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THE ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF FEXOFENADINE HYDROCHLORIDE COMBINATION WITH PHENYLEPHRINE HYDROCHLORIDE (API) AND LIQUID DOSAGE FORM BY RP-HPLC

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ABSTRACT

The present study focuses on the development and validation of a simple, precise, and reliable analytical method for the estimation of fexofenadine hydrochloride combination with phenylephrine hydrochloride (API) and liquid dosage form using reverse phase high-performance liquid chromatography (RP-HPLC). The primary objective of this work was to establish an efficient chromatographic method suitable for routine quality control analysis. Chromatographic separation was achieved using a C18 column with a mobile phase consisting of methanol, Ammonium acetate buffer in gradient elution. The analysis was carried out at a detection wavelength of 220nm. The optimized conditions provided a well-defined chromatogram with good peak shape and resolution for fexofenadine & phenylephrine. The developed method was validated according to ICH guidelines, demonstrating acceptable levels of accuracy, precision, linearity, and specificity. The method showed consistent and reproducible

results for the quantification of fexofenadine hydrochloride combination with phenylephrine hydrochloride (API) and suspension formulation.

KEYWORDS: Fexofenadine Hydrochloride, Phenylephrine Hydrochloride, Hplc, Method Development, Validation.

INTRODUCTION

The combination of fexofenadine HCl and phenylephrine HCl provides complementary effects: fexofenadine controls the allergic component by blocking histamine H_1 receptors, while phenylephrine relieves the congestive component by producing α_1-mediated vasoconstriction of nasal blood vessels. Therefore, the combination is useful for relieving multiple symptoms of allergic rhinitis, particularly sneezing, itching, rhinorrhea, watery eyes, and nasal congestion.

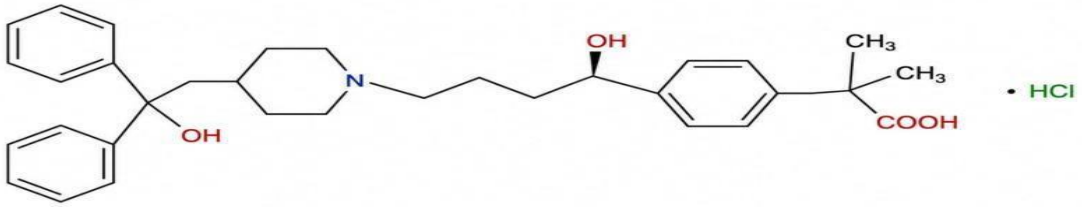
High-performance liquid chromatography is an efficient type of chromatography that uses a high-pressure gradient, rather than simple gravity, to propel a sample through a column. A sample is injected, then a pump containing high amount of pressure helps to move the sample along a packed column, where it is separated and quantitated as individual components. The separation is then analysed by a detector to yield results.

Gradient elution in HPLC is a technique where the composition of the mobile phase changes gradually over time. It starts with a weak solvent and slowly adds more of a strong solvent. This method helps separate complex mixtures with different compound speeds, shortens total test time, and makes peak shapes better.

The principle of separation in normal phase and reverse phase mode is adsorption. When a mixture of components is introduced into a HPLC column, they travel according to their relative affinities towards the stationary phase. The component which has more affinity towards the adsorbent travels slower. The components which have less affinity towards the stationary phase travel faster. Since no two components have the same affinity towards the stationary phase, the components are separated. HPLC system suitability parameters include resolution, tailing factor, theoretical plates, retention time, signal-to-noise ratio, and precision, which collectively ensure accurate and reproducible chromatographic performance.

DRUG PROFILE

FEXOFENADINE HYDROCHLORIDE



Chemical name : 2-[4-[1-hydroxy-4-[4-[hydroxy(diphenyl)methyl]piperidin-1-yl]butyl]phenyl]-2-methylpropanoic acid; hydrochloride.

Molecular formula : $C_{32}H_{40}ClNO_4$

Molecular weight : 538.13g/mol

Category : Antihistamine

Appearance : A white to off-white crystalline powder.

Melting point : 148-155°C

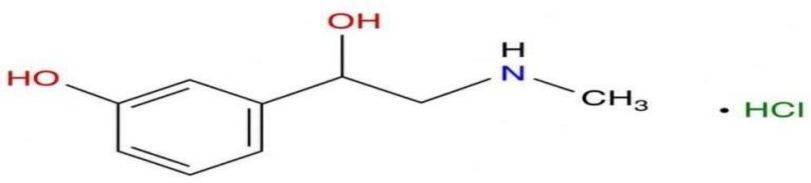
Storage : Store at room temperature (20-25°C) in a cool and dry place

Approval date : JULY 25,1996

Mechanism Of Action

Fexofenadine hydrochloride is a selective and competitive H_1-histamine receptor antagonist. During an allergic reaction, allergens stimulate mast cells to release histamine. Histamine binds to H_1 receptors in tissues and produces symptoms such as sneezing, itching, watery eyes, rhinorrhoea (runny nose), and nasal swelling. Fexofenadine competitively binds to peripheral H_1 receptors and prevents histamine from activating these receptors. As a result, histamine-mediated allergic responses are reduced, providing relief from sneezing, itching, watery eyes, and runny nose. Because fexofenadine has limited penetration into the brain, it produces relatively little central H_1-receptor blockade and therefore causes less sedation than many older antihistamines.

PHENYLEPHRINE HYDROCHLORIDE



Chemical Name :3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride.

Molecular Formula : $C_9H_{14}ClNO_2$.

Molecular Weight : 203.67g/mol.

Category : Decongestant (Sympathomimetic).

Appearance : A white or almost white, crystalline powder.

Melting point : 140-145°C.

Storage : Store at room temperature (20-25°C) in a cool and dry place.

Approval date : OCTOBER 21, 2019.

Mechanism of Action

Phenylephrine hydrochloride is a selective α_1-adrenergic receptor agonist and acts mainly as a nasal decongestant. It stimulates α_1-adrenergic receptors present on the smooth muscle of blood vessels in the nasal mucosa. Activation of these receptors is coupled to Gq protein, which activates phospholipase C (PLC). PLC produces inositol trisphosphate (IP_3) and diacylglycerol (DAG). IP_3 increases intracellular Ca^{2+}, while DAG activates protein kinase C (PKC). These pathways promote contraction of vascular smooth muscle, resulting in vasoconstriction. Vasoconstriction decreases blood flow and vascular congestion in the nasal mucosa, thereby reducing nasal swelling and obstruction and making nasal breathing easier.

MATERIALS AND METHODS

Chemicals and reagents

- Methanol (HPLC Grade)
- Milli-Q Water (HPLC Grade)
- Ammonium acetate (Laboratory Grade)

Instrumentation

- Digital Balance
- SHIMADZU – HPLC-DLC20AD
- Sonica Ultrasonic cleaner – Model 2200 MH
- SHIMADZU - IR Spectroscopy
- Digital pH Meter

PROCEDURE

Preparation of solvent

50 % of methanol and the 50 % of water with HPLC grade were transferred into a 1000 ml Standard Flask and mixed well.

Preparation of buffer: (Ammonium acetate buffer pH 3.5)

Weigh accurately 0.78g of ammonium acetate and dissolve in 900ml of HPLC grade water in 1000ml standard flask and actual pH was 4.6, we adjust into pH-3.5 then make up into 1000ml by using HPLC grade water.

Preparation of mobile phase

Mobile phase A- Ammonium acetate buffer.

Mobile phase D- Methanol.

Preparation of standard stock solution

Stock-A (Fexofenadine hydrochloride)

Weigh accurately about 60mg of fexofenadine hydrochloride and transferred into a 100 ml volumetric flask, then add solvent to dissolve and make up the volume upto the mark.

Stock-B (Phenylephrine hydrochloride)

Weigh accurately about 25mg of phenylephrine hydrochloride and transferred into a 100 ml volumetric flask, then add solvent to dissolve and make up the volume upto the mark.

Preparation of standard solution

Then pipette out 2.5ml of stock-A and 0.5ml of stock-B from the above solution and transferred into 10ml of volumetric flask then add 5ml of solvent shake vigorously & make up the volume upto the mark with same solvent.

The concentration of resultant solution (fexofenadine hcl is 150 µg/ml & phenylephrine hcl is 12.5 µg/ml).

CALCULATION

Density

Weight of empty specific gravity bottle (W_1) = 17.820g

Weight of empty specific gravity bottle + water (W_2) = 43.311g

Weight of empty specific gravity bottle + liquid (W_3) = 46.811g

Density of water (ρ_2) = 0.9970gm/ml.

Density of unknown liquid (ρ_1).

$$\rho_1 = \frac{W_3 - W_1}{W_2 - W_1} \times \rho_2$$

(ρ_1) =

$$\frac{46.811-17.820}{43.311-17.820} \times 0.9970$$

(ρ_1) =

$$\frac{28.991}{25.491} \times 0.9970$$

(ρ_1) = 1.133gm/ml.

The density of suspension is 1.133gm/ml, therefore we take 5ml of sample from liquid dosage form. It contains 30mg of fexofenadine hcl and 2.5mg of phenylephrine hcl.

= 5×1.133

= 5.669 gm

Preparation of sample stock solution

30mg equivalent of fexofenadine hydrochloride & 2.5mg equivalent of phenylephrine hydrochloride (suspension 5.669g [5ml]) and transferred into a 50 ml volumetric flask, then add 50ml solvent to dissolve.

Preparation of sample solution

Then pipette out 2.5ml from the above solution and transferred into 10ml of volumetric flask, then add 5 ml of solvent shake vigorously and make up the volume upto mark with the same solvent.

The concentration of the resultant solution was fexofenadine hcl 150 µg/ml and phenylephrine hcl 12.5 µg/ml.

METHOD DEVELOPMENT

The developed method was fully validated for the parameters as per ICH guidelines.

Linearity

Take a 1.25ml, 1.87ml, 2.5ml, 3.12ml, 3.75ml of stock solution A and Take a 0.25ml, 0.37ml,

0.5ml, 0.62ml, 0.75ml of stock solution B is transfer into 10ml of volumetric flask and make up with solvent upto the volume. To prepare linearity concentration of 50%, 75%, 100%, 125%, 150%.

Accuracy

Weigh accurately suspension (5.669g [5ml])average weight of sample and transfer into 100ml of volumetric flask dissolve and makeup to the volume with the solvent. Take 2ml, 2.5ml, 3ml of stock solution was transferred into 10ml of volumetric flask and makeup with solvent upto the volume. To prepare concentration of 80%, 100%, 120%.

Precision

Weigh accurately suspension (5.669g [5ml]) average weight of sample and transfer into 100ml of volumetric flask dissolve and makeup to the volume with the solvent.1ml of stock solution was transferred into 10ml of volumetric flask and makeup with the solvent upto the volume. Six-time replicate of injection to produce the similar of the result no maximum deviation.

Robustness

Small deliberate changes in method like flow rate, wavelength, mobile phase and ratio were made but there was no recognized change in the result and were within range as per ICH guidelines. Robustness conditions like flow rate increasing, flow rate decreasing was maintained, and samples were injected in duplicated manner system suitability parameters were not much affected and all the parameters were passed. % RSD was within the limit.

Ruggedness

Ruggedness is a measure of reproducibility of test results under normal, expected operational conditions from laboratory to laboratory and from analyst to analyst. The method was fully validated for the parameters as per ICH guidelines.

RESULTS AND DISCUSSION

A simple Reverse phase high-performance liquid chromatographic method has been developed and subsequently validated for fexofenadine hydrochloride & phenylephrine hydrochloride.

The separation was carried out by using a Buffer (Ammonium acetate), Methanol. The detection was carried out at 220 nm. The column used is C18 Column (250 mm x 5,4.5micron). The flow rate was selected as 1mL/min.

Method Development

Mode of operation : Gradient elution

Stationary phase : C18 Column (250 mm x 5,4.5micron)

Mobile phase : Methanol : Ammonium acetate buffer

Detection wavelength : 220 nm

Flow rate : 1ml/min

Temperature : 25℃

Run time : 25.01minutes

Retention time:

1. Phenylephrine hydrochloride - 2.882 minutes.
2. Fexofenadine hydrochloride - 15.578 minutes.

Table 1: Data for Optimized chromatographic conditions.

TIME INTERVAL	Mobile phase D	Mobile phase B	Mobile phase A
0.1-5 minutes	25	20	55
5.01-8 minutes	40	20	40
8.01- 12minutes	80	20	0
12.01- 15minutes	80	20	0
15.01- 17minutes	50	20	30
17.01- 22minutes	25	20	55
22.01- 25minutes	25	20	55
25.01- minutes(stop)			

METHOD DEVELOPMENT

Optimized Chromatogram

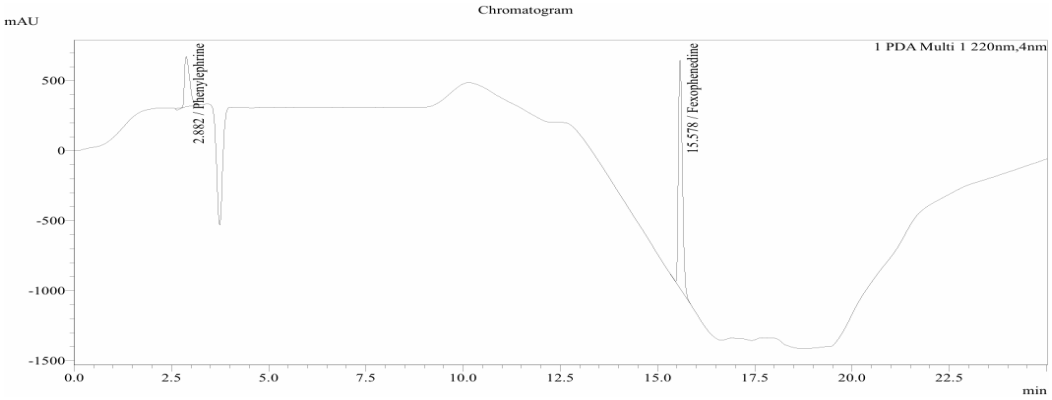


Figure 1: Optimized Chromatogram.

Table 2: Data For Optimized Chromatogram.

PEAK	NAME	RETENTION TIME	AREA	THEORETICAL PLATE	TAILING FACTOR	RESOLUTION
1	Phenylephrine	2.882	3168627	2215	1.788	-
2	Fexofenadine	15.578	11626500	105071	1.345	58.242
Total			14795127			

Linearity

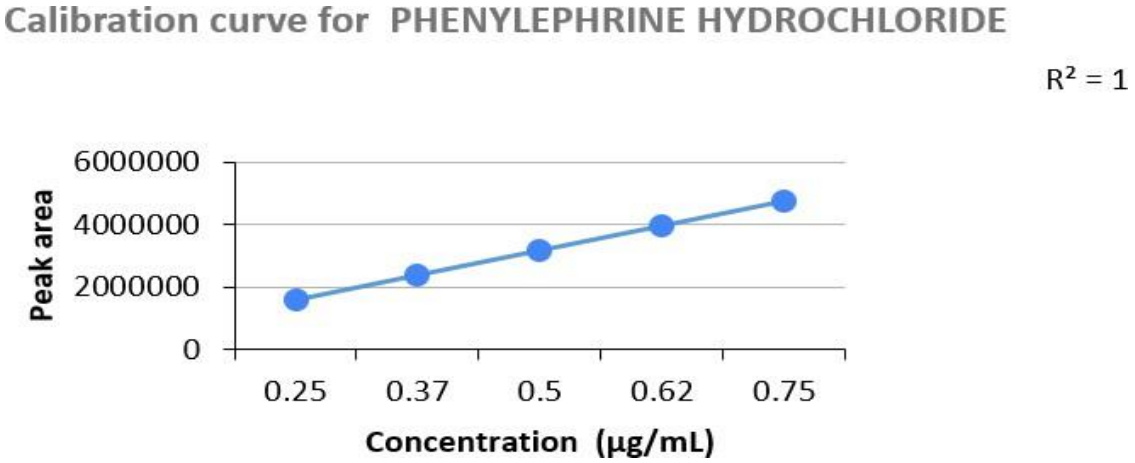


Figure 2: Calibration curve of Phenylephrine Hydrochloride.

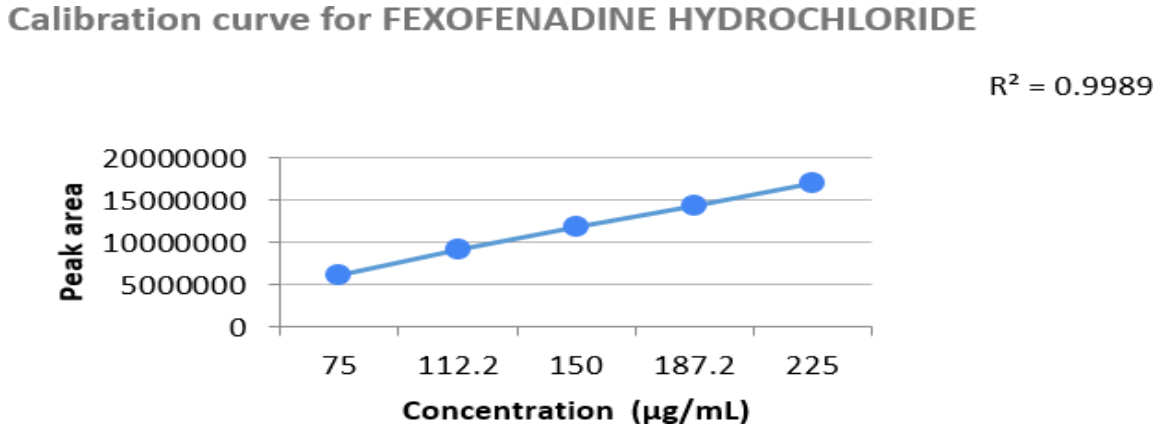


Figure 3: Calibration curve of fexofenadine Hydrochloride.

Table 3: Data for linearity.

NAME	CONCENTRATION	RETENTION TIME	AREA	THEORETICAL PLATE	TAILING FACTOR
1.Phenylephrine	50%	2.877	1585324	2374	1.896
	75%	2.878	2376362	2318	1.854
	100%	2.882	3168627	2215	1.788
	125%	2.879	3962874	2128	1.779
	150%	2.881	4753042	2238	1.758
2.Fexofenadine	50%	15.442	6098833	141621	1.299
	75%	15.430	9106831	120435	1.329
	100%	15.578	11826500	105071	1.345

	125%	15.415	14363600	90315	1.339
	150%	15.497	16980678	82859	1.323

Assay

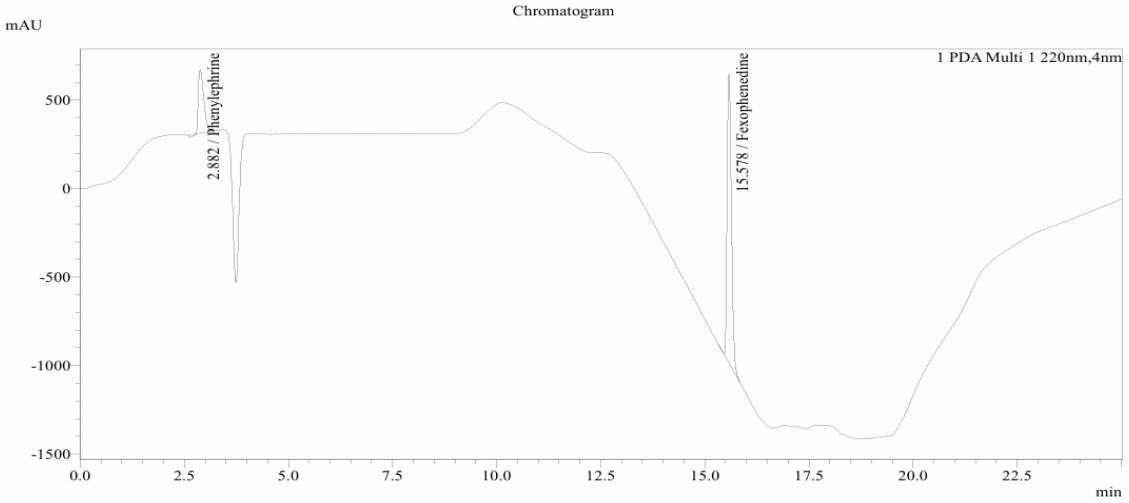


Figure 4: Standard solution injection.

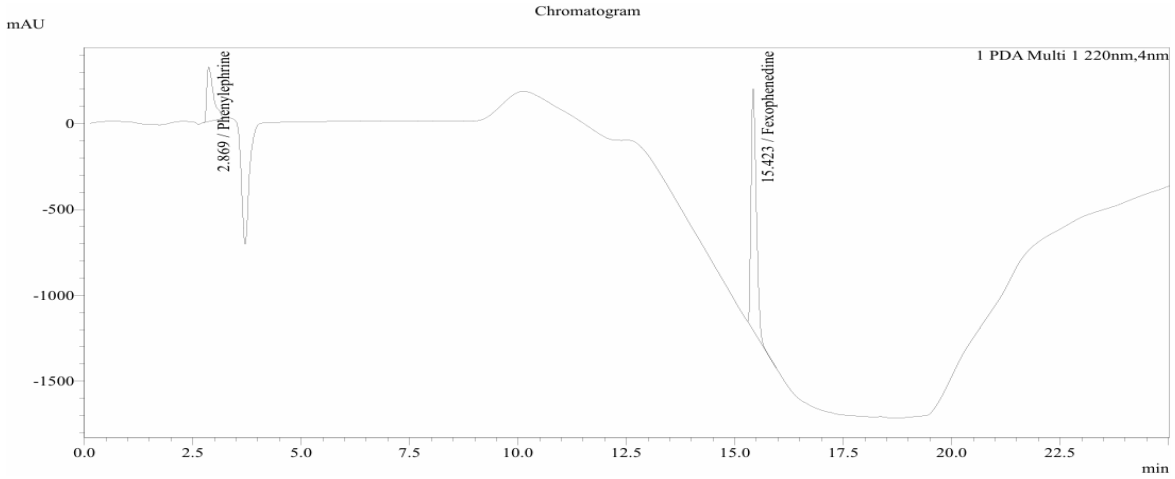


Figure 5: Sample solution injection.

1) phenylephrine

Table 4: Data for Assay (Phenylephrine hydrochloride)

SOLUTION	RETENTION TIME	AREA	AVERAGE AREA	SD	%RSD	PERCENTAGE AVERAGE
STD-01	2.882	3568627	3567614.167	11577.03191	0.324503	100.0059982
STD-02	2.292	3579263				
STD-03	2.888	3555293				
STD-04	2.886	3561184				
STD-05	2.886	3557976				
(BKT)-06	2.884	3583342				
SAMPLE-01	2.869	3568995	3566569	3430.882102	0.096195	
SAMPLE - 02	2.884	3564143				

2) fexofenadine

Table 5: Data for Assay (Fexofenadine hydrochloride).

SOLUTION	RETENTION TIME	AREA	AVERAGE AREA	SD	%RSD	PERCENTAGE AVERAGE
STD 1	15.578	11626500	11592128.67	37285.08393	0.32164139	100.822999
STD 2	15.595	11549381				
STD 3	15.596	11552378				
STD 4	15.601	11628377				
STD 5	15.606	11620176				
(BKT) 6	15.599	11575960				
SAMPLE 1	15.423	11744055	11683407	85769.22413	0.734111412	
SAMPLE 2	15.463	11622759				

Accuracy

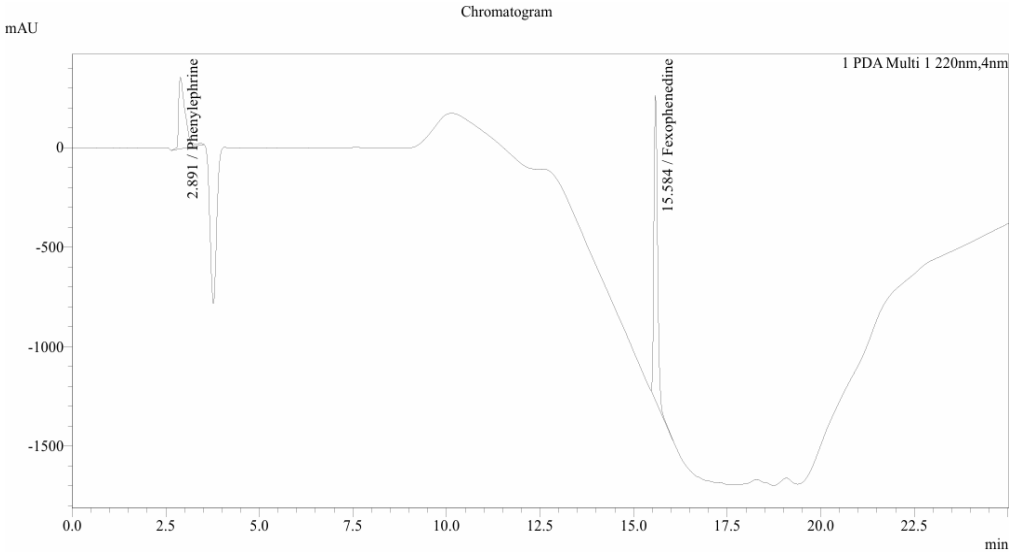


Figure 6: Accuracy – 80% solution.

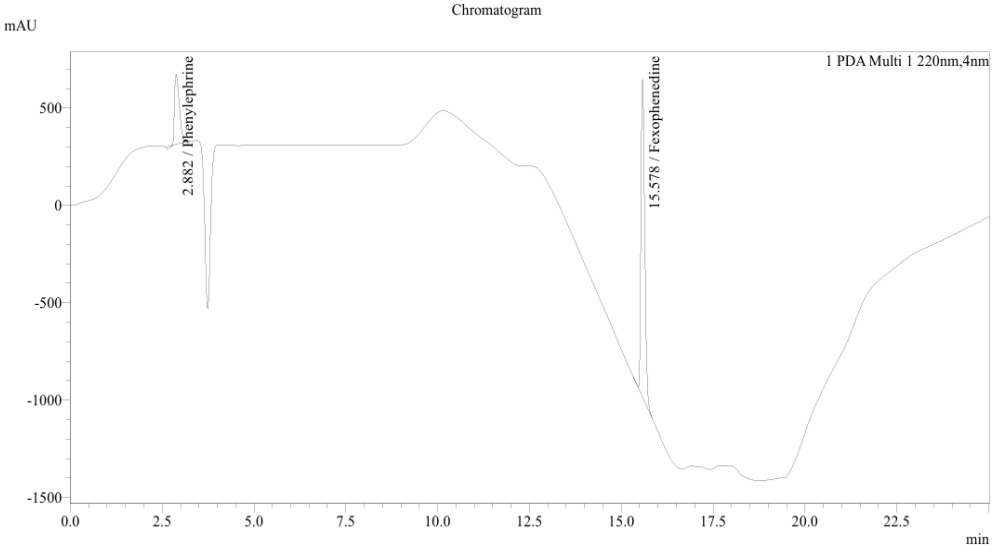


Figure 7: Accuracy -100% solution.

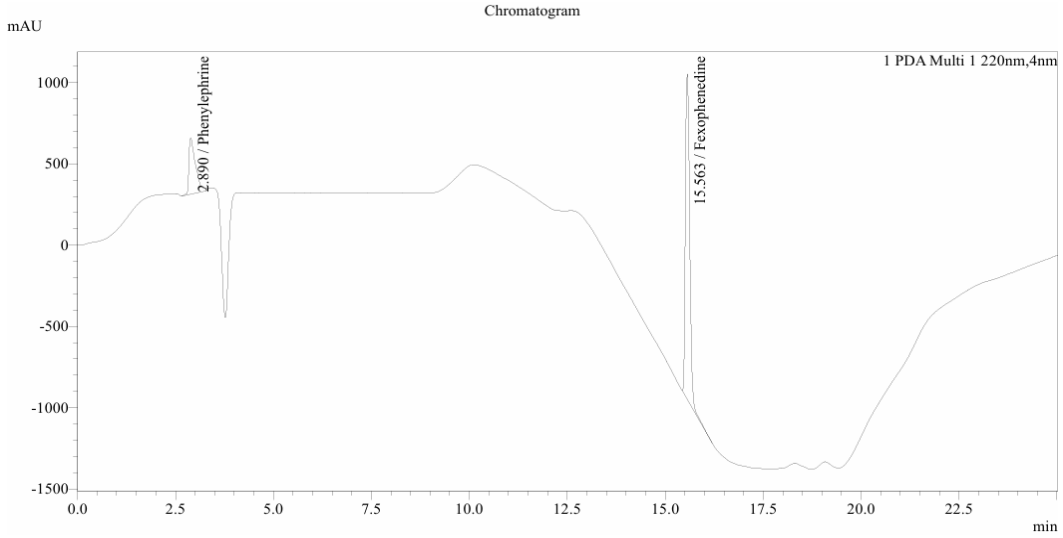


Figure 8: Accuracy -120% solution.

Table 6: Data for Accuracy.

NAME	%CONC	AVERAGE AREA	PERCENTAGE RECOVERY	MEAN RECOVERY
1)PHENYLEPHRINE	80%	2733985	99.51082675	99.778676773
	100%	3430927	99.90234248	
	120%	4117958	99.92286109	
2)FEXOFENADINE	80%	9291193	100.1885985	100.91254
	100%	11686500	100.8140984	
	120%	14151844	101.7345793	

Precision

A.) Interday precision : 1.) Phenylephrine

Table 7: Data for Inter-day precision (phenylephrine hydrochloride).

SOLUTION	RETENTION TIME	AREA	MEAN AREA	%RSD
01	2.882	3434056	3442524.167	0.677950529
02	2.882	3405910		
03	2.884	3460875		
04	2.891	3473541		
05	2.894	3439123		
06	2.893	3441640		

2.) Fexofenadine

Table 8: Data for Inter-day precision (fexofenadine hydrochloride).

SOLUTION	RETENTION TIME	AREA	MEAN AREA	%RSD
01	15.375	11327512	11452682.33	1.146278062
02	15.387	11341795		

03	15.447	11343425		
04	15.555	11514031		
05	15.559	11561584		
06	15.561	11627747		

B) Intraday precision

1.) Phenylephrine

Table 9: Data for Intra-day precision (Phenylephrine hydrochloride).

SOLUTION	RETENTION TIME	AREA	MEAN AREA	%RSD
01	2.894	3390205	3420651.833	1.224976516
02	2.894	3484700		
03	2.897	3366295		
04	2.895	3445414		
05	2.895	3427974		
06	2.893	3409323		

2.) Fexofenadine

Table 10: Data for Intra-day precision (fexofenadine hydrochloride).

SOLUTION	RETENTION TIME	AREA	MEAN AREA	%RSD
01	15.564	11680691	11634863.83	0.2789535
02	15.575	11653185		
03	15.574	11612607		
04	15.579	11655033		
05	15.574	11602569		
06	15.583	11605098		

Robustness: (Changes in Flow rate)

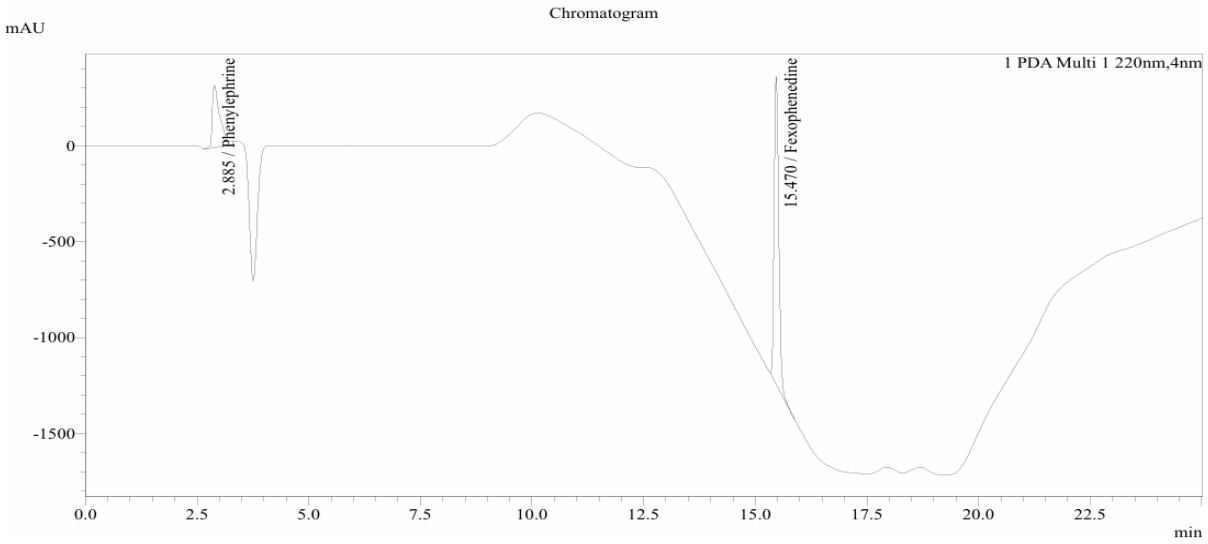


Figure 9: 0.9 ml of Flow rate.

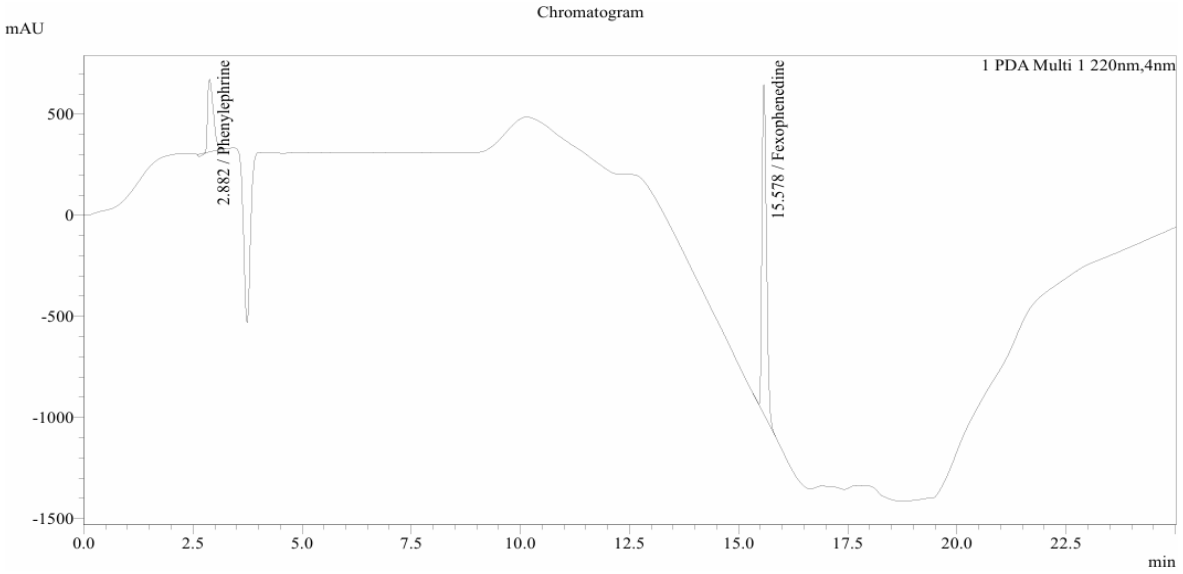


Figure 10: 1 ml of Flow rate.

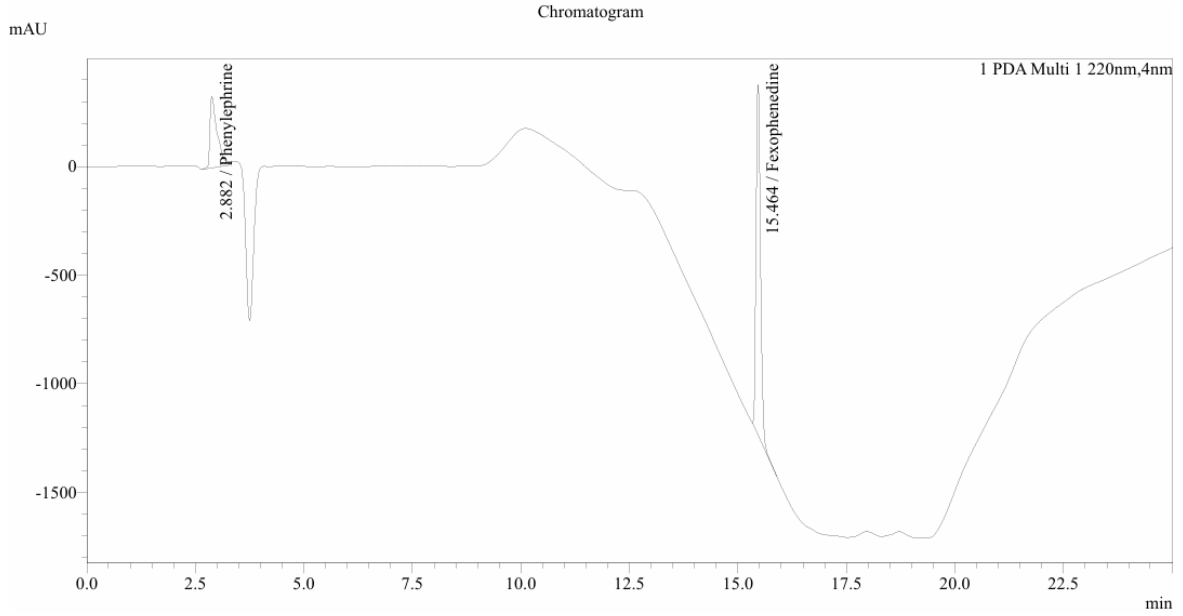


Figure 11: 1.1 ml of Flow rate.

1) Phenylephrine

Table 11: Data for robustness (change in Flow rate)-Phenylephrine hydrochloride.

FLOW RATE	RETENTION TIME	AREA	HEORETICAL PLATE	TAILING FACTOR	SD	%RSD
0.9 ml Flow	2.885	3111217	2178	1.748	57985.448	1.82965
1 ml Flow	2.882	3168627	2215	1.788		
1.1 ml Flow	2.882	3227186	2219	1.794		

2) Fexofenadine

Table 12: Data for robustness (change in Flow rate)-Fexofenadine hydrochloride.

FLOW RATE	RETENTION TIME	AREA	THEORETICAL PLATE	TAILING FACTOR	SD	%RSD
0.9 ml Flow	15.470	11590353	103156	1.250	64453.300	0.55694
1 ml Flow	15.578	11626500	105071	1.245		
1.1 ml Flow	15.464	11501269	105425	1.254		

Ruggedness

1) Phenylephrine

ANALYST	INJECTION	PEAK AREA	AVERAGE AREA	SD	%RSD
	01	3368627	3367614.167	11577.03191	0.343775484
	02	3379263			
ANALYST 1	03	3355293			
(std solution)	04	3361184			
	05	3357976			
	06	3383342			
ANALYST1	01	3368995	3416569	67279.79602	1.969221052
(sample solution)	02	3464143			
	001	3760263	3760535.667	28963.97935	0.770208872
	002	3771529			
ANALYST 2	003	3777203			
(std solution)	004	3777302			
	005	3774095			
	006	3702822			
ANALYST 2	001	3790240	3772007	25785.35588	0.683597774
(sample solution)	002	3753774			

2) Fexofenadine

ANALYST	INJECTION	PEAK AREA	AVERAGE AREA	SD	%RSD
	01	11626500	11592128.67	37285.08393	0.321641391
	02	11549381			
ANALYST 1	03	11552378			
(std solution)	04	11628377			
	05	11620176			
	06	11575960			
ANALYST1	01	11744055	11683407	85769.22413	0.734111412
(sample solution)	02	11622759			
	01	11599844	11418949.5	149955.9891	0.061423406
	02	11599894			
ANALYST 2	03	11388147			

(std solution)	04	11388507			
	05	11249617			
	06	11288988			
ANALYST 2	01	11606686	11588615.5	25555.54618	0.220522859
(sample solution)	02	11570545			

Table 13: Ruggedness.

NAME	ANALYST	AVERAGE PERCENTAGE
PHENYLEPHRINE	ANALYST 1	100.0056968
	ANALYST 2	100.3404574
FEXOFENADINE	ANALYST 1	101.2748445
	ANALYST 2	101.5216575

CONCLUSION

Analytical methods using RP-HPLC were successfully developed for fexofenadine hydrochloride & phenylephrine hydrochloride.

The developed methods were validated with various parameters like accuracy, precision, linearity, robustness, ruggedness, interday precision etc, as per ICH guidelines. The results obtained were within the limits of Indian pharmacopoeia (IP).

The simple, rapid, accurate and an isocratic RP-HPLC method showed excellent sensitivity, reproducibility, accuracy, and repeatability. Hence it is suggested that the proposed and Gradient RP-HPLC method can be effectively applied for the routine quality control analysis of the drug fexofenadine hydrochloride combination with phenylephrine hydrochloride (API) and suspension formulation.

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