Ind. J. Pharm. Edu. Res., 2026; Krupapharmacon:232-244.
https://www.ijper.org

Original Article

A New Sensitive Isocratic RP-HPLC Method Development and Validation for Simultaneous Estimation of Fexofenadine Hydrochloride, Paracetamol and Phenylephrine Hydrochloride in Fixed Dose Tablet

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ABSTRACT

Introduction: The purpose of this research project is to develop and validate a new simple, rapid and sensitive RP-HPLC method for Simultaneous Quantification of Fexofenadine Hydrochloride, Paracetamol and Phenylephrine Hydrochloride in fixed dose Tablet. **Materials and Methods:** The three analytes are separated by HPLC using an X-bridge Shield column (250 × 4.6 mmID, 5 µm) as the stationary phase and a moving phase that contains Orthophosphoric Acid (0.1%), pH was maintained to 6.0 with sodium hydroxide and acetonitrile in a 65:35 ratio. The HPLC analysis were carried out at flow rate of 1 mL min^{-1}, column oven temperature 35ºC at peak detection of 220nm with Photo diode array Detector. The analytical approach developed in this study was validated as per ICH recommendations. **Results:** These optimized RP-HPLC method shows excellent linearity between 24 to 36 µg/mL for Fexofenadine Hydrochloride, 4 to 6 µg/mL for phenylephrine hydrochloride and 128-192 µg/mL for Paracetamol and correlation coefficient were determined as 0.9998, 0.9994 and 0.9990 respectively. The precision of six repeated measurements RSD did not exceed 2%. **Conclusion:** The optimized RP-HPLC method demonstrated Linearity, accuracy, precision, specificity and Robustness for Simultaneous Quantitative estimation within short duration of time.

Keywords: Fexofenadine Hydrochloride (FEH), Paracetamol (PARA), Phenylephrine Hydrochloride (PEH), RP-High Performance Liquid Chromatography, Method Validation.

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INTRODUCTION

Fexofenadine Hydrochloride (FEH) is illustrated as 2-[4-[1-hydroxy-4-[4-[hydroxy(diphenyl)methyl] piperidin-1-yl] butyl] phenyl]-2-methylpropanoic acid, molecular formula $C_{32}H_{40}ClNO_4$ and molecular weight 538.10g/mol (Figures 1-4).[1]

Phenylephrine Hydrochloride (PEH) is described as 3-[(1R)-1-Hydroxy-2-(methylamino) ethyl] phenol, molecular formula $C_9H_{13}NO_2$ and molecular weight 167.20g/mol.[2]

Paracetamol (PARA) structurally written as N-(4-hydroxyphenyl) acetamide, molecular formula $C_8H_9NO_2$ and molecular weight 151.16g/mol.[3-5]

Fexofenadine Hydrochloride (FEH) is an antihistamine that belongs to second generation and primarily effective for allergic conditions.[6] Phenylephrine Hydrochloride (PEH) exhibits selective agonistic activity toward α_1-adrenergic receptors, widely employed for congestion reliever, vasopressor and mydriatic agent. Paracetamol (PARA) is used as analgesic- (pain reliever) and-antipyretic (fever reducer).[7,8]

The various literature review reveals that, several RP-HPLC, HPTLC, UV spectroscopy and bioanalytical methods, has been reported for Fexofenadine hydrochloride and also in combination with paracetamol or with phenylephrine.[9-24] Yet no RP-HPLC technique has been specified so far for these three component dosage forms. Hence, the thought of interest in the field of developing a new sensitive RP-HPLC technique for concurrent quantification of Fexofenadine Hydrochloride, Phenylephrine and Paracetamol in Fixed dose tablet. Hence, This particular study was developed and validated in accordance with ICH Q2(R1) guideline.[25]

DOI: 10.5530/ijper.krupapharmacon.40

MATERIALS AND METHODS

Chemicals and Reagents

Paracetamol (PARA), Fexofenadine Hydrochloride (FEH) and Phenylephrine Hydrochloride (PEH) standard drugs were sourced from BioOraganics Pvt. Ltd., Peenya, Bengaluru, India. For HPLC and analytical method solvents and reagents used were highly graded. For all the analysis purpose Milli Q HPLC water was used. Acetonitrile & Orthophosphoric Acid were obtained from JT Baker and Spectrochem respectively. Fexofenadine Hydrochloride, Paracetamol and Phenylephrine Hydrochloride (NAMCOLD FX) label claim 60mg, 325 mg and 10 mg respectively were brought from local market.

Instrumentation

HPLC (Waters E2695 HPLC) consists of quaternary pump, standard auto sampler, X-Bridge Shield (250 × 4.6 mmID, 5 µm), PDA detector with empower Software, Mettler Toledo weighing balance, Horiba pH meter and SV scientific ultrasonicator were used while performing the analysis.

Method

Preparation of Diluent

500 mL of Water and acetonitrile equally were measured accurately and transferred to a 1-L glass bottle, mixed well, further sonicated to degas. These diluents were used in the preparation of standard and sample solution

Preparation of mobile phase

- **Mobile Phase-A:** Dissolved 1 mL of 0.1% orthophosphoric acid in 1 L-of water; the pH was modified to 6 through the addition of sodium hydroxide solution. Degassing of prepared mobile phase was done by mixing and sonication.
- **Mobile Phase B:** Accurately measured 1000 mL of acetonitrile and placed in a 1000 mL glass bottle, sonicated to degas.

PREPARATION OF STANDARD-STOCK SOLUTIONS

Preparation of Fexofenadine hydrochloride (FEH) stock solution

Precisely weighed portion of 30.110 mg of FEH was aliquoted into a 50 mL volumetric flask, and the flask was filled up to the calibration mark with diluent after complete dissolution. Pipetted out 1 mL of FEH stock solution into a 20 mL volumetric flask and volume was adjusted to 20 mL using diluent to obtain solution strength of 30 µg/mL.

Preparation of Phenylephrine hydrochloride (PEH) stock solution

An exactly weighed measure of 20.070 mg Phenylephrine Hydrochloride (PEH) was added to 100 mL volumetric flask, the analyte was completely dissolved and subsequently diluted to the calibration mark with diluent. An aliquot of 0.5 mL of PEH was accurately introduced to a 20 mL volumetric flask and the solution was diluted to 20 mL using diluent to get the solution strength as 5 µg/mL.

Preparation of paracetamol stock solution

Precisely weighed quantity of 32.530 mg of paracetamol was taken to a 20 mL volumetric flask, upon complete dissolution, the flask was filled to the calibration mark using diluent. 2 mL of paracetamol was pipetted out and transferred into a 20 mL volumetric flask and volume was made up to 20 mL using diluent to obtain solution strength to 162 µg/mL.

Preparation of mixed standard solution

A trinary mixed solution for standards was formulated by aliquoting 0.5mL of phenylephrine hydrochloride, 2 mL of paracetamol and 1 mL of Fexofenadine hydrochloride stock solutions to 20 mL volumetric flask respectively and volume was made up to 20 mL with diluent.

Preparation of assay sample solution

20 marketed tablet formulation (Namcold FX, 325 mg, 60 mg and 10 mg) weighed exactly and pulverized. The powdered tablet weight equivalent to 325 mg of paracetamol, 60 mg of fexofenadine hydrochloride and 10mg of phenylephrine introduced into a 10 mL volumetric flask and sonicated for 15 min. The solution was cool down to room temperature and the volume was made up to 10 mL with diluent, the solution was first filtered using Whatman filter paper and subsequently passed through a 0.45 µm membrane filter. Pipetting out 0.5 mL of sample solution and-was added to a 100 mL volumetric flask and volume was made up to 100 mL using diluent to get the final concentration of 162 µg/mL of Paracetamol (PARA), 30 µg/mL of Fexofenadine Hydrochloride (FEH) and 5 µg/mL of Phenylephrine Hydrochloride (PEH).

RESULTS

Optimization of Chromatographic Conditions

RP-HPLC technique was enhanced to get reliable and consistent results. Mode of HPLC technique is selected depending upon the polarity, molecular weight and the solubility of the molecule of interest. The drugs of our interest are polar in nature due to which we have selected RP-HPLC technique. To develop an optimized reverse phase chromatographic technique, we have used non-polar stationary phases like C8 and C18 columns along with buffers like orthophosphoric acid were used. The core objective of the optimized RP-HPLC technique developed is to obtain well

resolved and sharp peaks having tailing-factor not exceeding 2, retention time-ranges 1 - 6 min and number of theoretical plates greater than 2000.

Hence, this developed method uses X-bridge, shield (250 mm × 4.6 mmID, 5 µm) column to achieve proper, separation of Fexofenadine Hydrochloride (FEH), Phenylephrine Hydrochloride (PEH) and Paracetamol (PARA). The mobile phases consist of 100% acetonitrile and 0.1%-orthophosphoric acid buffer in the proportion of 35:65. The pH of the orthophosphoric acid was adjusted to 6 using 1M sodium hydroxide solution. Flow rate of 1 mL/min was chosen to obtain well resolved and sharp peaks. Column temperature was set to 35°C to maintain sample stability throughout the analysis. The samples were detected at 220 nm with Photodiode Array (PDA) detector and injection volume was set to 20 µL.

The chromatograms obtained from the standard solution showed well resolved and sharp peaks for Fexofenadine hydrochloride, Phenylephrine hydrochloride and Paracetamol at 5.248 min, 2.687 min and 3.312 min respectively. The chromatogram obtained from the prepared sample solution of NAMCOLD FX tablets showed well resolved and sharp peaks for Fexofenadine hydrochloride, Phenylephrine hydrochloride and Paracetamol at 5.251 min, 2.703 min, and 3.382 min. The chromatogram of the standard solution is shown in Figure 5, while the chromatogram of NAMCOLD FX tablets sample solution is shown in Figure 6.

Method-Validation

Validation for the developed method were conducted recommended by ICH guideline Q2(R1) The subsequent validation parameters were system suitability, linearity, accuracy, precision, specificity and robustness.

System Suitability

The system suitability testing was carried out by 6 replicates of standard solution and chromatograms were obtained. System suitability is performed to verify the compatibility of the developed method for simultaneous quantification of Phenylephrine hydrochloride (PEH), Fexofenadine hydrochloride (FEH) and Paracetamol (PARA) using RP-HPLC. The % RSD for peak area, theoretical plates and tailing factor were obtained and discovered as within acceptance criteria. The obtained chromatogram and results are shown in Figure 7 and in Table 1 respectively.

Linearity

The linearity of this developed method-were tested preparing 5 standard-solutions from 80%-120% of phenylephrine-hydrochloride, fexofenadine hydrochloride and paracetamol and injected in triplicate. The calibration

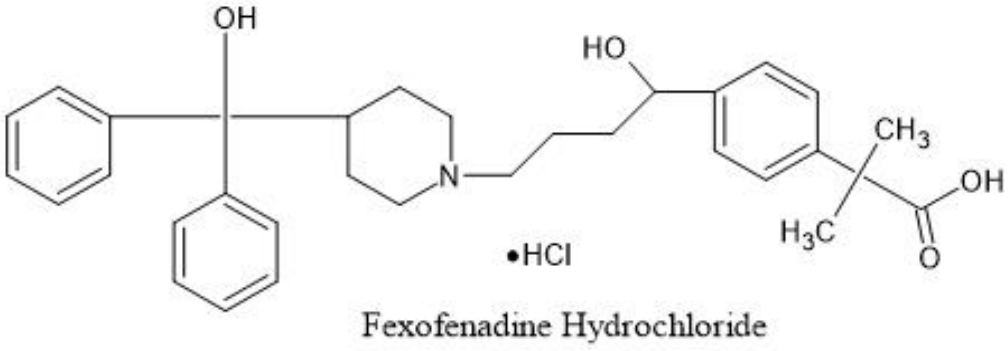

Figure 1: Structural representation of Fexofenadine Hydrochloride.

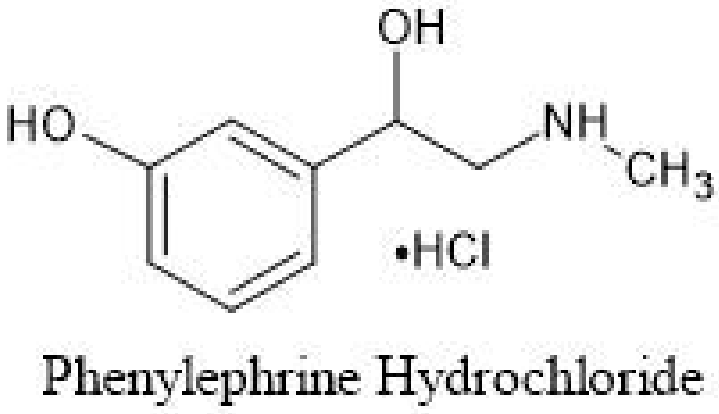

Figure 2: Structural representation of Phenylephrine Hydrochloride.

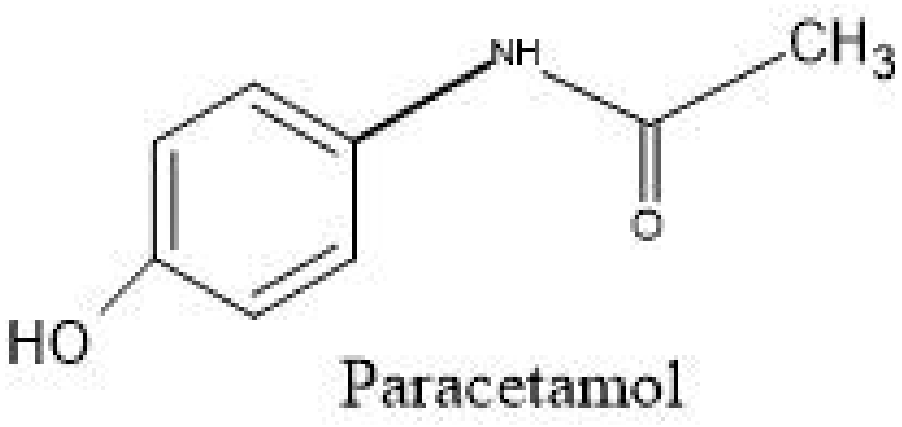

Figure 3: Structural representation of Paracetamol.

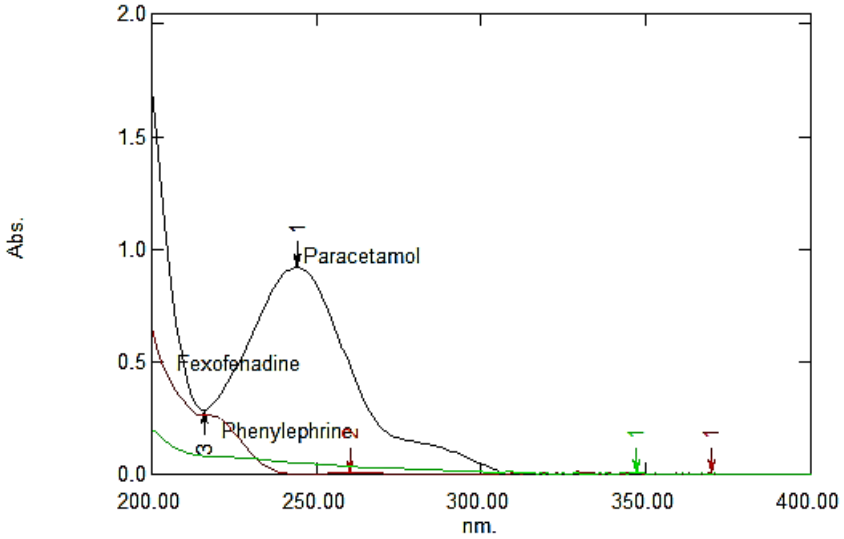

Figure 4: An Overlaid Spectrum of Paracetamol, Fexofenadine and Phenylephrine.

Table 1: System Suitability Test.

Sl. No.	System suitability parameter	Observations			Acceptable limits
		Fexofenadine hydrochloride	Phenylephrine hydrochloride	Paracetamol	
1.	In the chromatogram obtained with standard solution, the % RSD-for six replicate-injections of fexofenadine hydrochloride, phenylephrine hydrochloride, and paracetamol peak.	0.17	0.16	0.27	Not more than 2.0
2.	In the chromatogram obtained with standard solution, USP plate count obtained for fexofenadine hydrochloride, phenylephrine hydrochloride, and paracetamol peak.	6368	6515	5712	Not less than 2000
3.	In the chromatogram obtained with standard solution, USP tailing factor obtained for Fexofenadine Hydrochloride, Phenylephrine hydrochloride-and Paracetamol-peak.	1.2	1.2	1.1	In between 0.8 to 2.0

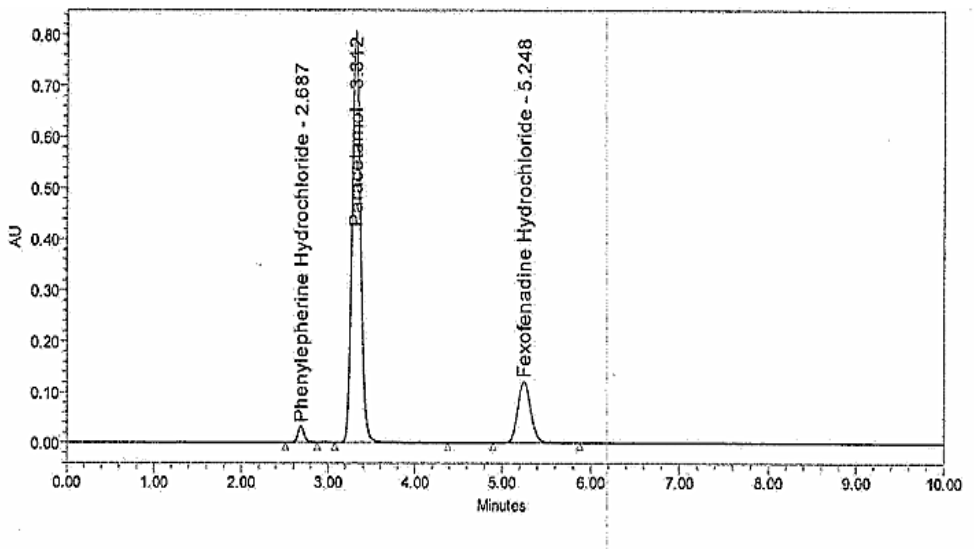

Figure 5: Chromatogram of the standard solution.

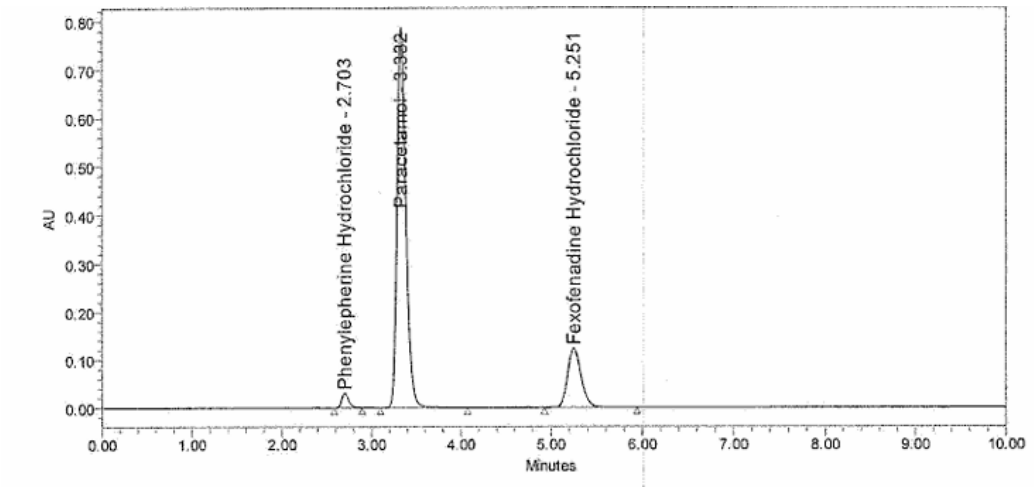

Figure 6: Chromatogram of the sample solution.

curve obtained for phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol are shown in Figures 8-10 respectively. The correlation coefficient for phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol was found out to be 0.9994, 0.9998 and 0.9990 respectively. The obtained results from linearity are illustrated in Table 2.

Precision

Standard solutions are used to identify the precision of the defined analytical procedure and ensure that the analytical system is operating as intended.

System Precision

System precision is executed to check repeatability and reproducibility of the developed procedure. System precision for above-mentioned method is determined by preparing 6 replicate injections of standard solutions. % RSD for peak area response of Phenylephrine hydrochloride (PEH), Fexofenadine hydrochloride (FEH), and Paracetamol (PARA) were calculated and found out 0.123%, 0.166% and 0.178% respectively. System precision outcomes are demonstrated in Tables 3-5.

Method Precision

Method precision was carried out preparing 6 replicates of assay samples and then the % RSD of assay results were calculated. The % RSD for Phenylephrine hydrochloride, Fexofenadine hydrochloride and paracetamol were found to be 0.945%, 0.617% and 0.621% respectively. Method precision observations are depicted in Table 4. The comparative data of method precision and intermediate precision for Phenylephrine hydrochloride, Fexofenadine hydrochloride and Paracetamol are presented in Table 6.

Accuracy

Accuracy of the developed method indicates the correlation with true value of the test results which are obtained from the developed method. Samples spiked 80% - 120% to obtain assay results. Then % RSD for the area responses were measured and

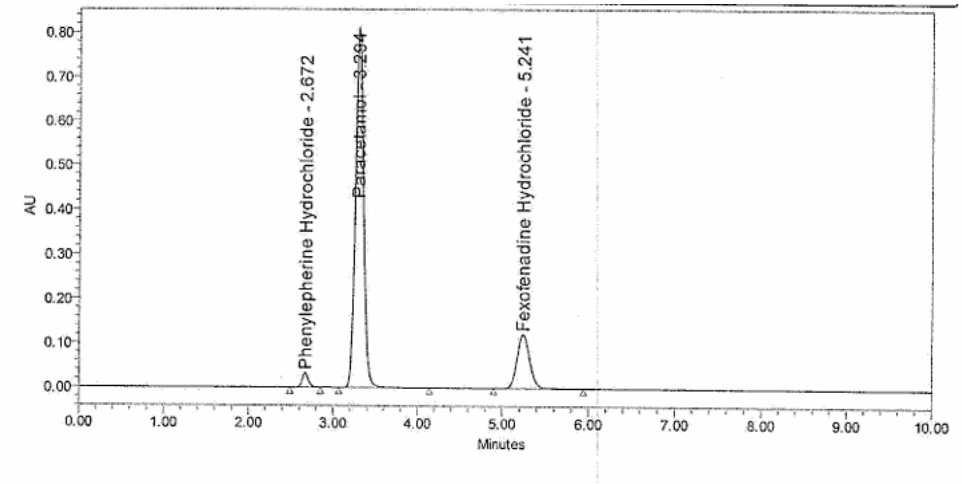

Figure 7: System suitability standard solution chromatogram.

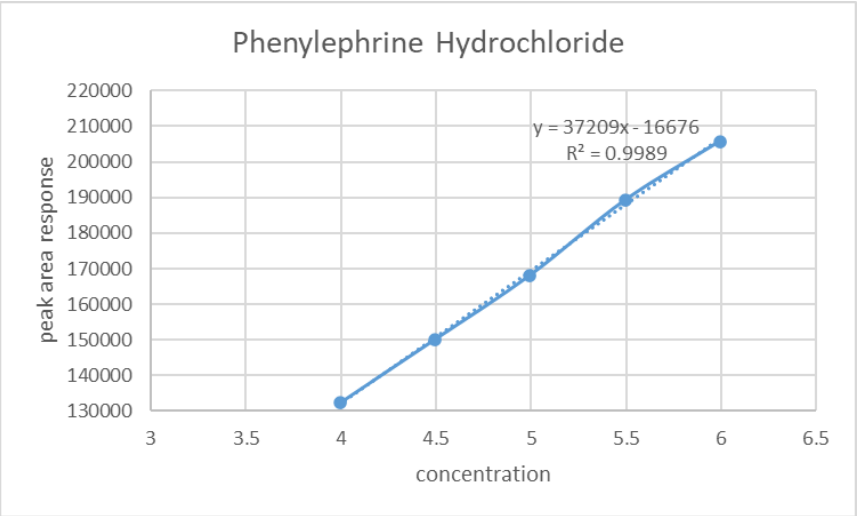

Figure 8: Linearity Plot for phenylephrine hydrochloride.

Table 2: Linearity.

Linearity level	Fexofenadine hydrochloride		Phenylephrine hydrochloride		Paracetamol	
	concentration	-Area response	concentration	-Area response	concentration	- Area response
80%	23.84712	1004184	3.9951342	132367	128.207236	4423589
90%	26.82801	1131205	4.49452598	150190	144.2331405	5081018
100%	29.8089	1276377	4.99391775	168177	160.259045	5662563
110%	32.7897	1408122	5.49330953	189237	176.2849495	6162541
120%	35.77068	1550011	5.9927013	205754	192.310854	6758918
Standard Deviation	216430		29397		910381	
Correlation Coefficient	0.9998		0.9994		0.9990	
slope	45912		37209		35893	
intercept	-94595		-16676		-134455	
Regression equation	Y=45912x-94595		Y=37209x-16676		Y=35893x-134455	

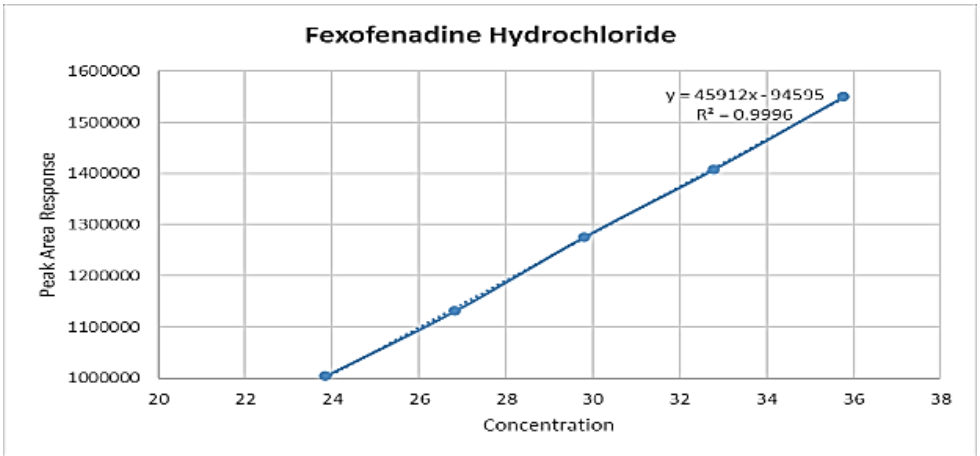

Figure 9: Linearity Plot for Fexofenadine Hydrochloride.

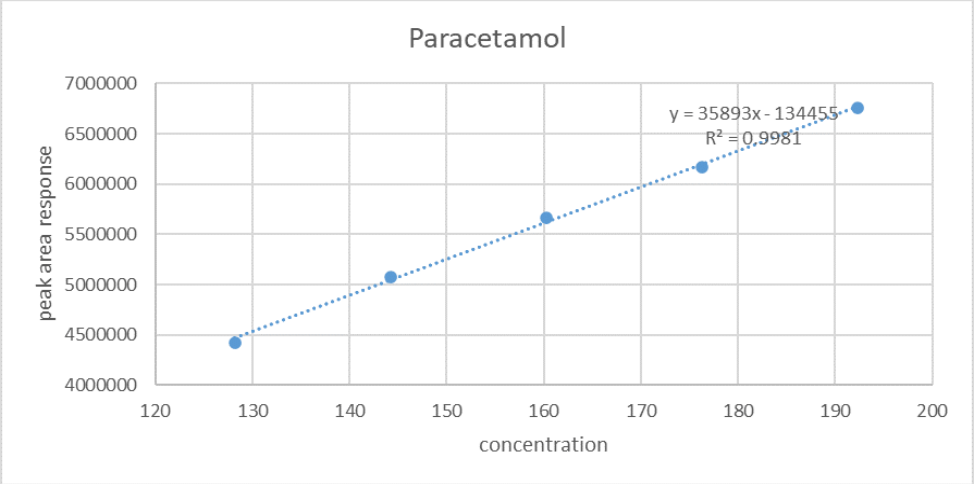

Figure 10: Peak area versus concentration plot for Paracetamol.

the % purity of these assay samples were obtained containing phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol. The % RSD obtained from these assays must be not more than 2% and % purity must lie within the range of 95% to 105% according to ICH Q2(R1) guideline. % purity of these assay samples of phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol were 96.4%, 103.1% and 99.1% respectively. The accuracy results for phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol are shown in Tables 7-9 respectively.

Robustness

Robustness is performed by intentionally varying the flow rate and temperature to authenticate the ruggedness and flexibility of the developed method. To carryout robustness the samples were eluted through column at a flow rate of 0.9 mL/min and 1.1 mL/min; and temperature was set at 33°C and 37°C. To ensure the robustness of developed method,% RSD of area responses was calculated and the chromatogram showed well resolved and sharp peaks. Robustness result for the developed method after deliberately changing the flow rate and temperature are depicted in Tables 10 and 11 respectively. The % RSD under flow rate 0.9 mL/min and 1.1 mL/min for fexofenadine hydrochloride, phenylephrine hydrochloride and paracetamol were 0.80%, 0.82% and 0.79% and 0.47%, 0.72% and 0.39% respectively. The % RSD for samples kept under the temperature of 33°C and 37°C for phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol were 0.50%, 0.45% and 0.42% and 0.59%, 0.54% and 0.53% respectively.

Specificity

Specificity of the approach was carried out to confirm the analyte peaks were not interfered with by other components of the formulation. specificity was demonstrated through a comparison of the chromatograms of the blank(diluent), standard and sample solutions. The blank solution showed no peaks at the retention times of the analytes, indicating that diluent or mobile phase did not contribute any interference. The standard solutions and sample solution demonstrated well-resolved peaks at retention times of 2.689 min for Phenylephrine Hydrochloride, 3.321 min

for Paracetamol and 5.246 min for Fexofenadine Hydrochloride with no co-eluting peaks observed in the vicinity of the analyte peaks. The obtained chromatograms of phenylephrine hydrochloride, fexofenadine hydrochloride and paracetamol are shown in Figures 11-13, respectively. Further, analytes peak purity result was evaluated by photodiode array detector (PDA).

Table 3: System Precision.

Injection No.	PEAK AREA		
	Fexofenadine hydrochloride	Phenylephrine hydrochloride	Paracetamol
1	1218950	166387	5400949
2	1218220	166752	5407698
3	1214416	166217	5390987
4	1217015	166521	5396217
5	1217671	166516	5400638
6	1220438	166736	5418637
mean	1217785	166521.5	5402521
RSD	0.001664	0.001231	0.001786
%RSD	0.166439	0.123065	0.178564

Table 4: Method Precision.

Method Precision			
Number of Injection	Assay		
	Fexofenadine Hydrochloride	Phenylephrine Hydrochloride	Paracetamol
1	103.1460	96.4836	99.7893
2	103.3434	96.3446	99.9943
3	103.4590	96.7435	100.0788
4	103.4101	98.6672	100.0661
5	104.8953	97.9741	101.5009
6	103.4028	97.0625	100.0660
MEAN	103.6094	97.21258	100.2492
SD	0.639384	0.919042	0.622794
RSD	0.006171	0.009454	0.006212
%RSD	0.61711	0.945394	0.621245

Table 5: Intermediate Precision.

Area						
s.no	Phenylephrine		Paracetamol		Fexofenadine	
	Day 1	Day 2	Day 1	Day 2	Day 1	Day 2
1	160344	160845	5440163	5452281	1249414	1248765
2	160113	161547	5447973	5482635	1250967	1250762
3	160776	160864	5451569	5454022	1251948	1253868
4	163973	162066	5456600	5471022	1253031	1252984
5	162821	163025	5530059	5482642	1269753	1257586
6	161630	161542	5468380	5468357	1255456	1265432
Average	161609.5	161648.1667	5465790.667	5468493.167	1255094.833	1254899.5
Standard Deviation	1522.498571	818.7496361	32857.55322	13257.77875	7462.77609	5960.452458
%RSD	0.942084823	0.506501034	0.601149133	0.24243934	0.594598583	0.474974487

Table 6: Comparative Data of Method Precision and Intermediate Precision.

Parameter	Injection number	Area (phenylephrine)	Area(paracetamol)	Area(fexofenadine)
Method precision	1	160344	5440163	1249414
	2	160113	5447973	1250967
	3	160776	5451569	1251948
	4	163973	5456600	1253031
	5	162821	5530059	1269753
	6	161630	5468380	1255456
Intermediate Precision	1	160845	5452281	1248765
	2	161547	5482635	1250762
	3	160864	5454022	1253868
	4	162066	5471022	1252984
	5	163025	5482642	1257586
	6	161542	5468357	1265432
mean of 12 units		161628.8333	5467141.917	1254997.167
Standard deviation		1165.65431	23929.53296	6440.035062
%RSD		0.721192058	0.437697307	0.513151363

Table 7: Accuracy Data for Phenylephrine Hydrochloride.

%	Preparation	Peak Area of Preparation (At)	Average Peak Area of Standard (As)	Concentration of Standards (Cs)	Concentration of Preparation (Ct)	% Purity of Standard (%Ps)	mean% recovery ± SD	Average% Purity
80	1	126409	166522	0.00499	0.00399	94.490	94.608±0.122	96.4
80	2	126557	166522	0.00499	0.00399	94.601		
80	3	126734	166522	0.00499	0.00399	94.733		
120	1	196376	166522	0.00499	0.00599	97.779	98.145±0.319	
	2	197406	166522	0.00499	0.00599	98.292		
	3	120	166522	0.00499	0.006	98.363		
		120						

Table 8: Accuracy Data for Fexofenadine Hydrochloride.

%	Preparation	Peak Area of Preparation	Average Peak Area of Standard	Concentration of Standards (mg/mL)	Concentration of Preparation (mg/mL)	% Purity of Standard	mean% recovery ± SD	Average% Purity
80	1	982519	1217785	0.03007	0.02395	101.287	101.558 ± 0.377	103.1
80	2	985270	1217785	0.03007	0.02399	101.402		
80	3	989293	1217785	0.03007	0.02395	101.986		
120	1	1522082	1217785	0.03007	0.03598	104.447	103.611±0.185	
120	2	1526273	1217785	0.03007	0.03595	104.822		
120	3	1530481	1217785	0.03007	0.03603	104.878		

For each analyte, the peak purity angle was observed to be fewer than the peak purity threshold, confirms the peaks were spectrally homogeneous and free from interference. This observation concludes that the developed analytical method is specific for the simultaneous quantification of PEH, PARA and FEH, even in the absence of a placebo formulation and it is shown in Tables 12-14 respectively

DISCUSSION

The developed method displayed acceptable linearity in the concentration range 80%-120% and regression coefficient was found out to be greater 0.999 for the simultaneous quantification of PEH, FEH and PARA. The % RSD value has not extended by 2% indicates this proposed method is precise and robust for simultaneous quantification of PEH, FEH and PARA. Percentage purity of PEH, FEH and PARA were discovered to be 96.4%, 103.1% and 99.1% respectively, according to ICH Q2 (R1) guideline

Table 9: Accuracy Data for Paracetamol.

%	Preparation	Peak Area of Preparation (At)	Average Peak Area of Standard (As)	Concentration of Standards (Cs)	Concentration of Preparation (Ct)	% Purity of Standard (%Ps)	mean% recovery ± SD	Average% Purity
80	1	4325076	5402521	0.16056	0.12975	97.799	98.077 ± 0.319	99.1
80	2	4342297	5402521	0.16056	0.12999	98.007		
80	3	4353755	5402521	0.16056	0.12978	98.424		
120	1	6642158	5402521	0.16056	0.19494	99.966	100.203 ± 0.212	
120	2	6655674	5402521	0.16056	0.19475	100.268		
120	3	6678503	5402521	0.16056	0.19521	100.374		

Table 10: Robustness Data for Flow Rate Variation.

Analyte	Flow Rate (mL/min)	Mean RT (min)	Mean Peak Area	Tailing Factor (Avg)	%RSD of Peak Area	Resolution	Theoretical Plates
Paracetamol	0.9	4.137429	6830747	1.285714	0.392568	4.2	6220
	1.1	3.385714	5621929	1.2	0.7989	3.9	5680
Phenylephrine HCl	0.9	3.356	199222.3	1.3	0.474614	Nil	7633
	1.1	2.746714	164733	1.2	0.820796	Nil	6262
Fexofenadine HCl	0.9	6.500714	1544683	1.2	0.722978	8.8	6780
	1.1	5.336429	1272402	1.2	0.80591	8.6	6395

Table 11: Robustness Data for Temperature Variation.

Analyte	Column temperature (°C)	Mean RT (min)	Mean Peak Area	Tailing Factor (Avg)	%RSD of Peak Area	Resolution	Theoretical plates
Paracetamol	33	3.505429	5757535	1.2	0.421954	4	5680
	37	3.562143	5911583	1.3	0.53719	3.9	5840
Phenylephrine HCl	33	2.834143	169475	1.285714	0.501636	Nil	6526
	37	2.898143	172536.1	1.2	0.594305	Nil	6706
Fexofenadine HCl	33	5.521429	1302079	1.2	0.454436	8.5	6321
	37	5.624	1336276	1.2	0.549101	8.7	6582

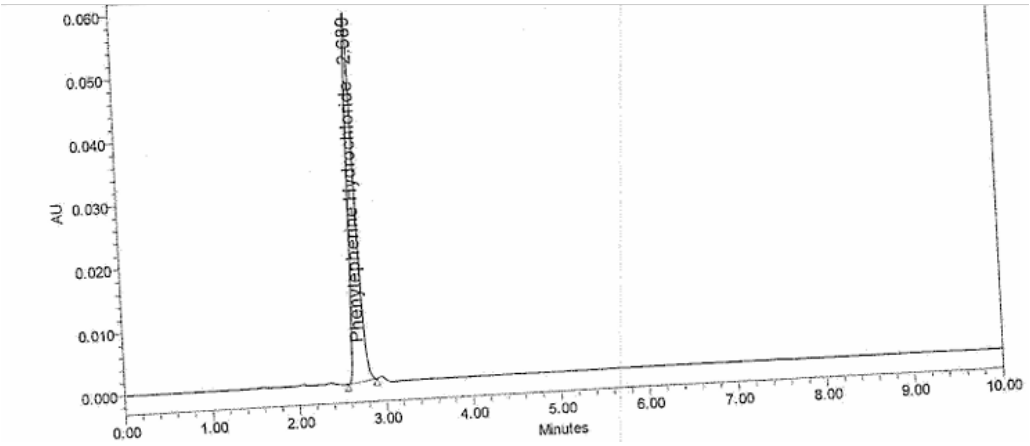

Figure 10: Phenylephrine Hydrochloride.

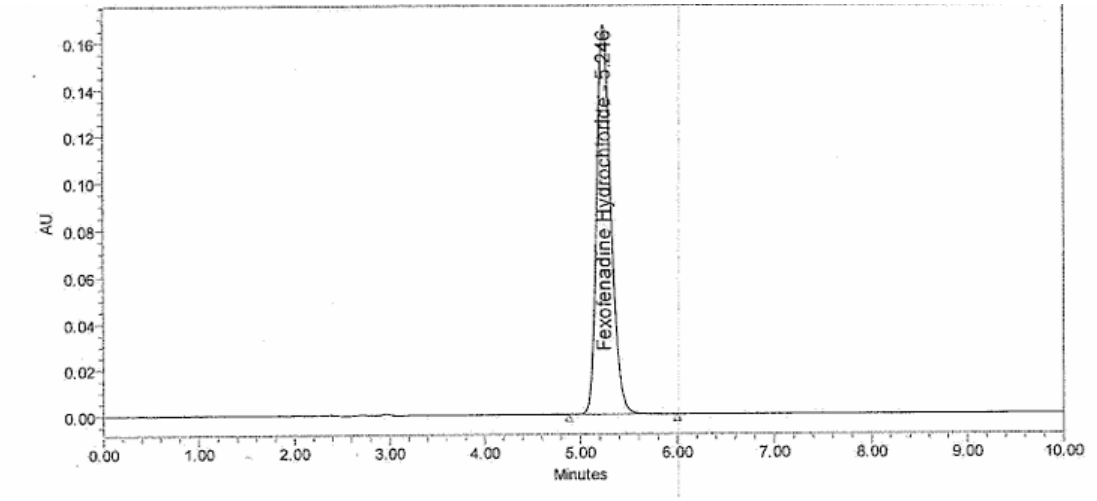

Figure 11: Fexofenadine Hydrochloride.

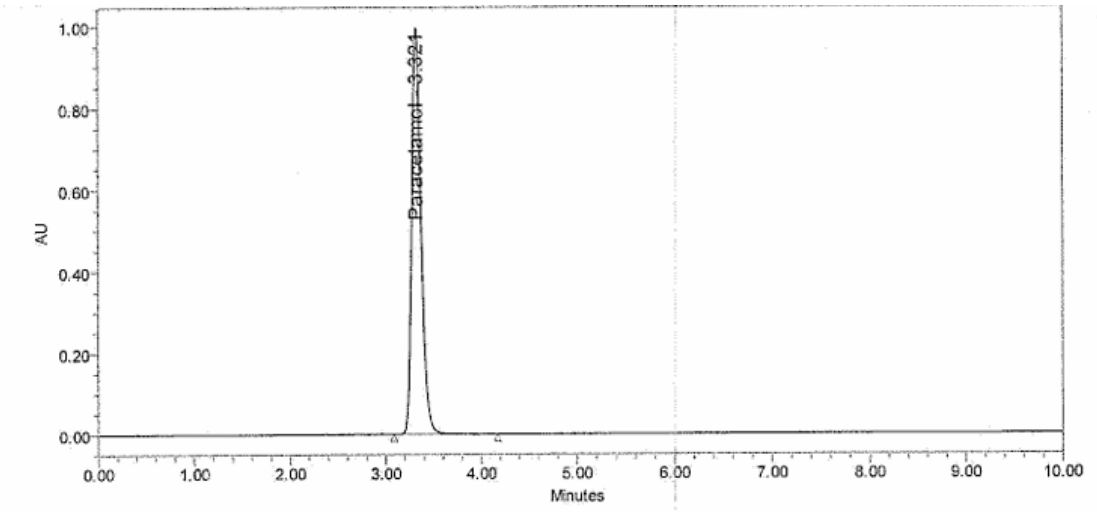

Figure 12: Paracetamol.

Table 12: Peak Purity Evaluation of Fexofenadine Hydrochloride.

Fexofenadine Hydrochloride			
Solution name	**Purity angle**	**Purity threshold**	**Results (peak purity)**
Standard	0.448	1.796	Pass
Sample	0.336	1.544	Pass

Table 13: Peak Purity Evaluation of Phenylephrine Hydrochloride.

Phenylephrine Hydrochloride			
Solution name	**Purity angle**	**Purity threshold**	**Results (peak purity)**
Standard	0.725	2.507	Pass
Sample	0.812	2.452	Pass

Table 14: Peak Purity Evaluation of Paracetamol.

Paracetamol			
Solution name	**Purity angle**	**Purity threshold**	**Results (peak purity)**
Standard	0.229	1.440	Pass
Sample	0.141	1.550	Pass

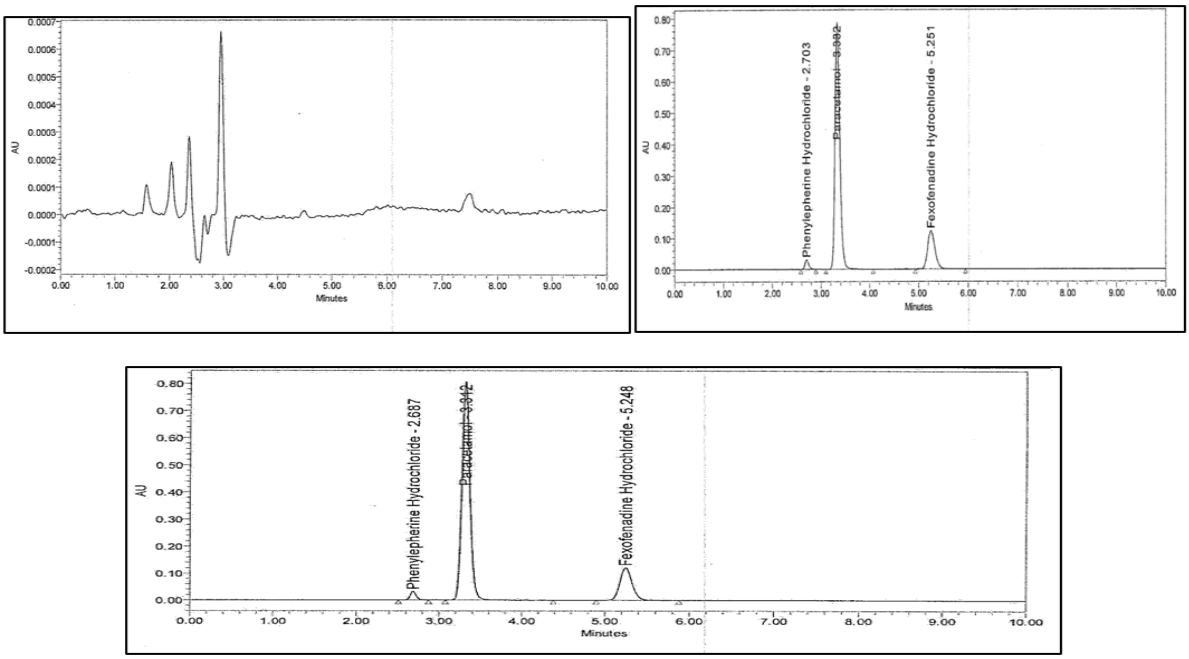

Figure 13: Specificity Chromatogram for Blank, Sample and Standard Showing no Interference at The RT of Analytes.

the % assay purity value lies in the range of 95-105%. Thus, the developed method is accurate in the range of 80% and 120%. The standard drugs along with the tablet formulation demonstrated well-resolved peaks and also none of the formulation excipients were showing interference with formulation drug peaks.

CONCLUSION

The developed isocratic RP-HPLC analytical procedure for concurrent Quantification of PEH, FEH and PARA were determined to be simple, specific, accurate and analysis require less run time with less consumption of solvents. The interpretation of analytical data prove that the proposed method is reproducible, selective for the analysis of PEH, FEH and PARA in bulk and tablet formulations with no intrusion from excipients. The developed method can be used for routine analysis of PEH, FEH and PARA tablets.

ACKNOWLEDGEMENT

The authors are grateful to BioOrganics Bangalore, India for providing gift samples and to the department of pharmaceutical analysis, Institute of Pharmacy, PES University for providing laboratory facilities for their research.

ABBREVIATIONS

PEH: Phenylephrine Hydrochloride; **FEH:** Fexofenadine Hydrochloride; **PARA:** Paracetamol.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Cite this article: Babu VC, Patra BR. A New Sensitive Isocratic RP-HPLC Method Development and Validation for Simultaneous Estimation of Fexofenadine Hydrochloride, Paracetamol and Phenylephrine Hydrochloride in Fixed Dose Tablet. Indian J of Pharmaceutical Education and Research. Krupapharmacon 2026:232-44.