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RP-HPLC Method Development Validation for the Concurrent Identification of Tamsulosin and Tadalafil in Pharamaceutical Dosage Form

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A B S T R A C T

A robust and validated RP-HPLC method was developed for the simultaneous estimation of Tamsulosin and Tadalafil in bulk and pharmaceutical dosage forms, in accordance with ICH Q2(R1) guidelines. Chromatographic separation was achieved using a Spursil C18-EP column (150×4.6 mm, 3 µm) with a mobile phase consisting of 34% perchloric acid and 66% acetonitrile, at a flow rate of 1.0 mL/min and detection wavelength of 223 nm. The method provided sharp and well-resolved peaks with retention times of 3.7 min for Tamsulosin and 4.7 min for Tadalafil. System suitability parameters, including resolution (>2), theoretical plates (>2000), and tailing factor (<2), met all acceptance limits. The method was validated and found to be accurate, with mean recoveries within 98–102**%**, linear over the ranges 1.6–8 µg/mL for Tamsulosin and 20–100 µg/mL for Tadalafil (R^2 > 0.999), precise (%RSD <1), sensitive with LODs of 0.02 µg/mL and LOQs of 0.07–0.08 µg/mL. Robustness and ruggedness studies confirmed reliability under small variations in chromatographic conditions, while forced degradation studies demonstrated its stability-indicating capability. Overall, the proposed method is simple, rapid, accurate, and cost-effective, making it highly suitable for routine quality control, stability assessment, and regulatory submission of Tamsulosin–Tadalafil formulations.

Keywords: RP-HPLC Method Development and Validation, Spursil C18-EP Column Chromatography, Perchloric Acid–Acetonitrile Mobile Phase, Stability-Indicating Assay of Combination Therapy, Linearity, Precision, Sensitivity, Lower Limits of Detection LOD, Limits of Quantification (LOQ), Routine Quality Control, Degradation, Robustness Testing

A R T I C L E I N F O

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1. Introduction

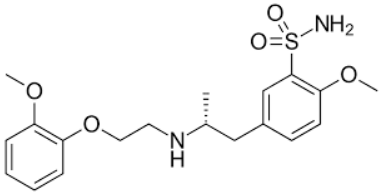

Fig.1: Tamsulosin

Table.1: Drug profile of Tamsulosin

Molecular Formula	$C_{20}H_{28}N_2O_5S$
Molecular Weight	408.52 g/mol
IUPAC Name	5-[(2R)-2-[[2-(2-Ethoxy phenoxy) ethyl] amino]propyl]-2-methoxy benzene sulfonamide
Chem Spider ID	4444067

Density	1.22 g/cm3
Boiling Point	543.4°C
Vapour Pressure	1.43E-10 mmHg
Flash Point	233.8°C
Refractive Index	1.54
Polar Surface Area	84.36 Å2
LogP	3.3 (Octanol/Water)
Generic Name	Tamsulosin
Brand Names	Flomax, Urimax
Drug category	Alpha-1 adrenergic receptor antagonist
Indications	Benign Prostatic Hyperplasia BPH
Pharmacology	Relaxation of smooth muscle in the prostate and bladder neck
Potency	High affinity for alpha-1A and alpha-1D adrenergic receptors
Tolerability	Generally well-tolerated, but may cause orthostatic hypotension and dizziness
Contraindications	Hypersensitivity to tamsulosin or any component of the formulation
Adverse Effects	Orthostatic hypotension, dizziness, headache, fatigue, nasal congestion
Availability	Prescription-only medication, available in oral capsules or tablets
Mechanism of Action	Tamsulosin works by selectively blocking alpha-1 adrenergic receptors in the prostate and bladder neck, leading to relaxation of smooth muscle in these areas and improved urine flow

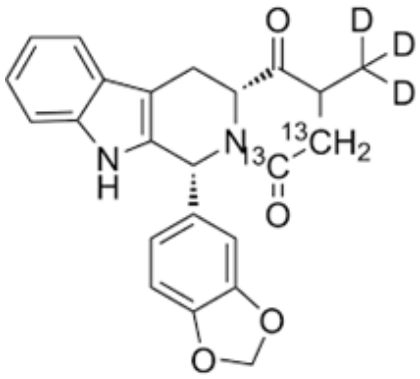

Fig.2: Taladafil

Table.1: Drug profile of taladafil

Molecular Formula	$C_{22}H_{19}N_3O_4$
Molecular Weight	389.41 g/mol
IUPAC Name	(6R,12aR)-2-(1-Methyl pyrrolidin-2-yl)-5-(2 propoxyphenyl)-7,12-dihydro-6Hpyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione
Chem Spider ID	110716

Density	1.34 g/cm3
Boiling Point	484.4°C
Vapour Pressure	1.29E-11 mmHg
Flash Point	224.2°C
Refractive Index	1.52
Polar Surface Area	104.4 Å2
LogP	2.8
Generic Name	Tadalafil
Brand Names	Cialis, Adcirca
Drug category	Phosphodiesterase type 5 (PDE5) inhibitor
Indications	Erectile Dysfunction (ED), Pulmonary Arterial Hypertension (PAH), Benign Prostatic Hyperplasia (BPH)
Pharmacology	Inhibition of PDE5, increasing cGMP levels and smooth muscle relaxation
Potency	High potency and selectivity for PDE5
Tolerability	Generally well-tolerated, but may cause headache, dyspepsia, and flushing
Contraindications	Hypersensitivity to tadalafil or any component of the formulation, concurrent use of nitrates
Adverse Effects	Headache, dyspepsia, flushing, back pain, myalgia
Availability	escription-only medication, available in oral tablets
Mechanism of Action	Tadalafil works by inhibiting the enzyme phosphodiesterase type 5 (PDE5), which results in increased levels of cyclic guanosine monophosphate (cGMP). This leads to relaxation of smooth muscle and increased blood flow to specific areas of the body, such as the penis

2. Materials and Methods

Table 1: List of Equipment's used

S.N	Instrument	Model
1	Instrument	WATERS, software: Empower, 2695 separation module, PDA detector.
2	HPLC	LABINDIA UV 3000+
3	UV/VIS spectrophotometer	Thermo – Orion Star A111
4	pH meter	SCALETEC-Model SAB-203L
5	Weighing machine	Borosil
6	Pipettes & Burettes	Borosil

Table 2: List of Materials Used

S.N	Chemical	Company Name
1	Formic acid	Qualigens
2	KH_2PO_4	FINER chemical LTD
3	Water and Methanol for HPLC	LICHROSOLV (MERCK)
4	Acetonitrile for HPLC	MOLYCHEM
5	Ortho phosphoric Acid	MERCK

HPLC Method Development:

Wave length selection:

UV spectrum of 10µg/ml Tamsulosin Hcl and Taladafil in diluents (mobile phase composition) was recorded by scanning in the range of 200nm to 400nm and the isobestic λmax of both the drugs obtained at 243 nm.

Optimization of Column:

DIKMA SPURSIL C18-EP (3.0 x 150mm, 3µm) was found to be ideal as it gave good peak shape and resolution at 1.0 ml/min flow.

Optimization of chromatographic conditions

Optimized chromatographic conditions

Instrument used: High performance liquid chromatography equip With Auto Sampler and PDA detector

Temperature : Ambient

Column : SPURSIL C18-EP (3.0 x 150mm, 3µm)

Mobile phase : 0.1%Formic acid: ACN (34:66ml)

Flow rate : 1ml/min

Wavelength : 243 nm

Injection volume : 10 µl

Run time :10 min.

Preparation of buffer and mobile phase:

Preparation of 0.1% Formic acid pH 4.5: To prepare phosphate buffer solution, by adding 0.1ml of formic acid in a 1000ml water. Adjust this solution to pH 4.5 by using sodium hydroxide.

Preparation of mobile phase:

Mix a mixture of above Formic acid 340ml (34%), 660 ml Acetonitrile (66%) and degas in ultrasonic water bath for 5 minutes. Filter through 0.45 µ filter under vacuum filtration**.**

Diluent Preparation: 0.1% Formic acid ph 4.5: ACN (34%: 66%)

Method validation parameters:

ASSAY:

Standard Solution Preparation: Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (4.8 ppm Tamsulosin and 60ppm Taladafil).

Sample Solution Preparation:

Accurately weigh and transfer equivalent to 2mg of Tamsulosin and 25mg of Taladafil equivalent weight of the sample into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (4.8ppm Tamsulosin and 60ppm Taladafil).

Procedure: Inject 10 µL of the standard, sample into the chromatographic system and measure the areas for the Tamsulosin and Taladafil peaks.

$$\%\ Assay = \frac{AT}{AS} * \frac{WS}{DS} * \frac{DT}{WT} * \frac{Average\ weight}{Label\ Claim} * \frac{P}{100} * 100$$

Where:

AT = average area counts of sample preparation.

AS = average area counts of standard preparation.

WS = Weight of working standard taken in mg.

P = Percentage purity of working standard

LC = Label Claim mg/ml.

LINEARITY:

Preparation of stock solution: Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Preparation of Level – I (1.6ppm of Tamsulosin and 20ppm of Tadalafil): 0.2ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – II (3.2ppm of Tamsulosin and 40ppm of Tadalafil): 0.4ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – III (4.8ppm of Tamsulosin and 60ppm of Tadalafil): 0.6ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – IV (6.4ppm of Tamsulosin and 80ppm of Tadalafil): 0.8ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Preparation of Level – V (8.0ppm of Tamsulosin and 100ppm of Tadalafil): 1.0ml of stock solution has taken in 10ml of volumetric flask dilute up to the mark with Diluents.

Procedure: Inject each level into the chromatographic system and measure the peak area. Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient.

Precision:

Preparation of stock Solution:

Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (4.8 ppm Tamsulosin and 60ppm Taladafil).

Procedure: The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Intermediate precision/ruggedness: To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different day within the laboratory.

Preparation of stock solution: Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (4.8 ppm Tamsulosin and 60ppm Taladafil).

Procedure: The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Accuracy: For accuracy determination, three different concentrations were prepared separately i.e. 50%, 100% and 150% for the analyte and chromatograms are recorded for the same.

Preparation of Standard stock solution: Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents (4.8 ppm Tamsulosin and 60ppm Taladafil).

Preparation Sample solutions:

For preparation of 50% solution (With respect to target Assay concentration): Accurately weigh and transfer 1mg of Tamsulosin and 12.5mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

For preparation of 100% solution (With respect to target Assay concentration): Accurately weigh and transfer 2mg of Tamsulosin and 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

For preparation of 150% solution (With respect to target Assay concentration): Accurately weigh and transfer 3mg of Tamsulosin and 37.5mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Inject the standard solution, Accuracy -50%, Accuracy -100% and Accuracy -150% solutions.

Calculate the Amount found and Amount added for Tamsulosin and Tadalafil and calculate the individual recovery and mean recovery values.

Limit of detection:

Preparation of Tamsulosin and Tadalafil solution:

Preparation of 0.02µg/ml Tamsulosin solution:

Accurately weigh and transfer 2mg of Tamsulosin working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 4ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Preparation of 0.02µg/ml Taladafil solution:

Accurately weigh and transfer 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)**.** Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.4ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Limit of quantification:

Preparation of Tamsulosin and Tadalafil solution:

Preparation of 0.07µg/ml Tamsulosin solution:

Accurately weigh and transfer 2mg of Tamsulosin working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 3.5ml of the above stock solution into a 25ml volumetric flask and dilute up to the mark with Diluents.

Preparation of 0.08µg/ml Tadalafil solution:

Accurately weigh and transfer 25mg of Taladafil working standard into a 25ml clean dry volumetric flask add Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 0.6ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 0.1ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents. Further pipette 1.4ml of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluents.

Robustness:

As part of the Robustness, deliberate change in the Flow rate, Mobile Phase composition, Temperature Variation was made to evaluate the impact on the method.

The flow rate was varied at 0.8 ml/min to 1.2ml/min.

Standard solution 30 µg/ml of Tamsulosin and Tadalafil prepared and analysed using the varied flow rates along with method flow rate.

The Organic composition in the Mobile phase was varied from 59.4% to 72.6%: Standard solution 30 µg/ml of Tamsulosin and Tadalafil was prepared and analysed using the varied Mobile phase composition along with the actual mobile phase composition in the method.

3. Results and Discussion

Optimized Chromatographic Conditions:

Instrument used : High performance liquid chromatography equipped with Auto Sampler and PDA or UV detector
Temperature : Ambient
Column : Spursil C18-EP, (150×4.6mm, 3µm)
Mobile phase : 34%: 66 %(Per chloric acid; ACN)
Flow rate : 1.0 ml per min
Wavelength : 223 nm
Injection volume : 10 µl
Run time : 15 min.
Retention time : 6.869

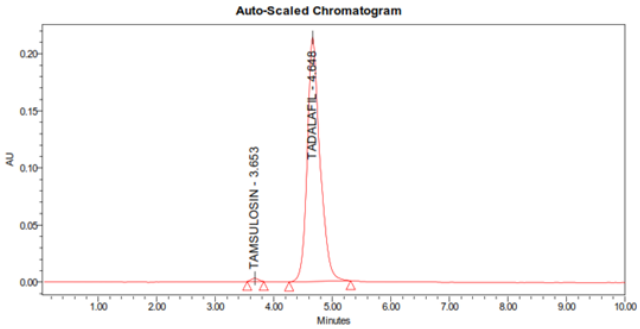

Fig.3: Optimized Chromatogram

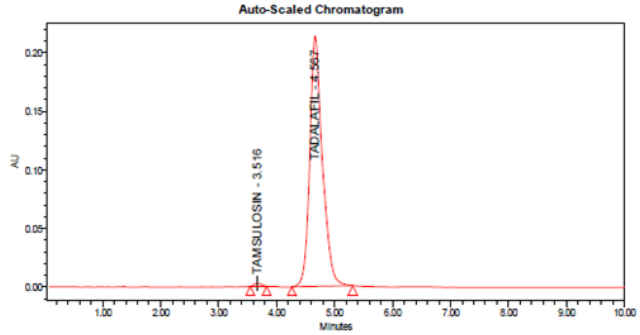

Fig.5: Chromatogram for Sample

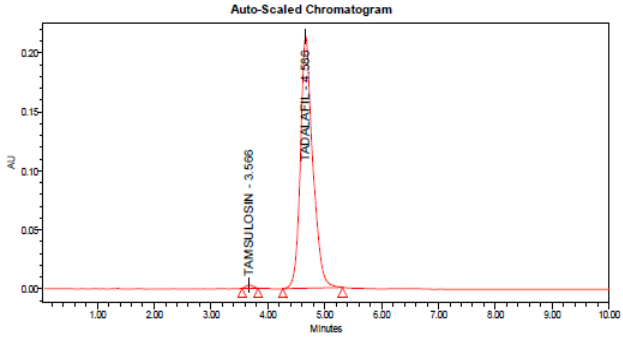

Fig.6: Chromatogram for Standard

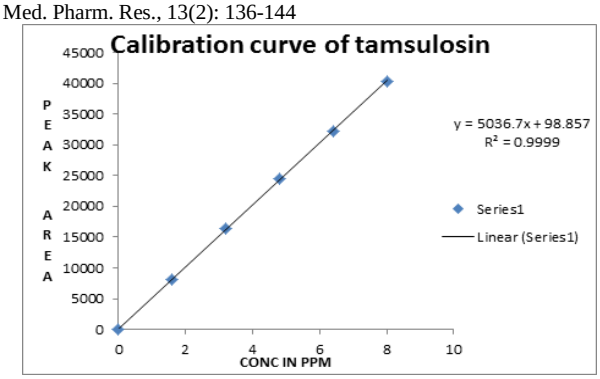

Fig.7: Calibration graph for Tamsulosin

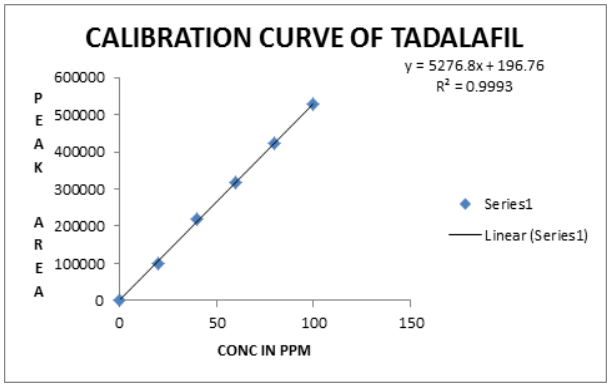

Fig.8: Calibration graph for Tadalafil

Table 3: Analytical performance parameters of Tamsulosin and Tadalafil

Parameters	Tamsulosin	Tadalafil
Slope (m)	5036.7	5276.8
Intercept (c)	98.857	196.76
Correlation coefficient (R^2)	0.9999	0.9993

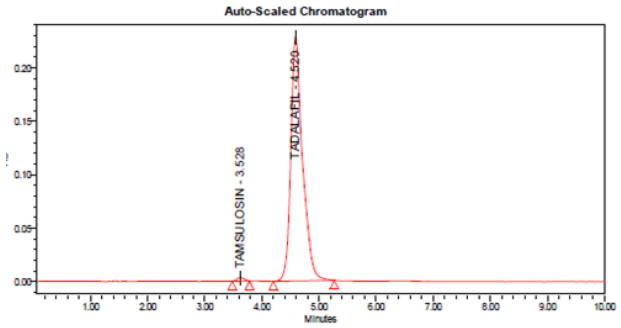

Fig.9: Chromatogram for Precision -6

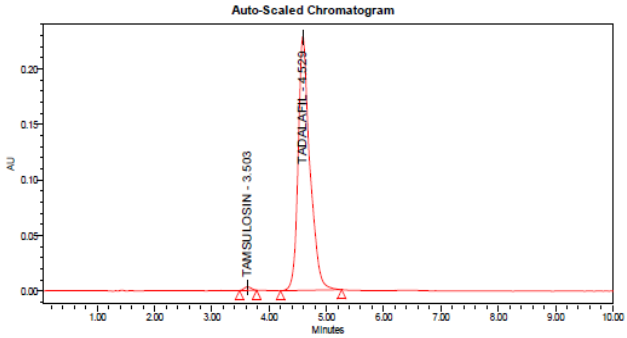

Fig.10: Chromatogram for Intermediate Precision -6

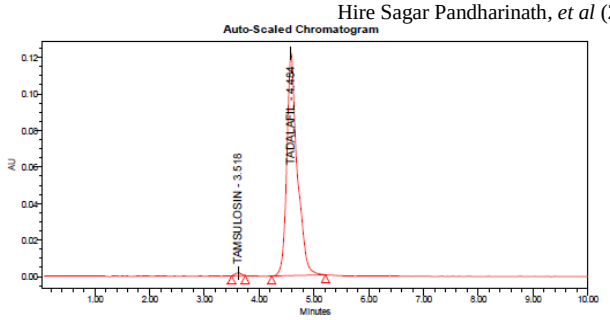

Fig.11: Chromatogram for Accuracy 50%-3

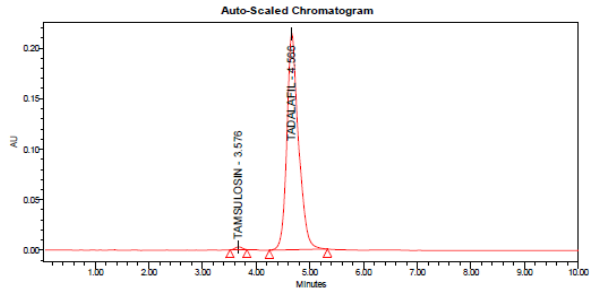

Fig.12: Chromatogram for Accuracy 100%-3

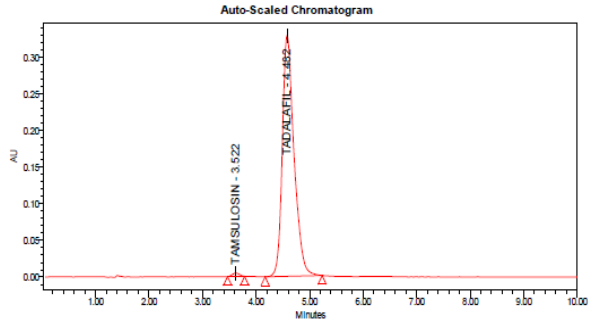

Fig.13: Chromatogram for Accuracy 150%-3

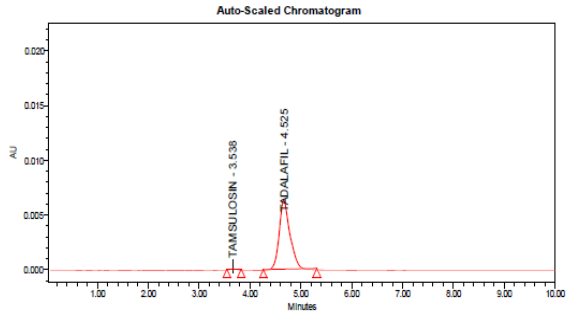

Fig.14: Chromatogram of Tamsulosin and Tadalafil showing LOD

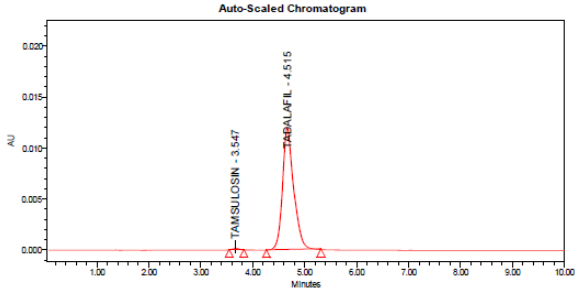

Fig.15: Chromatogram of Tamsulosin and Tadalafil showing LOQ

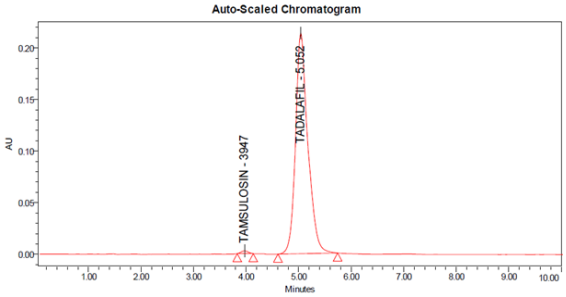

Fig.16: Chromatogram showing less flow

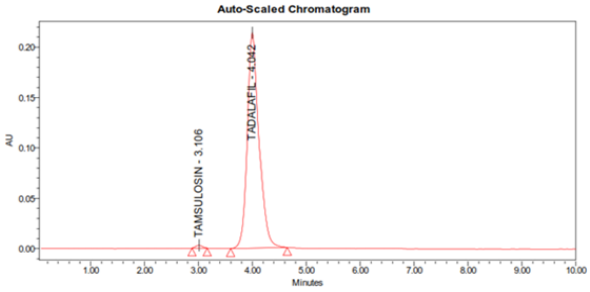

Fig.17: Chromatogram showing more flow

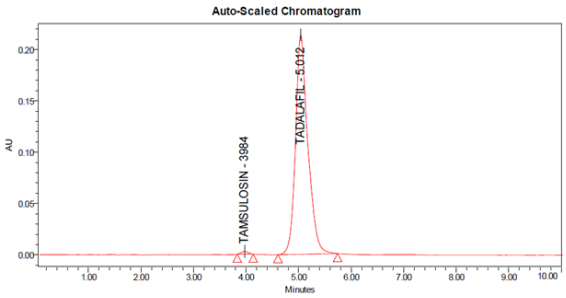

Fig.18: Chromatogram showing less organic composition mobile phase

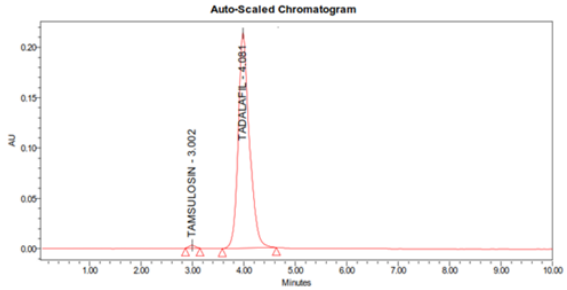

Fig.19: Chromatogram showing more organic composition mobile phase

Table 4: Results of Precision for Tamsulosin and Tadalafil

Injection	Tamsulosin Area	Tadalafil area
Injection-1	24585	316952
Injection-2	24547	316654
Injection-3	24563	316741
Injection-4	24521	316321
Injection-5	24589	315953
Injection-6	24514	316654
Average	24553.17	316545.8
Standard Deviation	31.62541	354.5315
%RSD	0.13	0.11

Table 5: Results of Intermediate precision for Tamsulosin and Tadalafil

Injection	Tamsulosin Area	Tadalafil
Injection-1	24685	317965
Injection-2	24688	317684
Injection-3	24532	317324
Injection-4	24643	316453
Injection-5	24526	317741
Injection-6	24614	317951
Average	24614.67	317519.7
Standard Deviation	71.86562	572.0887
%RSD	0.29	0.2

Table 6: Accuracy (recovery) data for Tamsulosin

%Concentration tamsulosin (at specification Level)	Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	12157	1	1.0	99.2	98.9%
100%	**23357**	2	2.0	99.0	
150%	36247	3	3.0	98.6	

Table 7: Accuracy (recovery) data for Tadalafil

%Concentration Tadalafil (at specification Level)	Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	155527	12.5	12.2	98.2	99.1%
100%	314574	25	24.8	99.4	
150%	475862	37.5	37.6	100.2	

Table 8: Results of LOQ

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio	Conc.
Tamsulosin	65	635	9.77	0.07µg/ml
Tadalafil	65	648	9.97	0.08µg/ml

Signal to noise ratio shall be 10 for LOQ solution

Table 9: Results of LOD

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio	Conc.
Tamsulosin	65	177	2.72	0.02µg/ml
Tadalafil	65	190	2.92	0.02µg/ml

Table 10: Results for variation in flow for Tamsulosin

S.No	Flow Rate (ml/min)	System Suitability Results tamsulosin	
		USP Plate Count	USP Tailing
1	0.8	3954	1.3
2	1.0	3941	1.42
3	1.2	3980	1.5

Table 11: Results for variation in flow for Tadalafil

S. No	Flow Rate (ml/min)	System Suitability Results tadalafil	
		USP Plate Count	USP Tailing
1	0.8	6618	1.01
2	1.0	6639	1.03
3	1.2	6679	1.08

Table 12: Results for variation in mobile phase composition for Tamsulosin

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results tamsulosin	
		USP Plate Count	SP Tailing
1	10% less	3954	1.3
2	*Actual	3941	1.42
3	10% more	3980	1.5

Table 13: Results for variation in mobile phase composition for Tadalafil

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results tadalafil	
		USP Plate Count	USP Tailing
1	10% less	6618	1.01
2	*Actual	6639	1.03
3	10% more	6679	1.08

4. Conclusion

A robust and precise RP-HPLC method was successfully developed and validated for the simultaneous estimation of Tamsulosin and Tadalafil in bulk and pharmaceutical dosage forms, in compliance with ICH Q2(R1) guidelines. The optimized chromatographic conditions employed a Spursil C18-EP column (150×4.6 mm, 3 µm) with a mobile phase of 34% perchloric acid and 66% acetonitrile, flow rate of 1.0 mL/min, detection wavelength of 223 nm, and run time of 15 minutes, achieving retention times of 3.7 min for Tamsulosin and 4.7 min for Tadalafil. System suitability results, including resolution (>2), plate count (>2000), and tailing factor (<2), confirmed excellent method performance. Validation parameters demonstrated high accuracy with recoveries between 98–102%, linearity over the ranges of 1.6–8 µg/mL for Tamsulosin and 20–100 µg/mL for Tadalafil ($R^2 > 0.999$), precision with %RSD < 1%, and sensitivity with low LOD (0.02 µg/mL) and LOQ (0.07–0.08 µg/mL) values. Robustness and ruggedness testing confirmed that slight variations in flow rate and mobile phase composition did not significantly affect chromatographic parameters, establishing the method's reliability. Forced degradation studies under acid, base, oxidative, thermal, and photolytic conditions revealed controlled degradation, supporting the method's stability-indicating nature. Overall, the developed RP-HPLC method is simple, accurate, precise, sensitive, and cost-effective, making it highly suitable for routine quality control, stability studies, and regulatory applications for Tamsulosin and Tadalafil formulations in the pharmaceutical industry.

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