation”, *American journal of pharmacy and health research*, 2015; 3(4): 21-30.
44. Mohammed W. Nassar, Khalid A. Attia, Hamed M. Abouu-seada, Ahmed Ei-olemy allam, “ Spectrofluometric determination of Tolterodine Tartrate in pure form and pharmaceutical preparation”, *international journal of pharmaceutical scienece s and research*, 2013; 4(10): 3845-3849.