Research Article

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Development, Validation of a stability indicating method for the simultaneous determination of Levofloxacin hemihydrate and Ornidazole by High Performance Liquid Chromatography

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Abstract:

A simple, selective, rapid, precise and economical reverse phase high pressure liquid chromatographic method has been developed for the simultaneous estimation of Levofloxacin hemihydrate and Ornidazole in pharmaceutical Tablet dosage form. The mobile phase consisted of 70:30% (v/v) of Methanol & 0.1% v/v orthophosphoric acid operated on isocratic mode. The flow rate is 0.6 ml/min. Chromatographic separation of Levofloxacin hemihydrate and Ornidazole was performed on PHENOMENEX ION PAIR C_{18} column (150 X 4.6 mm id, ODS 2, 5µm). The wavelength of detection is 290 nm. The injection volume is 20µL. The retention time of Levofloxacin hemihydrate and Ornidazole are 2.4 ± 0.10 minutes and 3.8 ± 0.10 respectively. The run time of analysis is 6.2 minutes. The developed method was validated for parameters such as accuracy, precision, linearity, limit of detection, limit of quantitation and solution stability. The influence of acid, alkaline, oxidative Stress and photolytic stress conditions on both the drugs was studied. Results indicated complete degradation in alkaline medium for Levofloxacin hemihydrate and Ornidazole. The proposed method has been successfully used for the estimation in tablet dosage forms.

Keywords: Levofloxacin hemihydrate, Ornidazole, HPLC

Introduction

Levofloxacin(LFH),(-)-(S)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl]-7-oxo 7HPyridol[1,2,3-di]-1,4-benzoxazine-6-carboxylic acid hemihydrate (LFH),is chemically, a chiral fluorinated carboxy quinolone, is the pure (-)-(S)-enantiomer of the racemic drug substance ofloxacin [1] It is used mainly as an antibacterial agent. Ornidazole (ORN), [1-chloro-3 (2- methyl-5-nitroimidazole-1-yl) 2-propanol] is 5-nitroimidazole derivative [2] with antiprotozoal properties against anaerobic bacteria.

Literature survey revealed few methods have been reported for the spectrophotometric methods for the estimation of Levofloxacin hemihydarte, alone or in combination with other drugs in pharmaceutical formulation [3,4]. Ornidazole, alone or in combination with other drugs, is reported to be estimated by spectrophotometry [5-9]and HPLC [10-11]in biological fluids or pharmaceutical formulations. However, no HPLC method for the simultaneous estimation of Levofloxacin hemihydrate and Ornidazole in combined dosage forms has been reported so far. The present work describes the development of simple, precise and accurate isocratic reverse phase HPLC method for simultaneous estimation of LFH and ORN in tablets.

2. EXPERIMENTAL

2.1. Reagents and chemicals

Orthophosphoric acid (AR Grade, Merck ltd), Methanol (HPLC grade, Merck ltd), Milli-Q water, Levofloxacin hemihydrate (99.8 % w/w is a gift sample from Unichem Laboratories Ltd) and Ornidazole (100% w/w purchased from Sigma (LEONOZ), glacial acetic Acid

(GR Grade, SD Fine Chem Ltd). All other chemicals are of the highest grade commercially available unless otherwise specified. LEON OZ tablets for evaluation of the assay content were purchased for a local pharmacy.

2.2. Apparatus and chromatographic conditions

The Chromatographic system consisted of a Shimadzu Class VP Binary pump LC-10ATvp, SIL-10ADvp Auto sampler, CTO-10Avp Column Temperature Oven, SPD-10Avp UV-Visible Detector. All the components of the system are controlled using SCL-10Avp System Controller. Data acquisition was done using LC Solutions software.

The mobile phase consisted of 70:30 % (v/v) of Methanol and 20mM Orthophosphoric acid (pH adjusted to 3.0 with acetic acid) operated on isocratic mode. The flow rate is 0.6 ml/min. Chromatographic determination of Levofloxacin hemihydrate and Ornidazole was performed on C_{18} column (150 X 4.6 mm PHENOEX ION PAIR id, ODS 2, 5µm). The wavelength of detection is 290 nm. The injection volume is 20µL.

Fig-1a: Structure of Levofloxacin

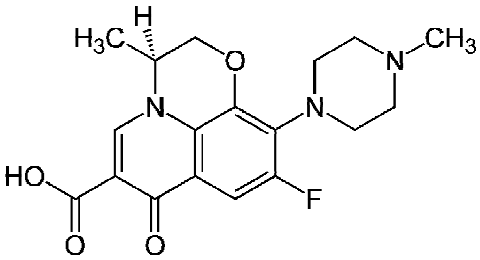
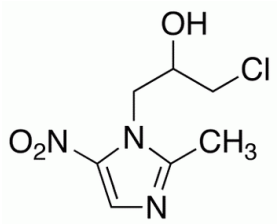


Fig-1b: Structure of Ornidazole



2.3. Preparation of standard solutions, Calibration Standards & Quality Control Samples

Stock solutions of Levofloxacin hemihydrate (1mg/mL), & Ornidazole (1mg/mL) were prepared separately in a volumetric flask using methanol and labeled accordingly. Suitable dilutions were then prepared using 50:50 %v/v Methanol & Milli-Q water as Diluent Solution. A Linear Calibration curve containing 8 non-zero standards were prepared using Diluent solution in the concentration range of 1-10 µg/mL for Ornidazole & 1-10 µg/mL for Levofloxacin hemihydrate. The calibration standard sample is then transferred into the auto sampler for analysis. Samples for Specificity (Sample with Ornidazole alone, sample with Levofloxacin hemihydrate alone, Blank Sample and sample containing both the drugs) were also prepared accordingly.

For the preparation of quality control samples, a separate stock containing approximately the same concentration of the Ornidazole and Levofloxacin hemihydrate were prepared and labeled as quality control stocks. From these stocks, quality control samples containing Ornidazole and Levofloxacin hemihydrate were prepared at three concentration levels namely LQC, MQC, HQC so as to obtain low, median and high concentration quality control samples. The performance of the linear calibration curve is then evaluated using quality control samples.

2.4. Assay

The assay of tablets containing Levofloxacin hemihydrate and Ornidazole (Brand name: LEON OZ) is done using the procedure given in Indian Pharmacopoeia under tablets. The active ingredients in each of 10 dosage units is taken by random sampling and analyzed by the developed method. The tablets are said to be compliant if the each individual content is 85 – 115 % of the average content or labeled claim.

For the current assay ten tablets were randomly taken and transferred separately into 100ml volumetric flasks and dissolved in 20 ml methanol. The solution was then ultrasonicated for 10min and then made up to volume. Required amount of solution is then taken and filtered through 0.45µ nylon membrane and diluted with diluent solution so that the resultant concentrations are within the calibration range of the developed method. The samples are then analyzed by using the validated method. The sample is then injected in triplicate.

2.5 Method Validation

2.5.1 System Suitability

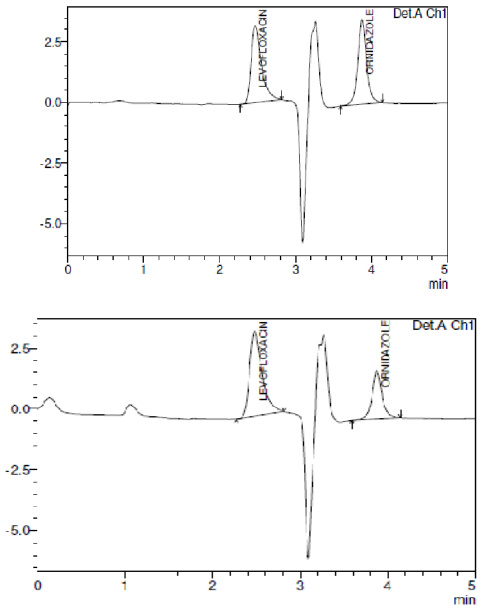
A sample containing mixture of Levofloxacin hemihydrate (at concentration of 50µg/ml) and Ornidazole (at concentration of 50µg/ml) was used as system suitability sample. System suitability was assessed by six replicate analysis. A percent coefficient

of variation (% CV) less than 1 % for retention times for the drugs is taken as the acceptance criterion.

2.5.2 Detection and Quantitation Limits (Sensitivity)

Limits of detection (LOD) and quantification (LOQ) (**Fig-2**) were estimated from both linearity calibration curve method and signal to noise ratio method. The detection limit was defined as the lowest concentration level resulting in a peak area of three times the baseline noise. The quantification limit was defined as the lowest concentration level that provided a peak area with signal to noise ratio higher than 5, with precision (%CV) and accuracy with (±) 20%.

Fig-2: Chromatograms shown below indicate limit of Detection (LOD) above and Limit of Quantitation (LOQ) below.



2.5.3 Linearity (Calibration Curve)

The calibration curve was constructed with eight non-zero standards ranging from 1.05 to 10.00 µg/mL for Ornidazole and 1.05 TO 9.98 for Levofloxacin hemihydrate. The linearity was evaluated by linear regression analysis, which was calculated by least square method. It is depicted in (**Fig- 3**).

2.5.4 Accuracy and Precision

Accuracy of assay method was determined for both intra-day and inter-day variations using triplicate analysis of the QC samples. Precision of the assay was determined by repeatability (intra-day) and intermediate precision (inter-day). Repeatability refers to the use of the analytical procedure within the laboratory over the shorter period of the time that was evaluated by assaying the QC samples during the same day. Intermediate precision was assessed by comparing the assays on different days (3 days).

2.5.5 Specificity

For demonstration of specificity, 4 samples namely blank sample, sample containing rabeprazole alone, sample containing levosulpiride alone and sample containing the mixture of levosulpiride and rabeprazole were prepared separately. Specificity of the method was determined by comparing results of all the samples (**Fig-4**). The developed method is said to be specific if the % interference calculated as peak area (if any) at the retention time of each of the analytes in the blank sample is less than 20% of peak area at the corresponding retention times of each of the drugs in the lowest calibration standard. Sample Specificity is also observed in the degradation study of the drug. None of the degraded products must interfere with the quantification of the drug.

2.5.6 Stability

The stability of the drug is determined by placing the MQC samples for the short term stability at room temperature up to 12 hours and then comparing the obtained peak area with that of the similarly prepared fresh sample. Further, auto-sampler stability for up to 24 hrs was studied and established.

2.5.7 Stress Degradation Studies

For Stress Degradation Analysis, 1 mL aliquots (in duplicate) of samples containing MQC level concentration are treated separately with 100 µL of 0.1N HCl (Acid stress), 0.1N NaOH (Alkaline stress), 5% v/v Hydrogen Peroxide (Oxidative Stress), for 24 Hrs. Samples for Photolytic stress are placed in a transparent glass vial & placed in a UV chamber for 24 Hrs. Samples are then injected for analysis. The results of analysis are then compared with similarly prepared fresh samples. The analysis is performed in triplicate.

3.0 RESULTS AND DISCUSSION

3.1 Method Development and Validation

The HPLC procedure was optimized with a view to develop a stability indicating assay method. Functional group analysis revealed the presence of acidic character to the molecules. Therefore we evaluated the

chromatographic behavior at different pH values ranging from pH 3.0 to pH 6.5 using various columns like Hypersil-BDS-C18, Symmetry C18, Ymc-pack C18, Ymc-pack pro, Spherisorb C18, Phenomenex C18 have been tried with different buffer salts such ammonium Formate, ortho phosphoric acid, di-potassium hydrogen orthophosphate, in combination with acetonitrile, methanol and tetrahydrofuran. However less tailing and high theoretical plates are obtained with Phenomenex Ion Pair column C18 250 X 4.6 cm 5µm column.. The peak response of Levofloxacin hemihydrate decreased with increased composition of Methanol in the mobile phase. Mobile phase composition consisted of (70:30 v/v) of Methanol and 20mM Orthophosphoric acid (pH adjusted to 3.0 ± 0.1 with glacial acetic acid) on isocratic mode. The flow rate of the method is 1.0 ml/min. Calibration standards were prepared in diluents solution containing 50:50 % v/v of Methaol and Milli-Q water. The wavelength of detection is 290nm. The column temperature is maintained at 25 ^{O}C. At the reported flow rate, peak shape was excellent; however increasing or decreasing the flow rate resulted in unacceptable tailing factor and poor peak shape. Hence 0.6 ml/min was optimized flow rate decreasing the consumption of the mobile phase, which in turn proves to be cost effective for long term routine quality control analysis. To evaluate the feasibility of the experiment under regular lab conditions, we assessed the stability of Ornidazole and Levofloxacin hemihydrate under room temperature and under normal light conditions.

3.2 Method Validation

3.2.1 System Suitability

The % RSD of the peak area for both drugs is within the acceptable criteria (**Table-1**). The efficiency of the column was expressed as the number of theoretical plates for the six replicate injections was around 4750 ±1 20 for Ornidazole and 15958 ± 70 for Levofloxacin hemihydrate. The USP tailing factor for Ornidazole and Levofloxacin hemihydrate is not more than 2.0 while that of Levofloxacin hemihydrate is 1.05 ±0.04.

3.2.2 Determination and Quantification Limits (Sensitivity)

Fig-2 represents the chromatogram of limit of detection and limit of quantification. The method is found to be sensitive which can be determined from the data obtained from the (**Table-2**).

3.2.3 Linearity

The linearity was demonstrated in triplicate. The results of the best fit line (y = mx + c) for the triplicate analysis is given in **Table 3**. The accuracy of the calibration standards was evaluated from the back calculated concentrations **(Table 4)**. All the standards were found to be within the range Levofloxacin hemihydrate is 87.43-109.28% and Ornidazole is 86.22-108.87%.

3.2.4 Accuracy and Precision

Accuracy and precision calculated for the QC samples during the intra- and inter –day run are given the (**Table-5**). The intra-day (day-1) and inter-day accuracy for Ornidazole ranged from 95.65- 105.75 % while that of Levofloxacin hemihydrate ranged from 99.97 – 110.18 %. The results obtained from intermediate precision (inter-day) also indicated a good method precision. All the data were within the acceptance criteria.

3.2.5 Specificity

Specificity was determined by comparison of the Blank chromatogram with that of the Standard chromatogram (**Fig-4**)

3.2.6 Room Temperature Stability

Stability studies were done for short term stability up to 12 hrs on the bench top for the MQC levels conditions. Stability is calculated as the ratio of the mean peak area of the stability sample to the mean peak area of the fresh sample and expressed as the percentage (n=6). The room temperature stability was found to be 101.02% for Ornidazole and 100.25 % for Levofloxacin hemihydrate. The results are tabulated in **Table-6**.

3.2.7 Stress Degradation

Stress studies revealed that Ornidazole is not susceptible to degradation under acid, light (UV) and oxidative stress conditions (**Fig 5**). However, in alkaline conditions (0.1N NaOH), the drug was instable and the degradation peak eluted earlier accompanied with a drastic peak distortion and increased tailing. Except for alkaline conditions, the drug content was within 95 –105 % for all stress conditions indicating the stability and specificity of the analytical method to differentiate the degradation peaks.

Stress studies on Levofloxacin hemihydrate indicated instability under alkaline and photolytic conditions. This has been clearly demonstrated by the help of overlap

spectra of all the stress samples as compared with that of freshly prepared sample of similar concentration **(Fig 5)**.

3.2.8 Robustness study

Robustness is the measure of method capacity to remain unaffected by deliberate small changes in the chromatographic conditions. The experimental conditions were deliberately altered to evaluate the robustness of the method. The impact of flow-rate (1.0 ± 0.1 ml/min), and effect of mobile-phase composition (± 5%) on chromatographic parameters such as retention time, theoretical plates, and tailing factor, were studied**.** At lower flow rate, the retention time of Ornidazole was 4.7 ± 0.04 minutes (n=6) while that of Levofloxacin hemihydrate was 3.0± 0.06 minutes. At lower flow rate, the tailing factor for Ornidazole decreased to 1.017 ± 0.03 while that of Levofloxacin hemihydrate decreased to 1.323± 0.03. At higher flow rate, tailing factor for both Levofloxacin hemihydrate and Ornidazole remained unchanged as compared to normal flow. The elution was earlier at higher flow rate; Ornidazole and Levofloxacin hemihydrate eluted at 3.34 ± 0.01 and 2.13± 0.02 minutes respectively. The retention time of Ornidazole and Levofloxacin hemihydrate were 2.57 ± 0.02 and 2.35 ± 0.03 minutes respectively (n=6) when the mobile phase composed of 75 parts of methanol and 25 parts of 20m orthophosporic acid (pH 3.0).

3.3 Application of the method to dosage forms

The HPLC method developed is sensitive and specific for the quantitative determination of Ornidazole and Levofloxacin hemihydrate. Also the method is validated for different parameters; hence it has been applied for the simultaneous estimation in pharmaceutical dosage forms LEON OZ was evaluated. The % assay of Levofloxacin hemihydrate in the tablet is 99.12 % and that of Ornidazole is 100.25 %. None of the tablets ingredients interfered with the analyte peak. The spectrum of Ornidazole and Levofloxacin hemihydrate in the extracted tablet was matching with that of standard compounds indicating the purity of the compounds in the tablets.

Conclusions

The method gave accurate and precise results in the concentration range of 1 - 10 µg/mL for Ornidazole and 1 to 10µg/mL for Levofloxacin hemihydrate. The mobile phase composition consists of (70:30 v/v) of Methanol and orthophosphoric acid (pH adjusted to 3.0 with glacial acetic acid), at the flow rate of 0.6 ml/min. The retention time of Ornidazole is 3.8± 0.2 minutes and that of Levofloxacin hemihydrate is 2.4 ± 0.2 minutes. The column is Phenomenex C18 column (150 X 4.6 mm id, ODS 2, 5µm) with the particle size of 5µm. A rapid sensitive and specific method for the simultaneous estimation of Ornidazole and Levofloxacin hemihydrate in the pharmaceutical tablet formulations has been developed and validated.

Fig-3a: Linear calibration curve of Ornidazole.

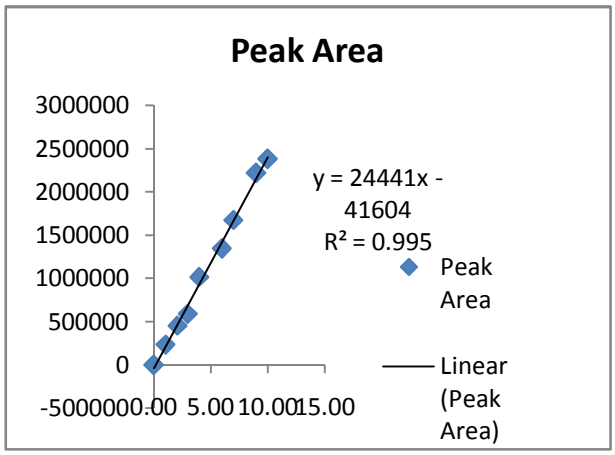


Fig-3b: Linear calibration curve of Levofloxacin

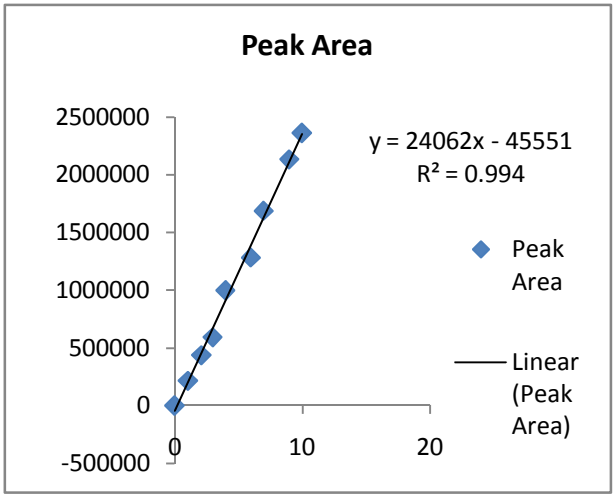


Table 1. System Suitability test for Ornidazole and Levofloxacin

ORNIDAZOLE				
Sample ID	**Peak Retention Time**	**Peak Area**	**Theoretical Plates**	**Tailing Factor**
1	3.84	1182358	15858	1.13
2	3.84	1187423	16029	1.13
3	3.85	1072857	15770	1.13
4	3.85	1108494	15882	1.13
5	3.85	1136790	15858	1.13
6	3.85	1095307	15859	1.13
MEAN	**3.847**	**1130538.2**	**15876.0**	**1.130**
STDEV	**0.0052**	**46935.19**	**84.40**	**0.00**
%CV	**0.13**	**4.15**	**0.53**	**0.00**

LEVOFLOXACIN HEMIHYDRATE				
Sample ID	**Peak Retention Time**	**Peak Area**	**Theoretical Plates**	**Tailing Factor**
1	2.45	1231742	4757	1.48
2	2.45	1233311	4674	1.47
3	2.45	1054018	4875	1.46
4	2.45	1078737	4815	1.45
5	2.45	1105579	4783	1.47
6	2.45	1091298	4778	1.51
MEAN	**2.450**	**1132447.5**	**4780.3**	**1.473**
STDEV	**0.0000**	**79352.44**	**66.37**	**0.0207**
%CV	**0.00**	**7.01**	**1.39**	**1.40**

Table 2. Sensitivity

ORNIDAZOLE
LOD

SR NO	DRUG	
	Retention Time	**Peak Area**
1	3.87	15967
2	3.87	16928
3	3.87	15762
MEAN	**3.9**	**16219.0**
ST DEV	**0.00**	**622.51**
% CV	**0.00**	**3.84**

LEVOFLOXACIN HEMIHYDRATE
LOD

SR NO	DRUG	
	Retention Time	**Peak Area**
1	2.48	35316
2	2.47	73015
3	2.47	72165
MEAN	**2.5**	**60165.3**
ST DEV	**0.01**	**21524.35**
% CV	**0.23**	**35.78**

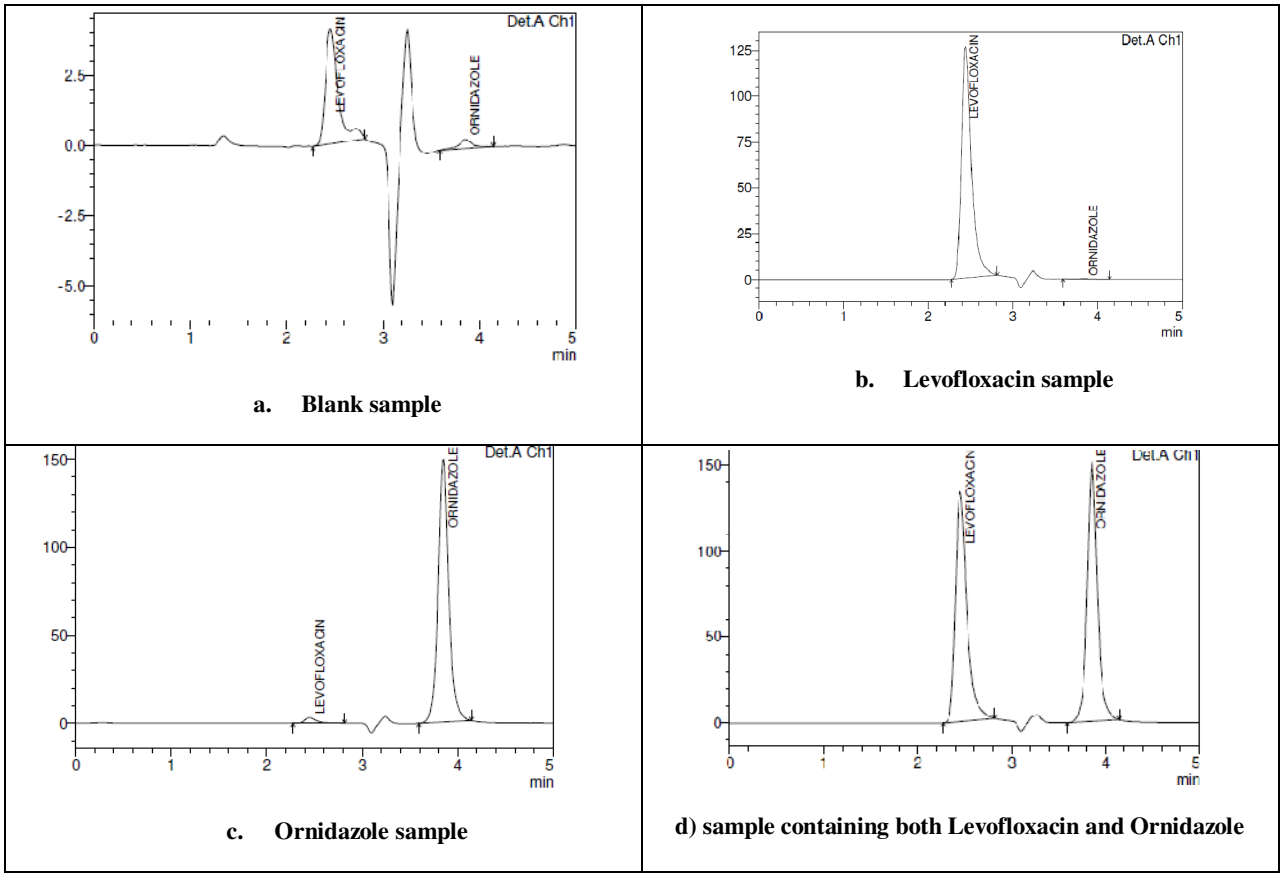
ORNIDAZOLE
LOQ

SR NO	DRUG	
	Retention Time	**Peak Area**
1	3.87	27927
2	3.87	25223
3	3.87	27714
MEAN	**3.9**	**26954.7**
ST DEV	**0.00**	**1503.44**
% CV	**0.00**	**5.58**

LEVOFLOXACIN HEMIHYDRATE
LOQ

SR NO	DRUG	
	Retention Time	**Peak Area**
1	2.46	30214
2	2.46	42652
3	2.47	34090
MEAN	**2.5**	**35652.0**
ST DEV	**0.01**	**6364.42**
% CV	**0.23**	**17.85**

Fig-4: Comparison of (a)Blank Chromatogram, (b) Levofloxacin hemihydrates (c) Ornidazole alone and (d) sample containing both Levofloxacin and Ornidazole



a. Blank sample

b. Levofloxacin sample

c. Ornidazole sample

d) sample containing both Levofloxacin and Ornidazole

Table 3. Results of best-fit line for triplicate analysis for Levofloxacin and Ornidazole

Ornidazole			
Curve	**Slope**	**Intercept**	**r^2**
1	244417	-41604	0.995
2	249965	-41059	0.994
3	254758	-28741	0.992
Mean	**249713.33**	**-92243.3**	**0.993**

Levofloxacin hemihydrate			
Curve	**Slope**	**Intercept**	**r^2**
1	240629	-45551	0.9943
2	248514	-60764	0.9948
3	250121	-26491	0.9942
Mean	**246421.33**	**-115145.3**	**0.9997**

Table 4. Linearity and Range for Levofloxacin and Ornidazole demonstrating accuracy, carryover effect and specificity of the method (Curve 1).

LEVOFLOXACIN					
Sample ID	**Concentration (Microgram/mL)**	**Retention Time**	**Peak Area**	**Back Calc Concentration**	**% Accuracy**
Blank	0	**NA**	**0**	NA	
CC - 01	1.05	2.45	215263	1.11	105.94
CC - 02	2.10	2.43	437077	2.03	96.74
CC - 03	3.00	2.45	592884	2.68	89.24
CC - 04	3.99	2.45	998993	4.36	109.28
CC - 05	5.99	2.45	1283758	5.54	92.49
CC - 06	6.99	2.46	1689102	7.22	103.29
CC - 07	8.99	2.46	2135687	9.07	100.90
CC - 08	9.98	2.45	2365345	10.02	100.43
Blank	**0**	**NA**	0	**NA**	**NA**

- NA - Not applicable

ORNIDAZOLE					
SAMPLE ID	**Concentration (Microgram/mL)**	**Retention Time**	**Peak Area**	**Back Calc Concentration**	**% Accuracy**
Blank	0.00	**NA**	**0**	NA	#VALUE!
CC - 01	1.05	3.85	234370	1.14	108.87
CC - 02	2.10	3.84	452945	2.04	96.96
CC - 03	3.00	3.86	590727	2.60	86.64
CC - 04	4.00	3.86	1017602	4.34	108.58
CC - 05	6.00	3.86	1347432	5.69	94.85
CC - 06	7.00	3.87	1676350	7.03	100.49
CC - 07	9.00	3.87	2223025	9.27	102.98
CC - 08	10.00	3.86	2385310	9.93	99.31
Blank	0	**NA**	**0**	**NA**	**NA**

NA - Not applicable

Table 5a. Results of inter and intra-day accuracy & precision for Ornidazole

	Nominal Concentration (µg/mL)		
	2.5	5.0	7.5
DAY 1			
MEAN (n=6)	2.67	4.79	7.47
SD	0.048	0.171	0.075
% CV	1.83	3.58	1.04
DAY 2			
MEAN (n=6)	2.64	4.78	7.45
SD	0.065	0.163	0.138
% CV	2.47	3.41	1.86
DAY 3			
MEAN (n=6)	2.62	4.77	7.44
SD	0.094	0.167	0.207
% CV	3.60	3.50	2.78

Table 5b. Results of inter and intra-day accuracy & precision for Levofloxacin

	Nominal Concentration (µg/mL)		
	2.5	4.99	7.49
DAY 1			
MEAN (n=6)	2.78	5.0	7.60
SD	0.047	0.068	0.07
% CV	1.697	1.37	2.73
DAY 2			
MEAN (n=6)	2.75	4.99	7.58
SD	0.064	0.075	0.164
% CV	2.35	1.51	2.17
DAY 3			
MEAN (n=6)	2.73	4.98	7.56
SD	0.094	0.106	0.148
% CV	3.46	2.14	1.97

Fig-5a: Overlay Chromatogram showing the influence of various stress conditions on Ornidazole; Data 1-Acid Stress, Data 2 – Oxidative Stress; Data 3 –Photolytic Stress; Data 4 – Alkaline Stress. Data 4 clearly indicates the spectral degradation of Ornidazole due to alkaline instability.

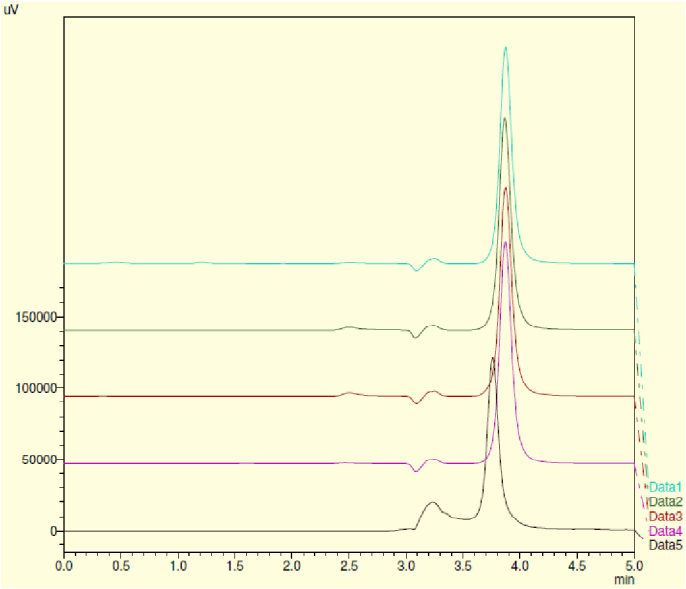


Fig-5b: Overlay Chromatogram showing the influence of various stress conditions on Levofloxacin hemihydrate; Data 1-Acid Stress, Data 2 – Oxidative Stress; Data 3 –Photolytic Stress; Data 4 – Alkaline Stress.. Data 3 shows the Photolytic degradation product of Levofloxacin hemihydrate Data 4 clearly indicates the spectral degradation of Levofloxacin hemihydrate due to alkaline instability.

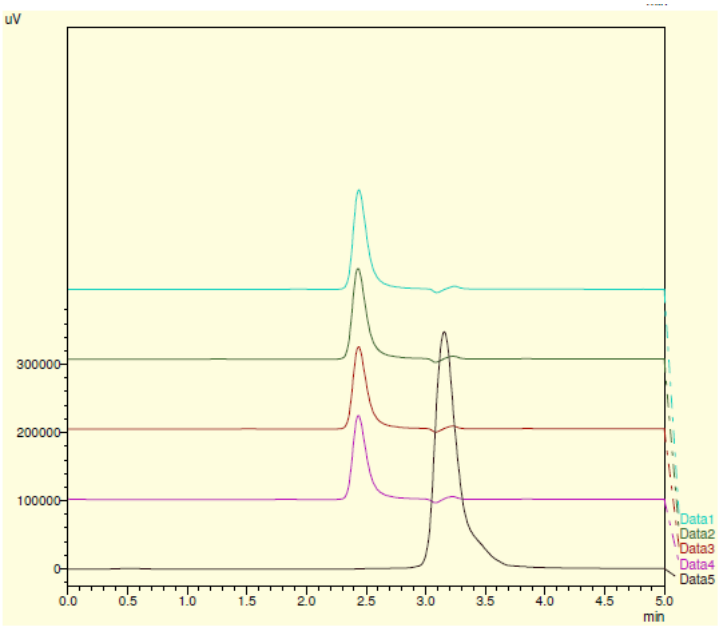


Table 6a. Room Temperature Stability of Ornidazole (n = 6).

ORNIDAZOLE

FRESH SAMPLE

SR NO	SAMPLE ID	CONC (µg/mL)	DRUG	
			Rt	PEAK AREA
1	FRESH	5.00	3.86	2008549
2	FRESH	5.00	3.85	1758466
3	FRESH	5.00	3.85	1958314
4	FRESH	5.00	3.86	1934337
5	FRESH	5.00	3.85	1874031
6	FRESH	5.00	3.86	1989972
Mean				**1920611.50**
Stdev				**92319.72**
%				**4.81**

STABILITY SAMPLE

SR NO	SAMPLE ID	CONC (µg/mL)	DRUG	
			Rt	PEAK AREA
1	STABILITY	5.00	3.78	1944382
2	STABILITY	5.00	3.83	1910479
3	STABILITY	5.00	3.87	1901739
4	STABILITY	5.00	3.85	1857202
5	STABILITY	5.00	3.86	1990677
6	STABILITY	5.00	3.87	1947552
Mean				**1925338.50**
Stdev				**45925.02**
% Cv				**2.39**

% Stability 100.25

Table 6b. Room Temperature Stability of Levofloxacin (n = 6).

LEVOFLOXACIN

FRESH SAMPLE

SR NO	SAMPLE ID	CONC (µg/mL)	DRUG	
			Rt	PEAK AREA
1	FRESH	4.99	2.48	2113327
2	FRESH	4.99	2.47	1774271
3	FRESH	4.99	2.47	2148034
4	FRESH	4.99	2.47	1915212
5	FRESH	4.99	2.46	1865315
6	FRESH	4.99	2.47	2005951
MEAN				
STDE				
% CV				

STABILITY SAMPLE

SR NO	SAMPLE ID	CONC (µg/mL)	DRUG	
			Rt	PEAK AREA
1	STABILITY	4.99	2.38	1835839
2	STABILITY	4.99	2.42	2049064
3	STABILITY	4.99	2.47	2051396
4	STABILITY	4.99	2.45	1921794
5	STABILITY	4.99	2.46	2078560
6	STABILITY	4.99	2.46	2005464
MEAN				**1990352.83**
STDE				**93548.87**
% CV				**4.70**

% Stability 101.02

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