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Rising Clinical Risks Linked to Herb-Drug Interactions in Modern Medical Practice

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ABSTRACT

Rapid, sensitive, and selective analytical techniques are crucial for tracking the many reaction stages in the creation of the antibacterial drug gatifloxacin. A straightforward isocratic reverse phase High Performance Liquid Chromatography [HPLC] technique was created to separate several intermediates and other contaminants at the same time. The technique was effectively used for drug testing, reaction stream analysis, and associated compounds in the end product.

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INTRODUCTION

Impurity profiling is the common name of a group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. Since this is the best way to characterize the quality and stability of bulk drugs and pharmaceutical formulations, this is the core activity in modern drug analysis. Due to the very rapid development of the analytical methodologies available for this purpose and the similarly rapid increase of the demands as regards the purity of drugs it is an important task to give a summary of the problems and the various possibilities offered by modern analytical chemistry
for their solution.

Gatifloxacin level in biological fluids, in different pharmaceutical formulations and as a raw material for related substances have previously been determined by spectrophotometric, gas chromatographic [HPLC] techniques. Literature surveys reveal hardly any method for the analysis of reaction mixture obtained in the preparation of Gatifloxacin. There is an increasing need for rapid and sensitive method for the determination of raw materials, intermediates and finished products in reaction stream during process development of Gatifloxacin. The HPLC system consisted of Jasco make UV/VIS detector model 1575, along with Borwin software (Integrator) were used. Analysis were performed on Stainless steel column containing C-18 packing, 5 □ ODS [25 cm x 4.6 mm].

EXPERIMENTAL

CHROMATOGRAPHIC CONDITION: -

COLUMN: 250 mm x 4.6 mm i.e. - Stainless steel column containing C18, 5 □

MOBILE PHASE: BUFFER: ACETONITRILE (80: 20)

FLOW RATE: 1.0 ml / minute.
DETECTOR WAVELENGTH: 210 nm.
SAMPLE SIZE: 20 □l.
The approximate Retention Times that should be obtained using these chromatographic conditions are:
GATIFLOXACIN approximate retention time = 1.85 Minutes
2-Methyl Piperazine approximate retention time =
04.46 Minutes.

PREPARATION OF MOBILE PHASE:
Buffer [0.025 gm Ortho Phosphoric acid] 80 v & 20 v of Acetonitrile. Adjust pH 3.0 by TEA.

PREPARATION OF THE TEST SOLUTION FOR ANALYSIS OF GATIFLOXACIN:
Amber glassware must be used when preparing these solutions because GATIFLOXACIN is Photosensitive.
ANALYTICAL STANDARD SOLUTION
Accurately weigh 100 mg [□ 5 mg] of Working standard of GATIFLOXACIN & transfer to a 50 ml volumetric flask. Add 10 ml of mobile phase &
sonicate until dissolved. Allow to cool to room temperature & dilute to volume with mobile phase.
Accurately weigh 5 mg [□ 1 mg] of the working standard of 2-Methyl Piperazine & transfer to 50 ml volumetric flask. Add 10 ml of mobile phase & dilute to volume with mobile phase.
Transfer 4.0 ml of solution [B], in solution [A] in volumetric flask. & Dilute to volume with Mobile phase & mix thoroughly.
PREPARATION OF SAMPLE SOLUTION:
Accurately weigh 100 mg of sample & transfer to 50 ml volumetric flask. Add 10 ml of Mobile phase & sonicate until dissolved. Allow to cool to room temperature & dilute to volume with mobile phase.

INJECTION PRECISION:
Make duplicate injections of the analytical standard solution. Using a computing Integrator measure the GATIFLOXACIN peak area in the injections made.
The relative Standard deviation must not be greater than + 2.0%.
CALCULATION OF RESULTS:
GATIFLOXACIN CONTENT:

$$\text{GATIFLOXACIN Content} = \frac{\text{ASamp.} \times \text{WStd.}}{\text{AStd.} \times \text{WSamp.}} \times P$$

ASamp = Area of GATIFLOXACIN peak in an injection of sample.
AStd. = Mean Area of GATIFLOXACIN Peak in injection of analytical standard solution.
WSamp. = Weight of the sample taken to prepare relevant sample solution. (in mg)
WStd. = Weight of GATIFLOXACIN reference standard taken to prepare analytical standard Solution. (in mg) P = Known Purity of GATIFLOXACIN Reference standard.
2-Methyl Piperazine CONTENT:

$$\text{2-Methyl Piperazine Content} = \frac{\text{ASamp.} \times \text{WStd.}}{\text{AStd.} \times \text{WSamp.}} \times P$$

ASamp. = Area of 2-Methyl Piperazine peak in an injection of sample.
AStd = Mean Area of 2-Methyl Piperazine peak in injections of analytical standard solution.
WSamp. = Weight of the sample taken to prepare relevant sample solution. (in mg)

WStd = Weight of 2-Methyl Piperazine reference standard taken to prepare analytical standard solution. (in mg)
P = Known Purity of 2-Methyl Piperazine reference standard.

RESULTS AND DISCUSSIONS

SYSTEM SUITABILITY:

System suitability data as shown in Table No. 1 shows method is accurate.

Table No. 1: -

Compound	Standard Deviation	RSD	Theoretical Plates	Resolution Factor	Tailing Factor
2-METHYL PIPERAZIN	5.04619	0.6621	5370	1.6	1.1
GATIFLOXACIN	302.6325	1.624284	7271	-	-

SUPPORTING DATA FOR TEST PROCEDURE REPRODUCIBILITY IN ASSAY TEST

Data in Table No. 2 shows method is rugged & reproducible.

Table No. 2

GATIFLOXACIN					2-Methyl Piperazine		
DAY	WEIGHT		X	DAY	WEIGHT		X
	[mg/ml]		[%]		[mg/ml]		[%]
28/09/2004	1		99.32	28/09/2004	0.01		98.73
			98.84				99.12
			99.5				99.36
29/09/2004	1			29/09/2004	0.01		
			99.57				98.83
			99.24				99.21
			99.14				99.08
30/09/2004	1			30/09/2004	0.01		
			99.38				99.33
			99.72				98.54
			99.71				99.34
	AVG. [%]		99.38				99.06
	S.D.		0.2844732				0.29580399
	RSD		0.2862479				0.29861093
	2V		0.5724959				0.59722186

RECOVERY-

Data in Table No. 3 shows method has recovery more than 99% so method is rugged and accurate.

Table No. 3

CONTENT OF GATTIFLOXACINE						SUPPORTING DATA		
						FOR TEST PROCEDURE		
						ACCURACY		

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	Concentration [STD]		A (mg/ml)		B (mg/ml)		X	
	1.0 [mg/ml]		1		0.9778		0.9778	
			1		0.9847		0.9847	
			1		0.9846		0.9846	
			1		1.0031		1.0031	
				X	0.98755			
				S	0.01086			
				CV	1.09949			
100% of Theoretical Concentration 95% Confidence Limits =					0.98755	0.01726426		
CONTENT OF 2-METHYL PIPERAZIN						SUPPORTING DATA		
						FOR TEST PROCEDURE		
						ACCURACY		
	Concentration [STD]		A (mg/ml)		B (mg/ml)		X	
	0.01 [mg/ml]		0.01		0.00993		0.9925	
			0.01		0.00995		0.9946	
			0.01		0.00991		0.9905	
			0.0096		0.00966		1.00614583	

A- Actual Concentration Taken.

S	0.00701		
CV	0.70377		
100% of Theoretical Concentration 95% Confidence Limits =	0.99594	0.01114444	

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B- Actual CONCENTRATION Recover.
C- X-Recovery.

SUPPORTING DATA FOR TEST PROCEDURE ACCURACY

Data in Table No 4.1 and 4.2 show the linearity curve (Slope) & regression data for the product and its impurity, which confirms method, is accurate & reproducible.

Table No. 4.1

CRITERIA MEASURED	DRUG SUBSTANCE ACCEPTANCE VALUE	RESULTS
Concentration Range	40 – 150%	-
Graphic Plot R R2	24 Points	0.99837 0.996743
Average Fractional Recovery [X] (Average of $\bar{x}$ X 100) i.e. = ---------- 6	99 – 101%	100.06%
Slope (A Vs B)	1.00 ideal	1.014
Cv= (i.e. Average of all Cv)	-	0.7730688

RESULTS AND DISCUSSIONS

OUTCOMES AND CONVERSATIONS

In accordance with USP XXVII, system appropriateness was evaluated using a newly made reference solution B to examine a number of metrics, including peak tailing, resolution, and efficiency, all of which were determined to meet USP standards. (See Table No. 1) the amount of a contaminant in gatifloxacin using the suggested technique. The method's accuracy and precision are shown by the lower repeatability numbers. The impurity mean recoveries ranged from 99.3% to 100%, indicating that the mobile phase is not interfering and confirming the method's repeatability and dependability.

CONCLUSION

i) The suggested approach is straightforward, quick, and accurate.

ii) The method's great precision and reproducibility are shown by the very slow percent relative standard deviation, which was less than

iii) The technique for analyzing gatifloxacin and its impurity mentioned above in bulk and in prepared doses for assays and for said Related Substance by HPLC is justified by its short analysis time (less than 10 minutes) as well as its simplicity and convenience of use.

iv) As a result, the procedure may be helpful for regular bulk quality control analysis.

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