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Page: 01-25

SIMULTANEOUS ESTIMATION OF PARACETAMOL AND EPERISONE IN PHARMACEUTICAL DOSAGE FORM BY HPLC

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ABSTRACT

Pharmaceutical analysis plays a very prominent role in quality assurance as well as quality control of bulk drugs and pharmaceutical formulations. Rapid increase in pharmaceutical industries and production of drug in various parts of the world has brought a rise in demand for new analytical techniques in the pharmaceutical industries. As a consequence, analytical method development has become the basic activity of analysis. RP-HPLC is the most, sensitive, universal analytical procedure. Quantitative estimation of Paracetamol and Eperisone Hydrochloride was estimated by RP-HPLC using MeOH: 0.1% Ortho phosphoric acid (60:40 %v/v) as a mobile phase and Phenomenex column (150mm×4.6mm, 5µ) as a stationary phase and the peaks were observed at 270nm which was selected as a wavelength for quantitative estimation. After development of the method it was validated for specificity, system suitability, accuracy, linearity, precision, ruggedness and robustness. The value of theoretical plates, tailing factor, retention time and peak area was found to be within limits, hence it is concluded that the system is suitable to perform assay.

KEYWORDS: Pharmaceutical Analysis, Quality Assurance, RP-HPLC, Paracetamol and Eperisone.

1. INTRODUCTION

Pharmaceutical analysis simply means analysis of pharmaceuticals. Webster' dictionary defines a pharmaceutical is a medical drug. A more appropriate term for a pharmaceutical is active pharmaceutical ingredient (API) or active ingredient to distinguish it from a formulated

product or drug product is prepared by formulating a drug substance with inert ingredient (excipient) to prepare a drug product that is suitable for administration to patients. It is well known in the pharmaceutical industry that pharmaceutical analyst in research and development (R&D) play a very comprehensive role in new drug development and follow up activities to ensure that a new drug product meets the established standards is stable and continue to approved by regulatory authorities ,assuring that all batches of drug product are made to the specific standards utilization of approved ingredients and production method becomes the responsibility of pharmaceutical analysts in the quality control (QC) or quality assurance department .[1]

The methods are generally developed in an analytical R&D department and transferred to QC or other departments as needed. At times they are transferred to other divisions.

By now it should be quite apparent that pharmaceutical analysts play a major role in assuring the identity, safety, efficacy, and quality of drug product, safety and efficacy studies required that drug substance and drug product meet two critical requirements.

1. Established identity and purity.
2. Established bio availability/dissolution.

1.1 Analytical chemistry[2-4]

A branch of chemistry that deals with the identification of compounds and mixtures (qualitative analysis) or the determination of the proportions of the constituents (quantitative analysis).The techniques commonly used are titration, precipitation, spectroscopy, chromatography, etc.

Analytical chemists work to improve the reliability of existing techniques to meet the demands for better chemical measurements, which arise constantly in our society. They adapt proven methodologies to new kinds of materials or to answer new questions about their composition. They carry out research to discover completely new principles of measurement and are at the forefront of the utilization of major discoveries such as lasers and microchip devices for practical purposes. They make important contributions to many other fields as diverse as forensic chemistry, archaeology, and space science.

Analytical chemistry serves the needs of many fields:

✓ In industry, analytical chemistry provides the means of testing raw materials and for assuring the quality of finished products whose chemical composition is critical. Many

household products, fuels, paints, pharmaceuticals, etc. are analyzed by the procedures developed by analytical chemists before being sold to the consumer.

✓ The nutritional value of food is determined by chemical analysis for major components such as protein and carbohydrates and trace components such as vitamins and minerals. Indeed even the calories in a food are often calculated from its chemical analysis.

✓ In medicine, analytical chemistry is the basis for clinical laboratory tests, which help physicians to diagnose disease and chart the progress in recovery.

Environmental quality is often evaluated by testing for suspected contaminants using the techniques of analytical chemistry.

✓ Analytical chemists also make important contributions to fields as diverse as forensic chemistry, archaeology, and space science[1].

1.2 DIFFERENT TYPES OF CHROMATOGRAPHY

1.2.1 Adsorption Chromatography

Adsorption chromatography is probably one of the oldest types of chromatography around. It utilizes a mobile liquid or gaseous phase that is adsorbed onto the surface of a stationary solid phase. The equilibration between the mobile and stationary phase accounts for the separation of different solutes.

1.3.2 Partition Chromatography

This form of chromatography is based on a thin film formed on the surface of the solid support by a liquid stationary phase. Solute equilibrates between the mobile phase and the stationary liquid.

1.2.2 Ion Exchange Chromatography

In this type of chromatography, the use of a resin (the stationary solid phase) is used to covalently attach anions or cations on it. Solute ions of the opposite charge in the mobile liquid phase are attracted to the resin by electrostatic forces.

1.3.4 Molecular Exclusion Chromatography

Also known as gel permeation or gel filtration, this type of chromatography lacks an attractive interaction between the stationary phase and solute. The liquid or gaseous phase passes through a porous gel, which separates the molecules according to its size. The pores are normally small and exclude the larger solute molecules, but allow smaller molecules to enter the gel, causing them to flow through a larger volume. This causes the larger molecules to pass through the column at a faster rate than the smaller ones.

1.3.5 Affinity Chromatography

This is the most selective type of chromatography employed. It utilizes the specific interaction between one kind of solute molecule and a second molecule that is immobilized on a stationary phase. For example, the immobilized molecule may be an antibody to some specific protein. When this molecule passes solute containing a mixture of proteins, only the specific protein is reacted to this antibody, binding it to the stationary phase.

This protein is later extracted by changing the ionic strength or pH.

1.4 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY:

HPLC is able to separate macromolecules and ionic species, labile natural products, polymeric materials and a wide variety of other high-molecular weight polyfunctional groups.

1.4.1 Basic principle of HPLC

High performance liquid chromatography (HPLC) is a separation technique utilizing differences in distribution of compounds to two phases; called stationary phase and mobile phase. The stationary phase designates a thin layer created on the surface of fine particles and the mobile phase designates the liquid flowing over the particles. Under a certain dynamic conditions, each component in a sample has difference distribution equilibrium depending on solubility in the phases and or molecular size. As a result the components move at different speeds over the stationary phase and are thereby separated from each other. The column is a stainless steel (or resin) tube, which is packed with spherical solid particles. Mobile phase is constantly fed into the column inlet at a constant rate by a liquid pump. A sample is injected from a sample injector located near the column inlet.

The injected sample enters the column with the mobile phase and the components in the sample migrate through it passing between the stationary and mobile phases. Compound move in the column only when it is in the mobile phase.

Compounds that tend to be distributed in the mobile phase therefore migrate faster through the column while compounds that tend to be distributed in the stationary phase migrate slower. In this way each component is separated on the column and sequentially elutes from the outlet. A detector connected to the outlet of the column detects each compound eluting from the column.

1.5 TYPES OF HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

i. Based on modes of chromatography

- Normal phase chromatography

- Reverse phase chromatography

ii. Based on principles of separation

- Adsorption chromatography
- Ion exchange chromatography
- Ion pair chromatography
- Size exclusion chromatography
- Affinity chromatography
- Chiral phase chromatography

iii. Based on elution technique

- Isocratic separation
- Gradient separation

iv. Based on the scale of operation

- Analytical HPLC
- Preparative HPLC[3-7]

1.5.1 Normal Phase High Performance Liquid Chromatography (NP-HPLC)

Normal-phase liquid-liquid chromatography uses a polar stationary phase and less polar mobile phase. To select an optimum mobile phase, it is best to start with a pure hydrocarbon mobile phase such as heptanes. If the sample is strongly retained, the polarity of the mobile phase should be increased, perhaps by adding small amounts of methanol or dioxane In the normal phase mode, separations of oil-soluble vitamins, essential oils, nitro phenols, or more polar homologous series have been performed using alcohol/heptanes as the mobile phase. Column used in normal phase chromatography for chiral separation: Chiracel OJ and Chiracel OD.

1.5.2 Reverse Phase High Performance Liquid Chromatography (RP-HPLC)

Reverse phase chromatography uses hydrophobic bonded packing, usually with an octadecyl or octyl functional group and a polar mobile phase, often a partially or fully aqueous mobile phase. Polar substances prefer the mobile phase and elute first. As the hydrophobic character of the solutes increases, retention increases. Generally, the lower the polarity of the mobile phase, the higher is its eluent strength. The elution order of the classes of compounds in table is reversed (thus the name reverse-phase chromatography).

Hydrocarbons are retained more strongly than alcohols. Also, the eluent strength of the various solvents in reverse-phase chromatography follows approximately the reverse order given in table. Thus water is the weakest eluent. Methanol and Acetonitrile are popular solvents because they have low viscosity and are readily available with excellent purity.

Table -1.1: COMPARISON OF NORMAL PHASE AND REVERSE PHASE HPLC.

Properties	Normal Phase	Reversed Phase
Polarity of Stationary Phase	High	Low
Polarity of mobile Phase	Low to medium	Low to high
Sample elution order	Least polar First	Most polar First
Retention will increase by	Increasing surface of stationary phase Increasing of n-alkyl chain length of stationary phase. Decreasing polarity of mobile phase Increasing polarity of sample molecules	Increasing surface of stationary phase. Increasing polarity of mobile phase Decreasing polarity of sample molecules

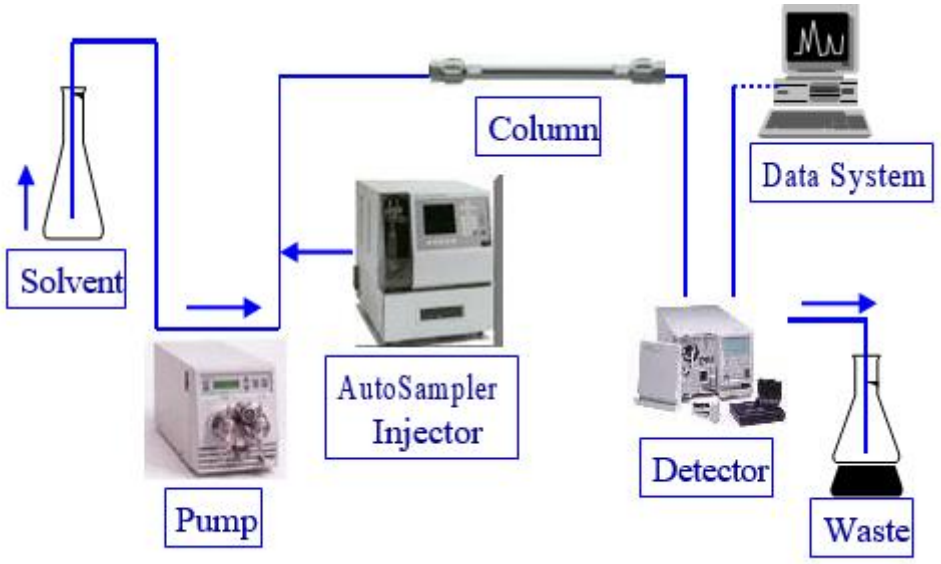


Figure-1 Schematic diagram for HPLC instrument.

2. EXPERIMENTAL WORK:

Method development:

Selection of wavelength:

An ideal wavelength is one that uses good response for the drugs to be detected. Paracetamol

and Eperisone hydrochloride in diluents the spectra were scanned on UV- Visible spectrophotometer in the range of 200 nm to 400 nm against diluent as blank. The Maximum absorbance of Paracetamol and Eperisone hydrochloride was found to be 261 nm and 295 nm respectively.

From the UV Visible spectrophotometric results, the iso-absorptive point of the combined spectrum of both drugs at 270 nm was chosen for detections of Paracetamol and Eperisone Hydrochloride.

Selection of chromatographic method:

Selection of chromatographic method in general is done taking into consideration several parameters like the nature of the drugs, molecular weight and solubility. Since both the drugs selected are polar in nature, reversed phase chromatography has been used. C_{18} and C_4 columns were chosen as stationary phase and a mixture of organic solvents and buffers are used to develop a method for the simultaneous estimation of Paracetamol and Eperisone hydrochloride.

Source:

Method development for the product was initiated based on the individual chemical characteristics and their methods given in some journals.

Trail-1(A):

Preparation of 0.1 % Ortho Phosphoric acid solution:

Add 0.5 mL of O-phosphoric acid in 500 mL of water. Mix well filter and degas through 0.45µm membrane filter.

Chromatographic conditions:

Mobile phase: MeOH: 0.1% OPA (70:30 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270 nm

Flow rate: 1 mL/min

Column temperature: ambient

Sample temperature: ambient

Injection volume: 20µL

Run time: 5 min

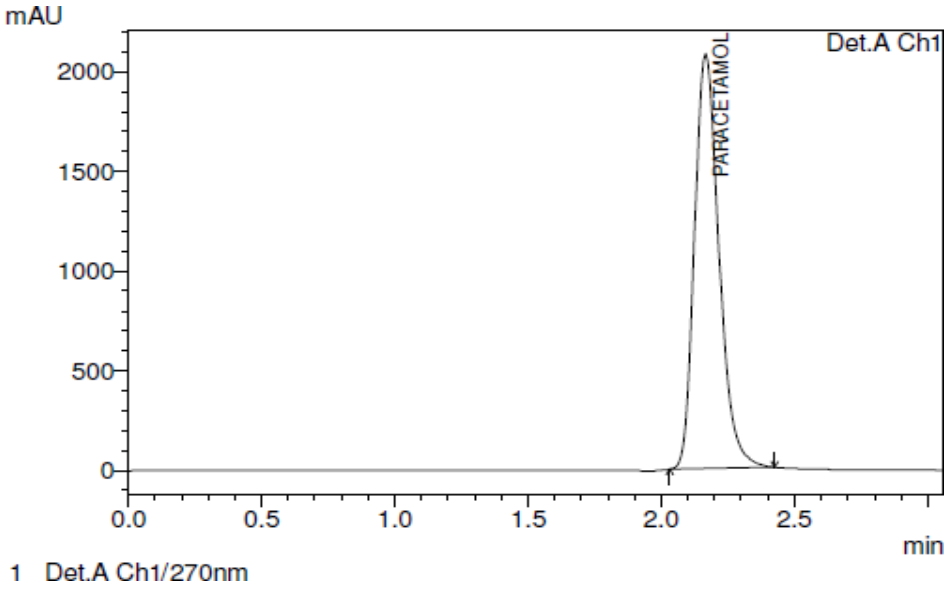


Fig 2: Chromatogram for Trail-1.

PeakTable

Detector A Ch1 270nm

Name	Ret. Time	Area	Theoretical Plate#	Tailing Factor	Resolution
PARACETAMOL	2.16	13303977	7071	1.25	0.00

Result:

By injecting the standard mix solution which contains Paracetamol, retention time were found to be at 2.16 min. Peak intensity of Paracetamol is very high, so further trails are conducted. It has tailing factor of 1.25 which is satisfactory.

Trail-1 (B):

Chromatographic conditions:

Mobile phase: MeOH: 0.1% OPA (70:30 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270 nm

Flow rate: 1 mL/min

Column Temperature: ambient Sample temperature : ambient Injection volume: 20µL

Runtime:6min:

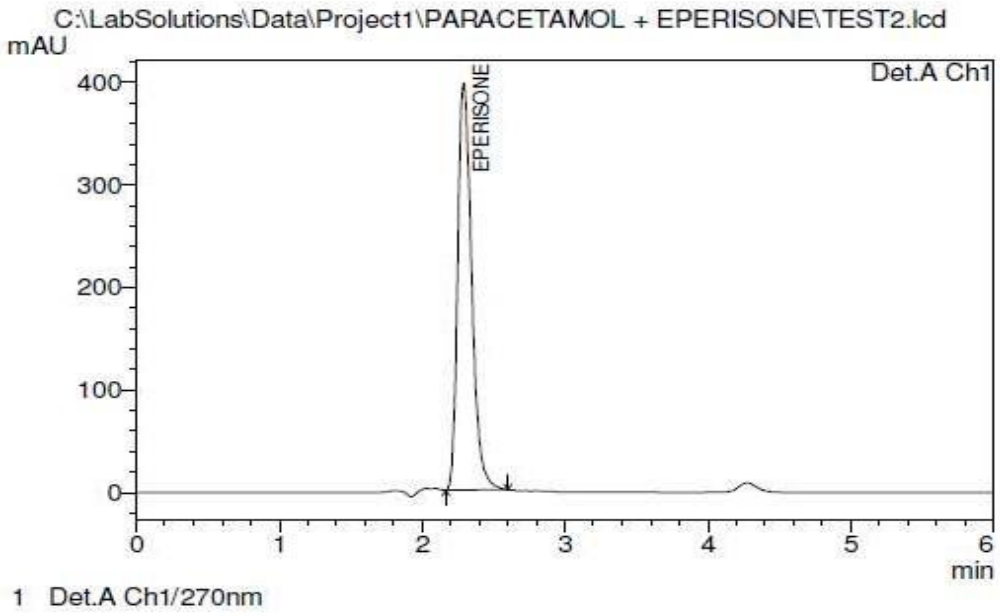


Fig 3: Chromatogram for Trail-2

PeakTable

Detector A Ch1 270nm

Name	Ret. Time	Area	Theoretical Plate#	Tailing Factor	Resolution
EPERISONE	2.29	2683331	7106	1.31	0.00

Result:

By injecting the standard mix solution which contains Eperisone hydrochloride, retention time was found to be at 2.29 min. it has good tailing factor of 1.31 which is with in limit.but at this Mobile phase composition (70/30 MeOH : 0.1% OPA) the retention times of paracetamol and Eperisone hydrochloride were found to be very close to each other and there is a possibility of both peaks merging with each other. Hence further trails were made with variation in flow rate.

Trail-2:

Chromatographic conditions:

Mobile phase: MeOH: 0.1% OPA(70:30 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270 nm

Flow rate: 0.8 mL/min Column temperature: ambient Sample temperature: ambient Injection volume: 20µL

Run time: 6 min

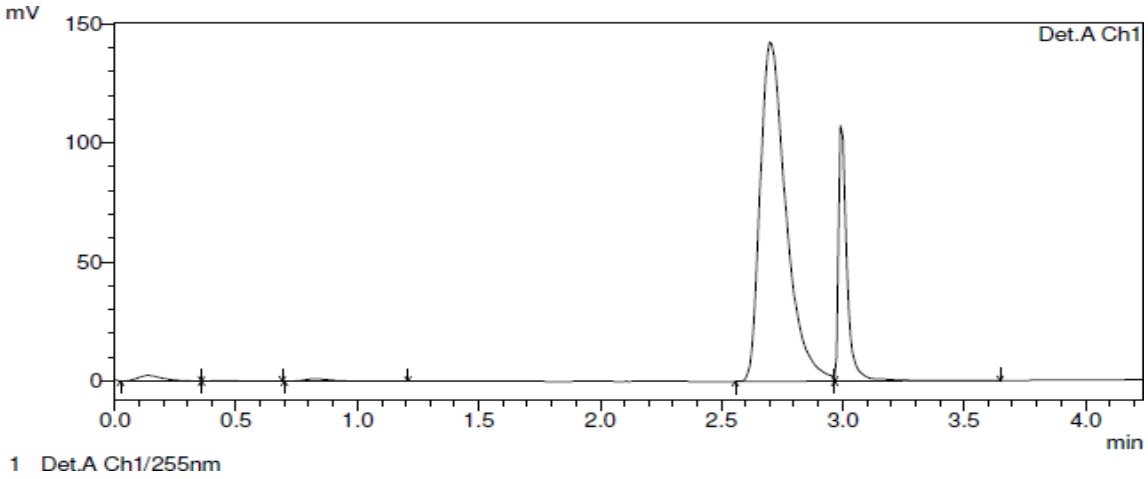


Fig 4: Chromatogram for Trail-3.

Result:

By injecting the standard mix solution which contains Paracetamol and Eperisone hydrochloride retention times were found to be at 2.64 and 3.15 mins for Paracetamol and Eperisone hydrochloride respectively. Both peaks were found to be merged with each other. Hence further trails were made by altering the mobile phase conditions in order to separate the peaks.

Trail-3:

Chromatographic conditions:

Mobile phase: MeOH: 0.1% OPA (65:35 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270nm nm

Flow rate: 1 mL/min Column temperature: ambient Sample temperature : Ambient Injection volume: 20µL Run time: 8 min

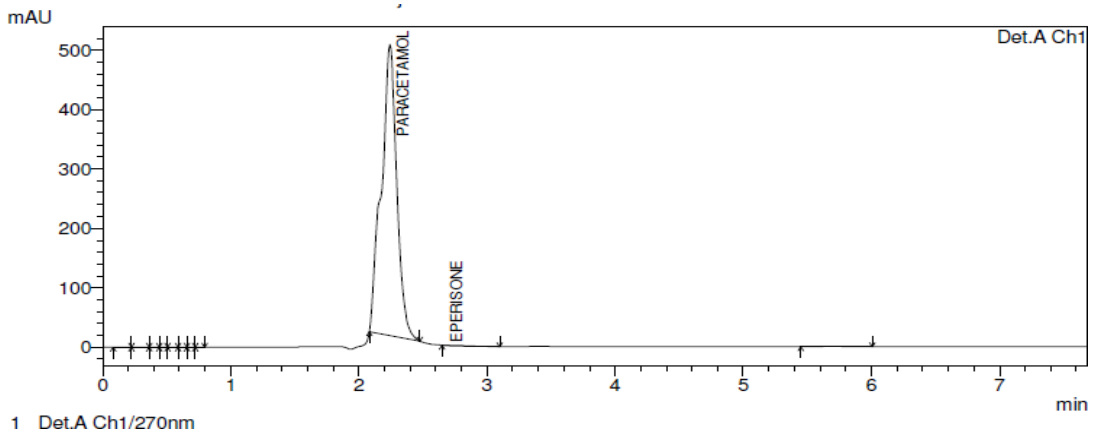


Fig 5: Chromatogram for Trail-4.

Result:

By injecting the standard mix solution which contains Paracetamol and Eperisone hydrochloride, the peaks of both the drugs were found to be merged with each other. Hence this method is not applicable. Further trails were made by altering the mobile phase conditions.

Trail-4:

Chromatographic conditions:

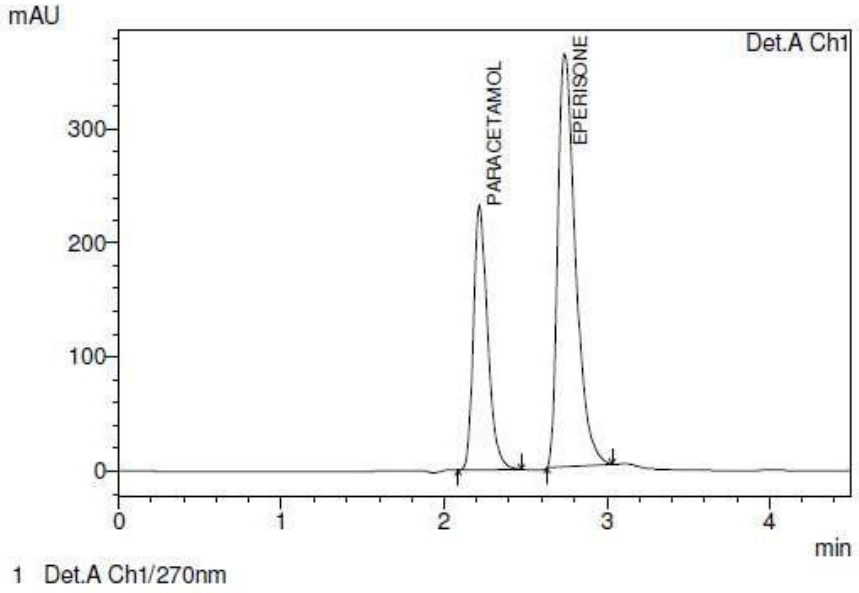
Mobile phase: MeOH: 0.1% OPA (60:40 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270 nm

Flow rate: 1.0 mL/min Column temperature: ambient Sample temperature: ambient Injection volume: 20µL

Run time: 6 min



PeakTable

Detector A Ch1 270nm

Name	Ret. Time	Area	Theoretical Plate#	Tailing Factor	Resolution
PARACETAMOL	2.21	1410232	8043	1.32	0.00
EPERISONE	2.74	2745088	7864	1.43	2.81

Fig 6: Chromatogram for Trail-5.

Result:

By injecting the solutions of Paracetamol and Eperisone hydrochloride, the retention times were found to be 2.21 and 2.74 and both peaks were found to have good resolution and seperated from each other. The tailing was found to be 1.32 and 1.43 for Paracetamol and

Eperisone hydrochloride respectively. Hence this method is selected for further studies.

Optimized chromatographic conditions:

The optimized mobile phase is MeOH: 0.1% OPA (60:40 % v/v), at a flow rate of 1mL/min at 270 nm, under these conditions Paracetamol and Eperisone hydrochloride were eluted at 2.21 and 2.74 min respectively.

Mobile phase: MeOH: 0.1% OPA (60:40 % v/v)

Column: Phenomenex column (150mm×4.6mm, 5µ)

Wavelength: 270 nm

Flow rate: 1.0 mL/min Column temperature : ambient Sample temperature: ambient

Injection volume: 20µL, Runtime: 6 min.

3. RESULT S AND DISCUSSION:

System suitability:

The % CV of peak area and retention time for the both drugs Paracetamol and Eperisone Hydrochloride are within 2 % indicating the suitability of the system.

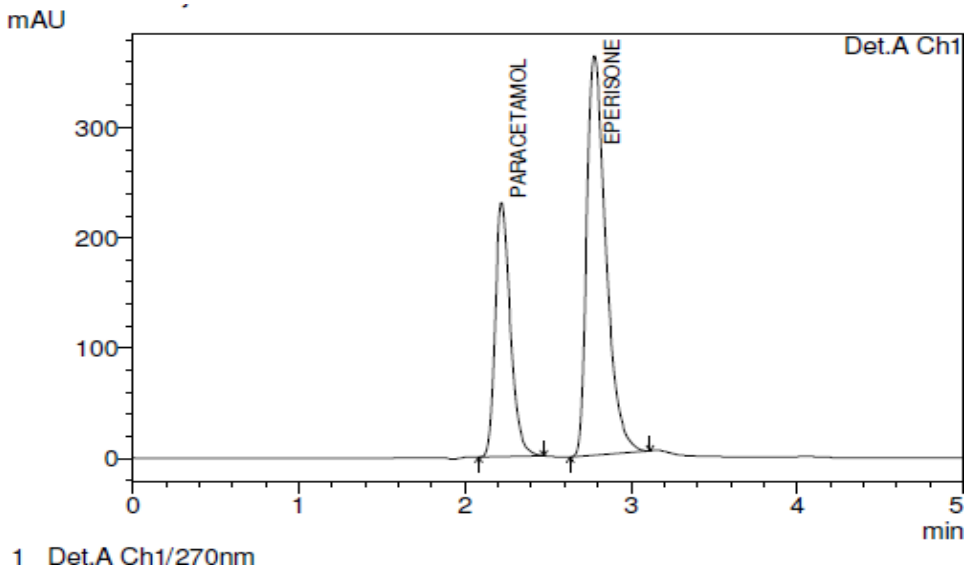


Fig 7: Chromatogram for system suitability.

Table 2: system suitability data:

System suitability parameters	Paracetamol	Eperisone Hydrochloride
%RSD for six replicate injections of standard	0.23	0.53
Tailing factor	1.340	1.452
Theoretical plates	7400	7299
Resolution	-	2.81

Specificity:

The specificity of the analytical method was indicated in fig 7.2, where the retention time of Paracetamol does not interfere with the retention time of the Eperisone hydrochloride

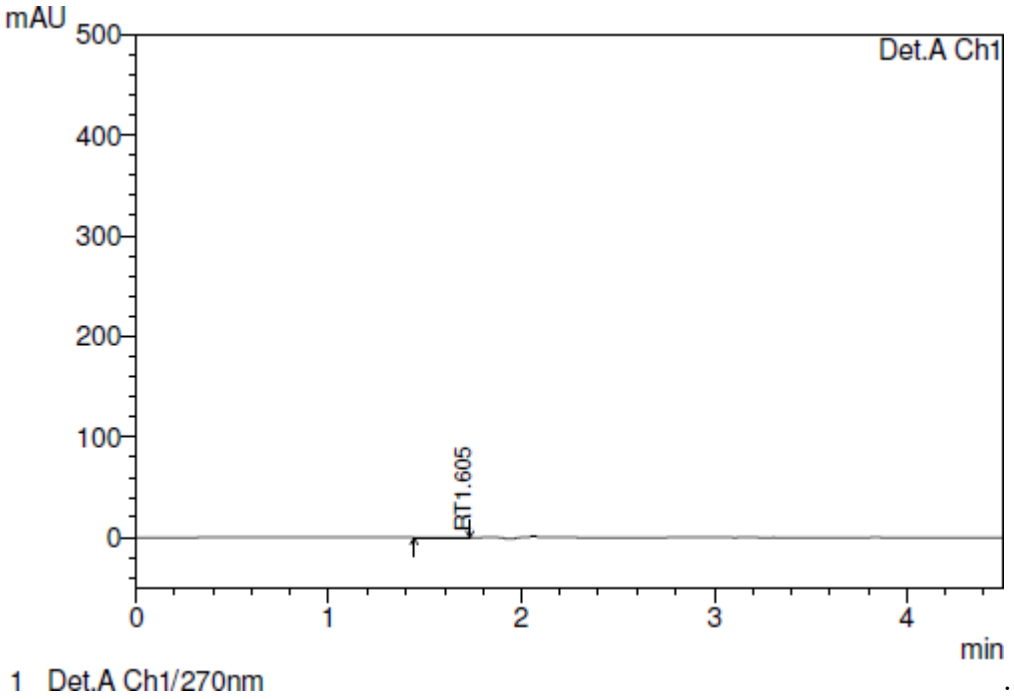


Fig 8: Chromatogram for Specificity Blank solution.

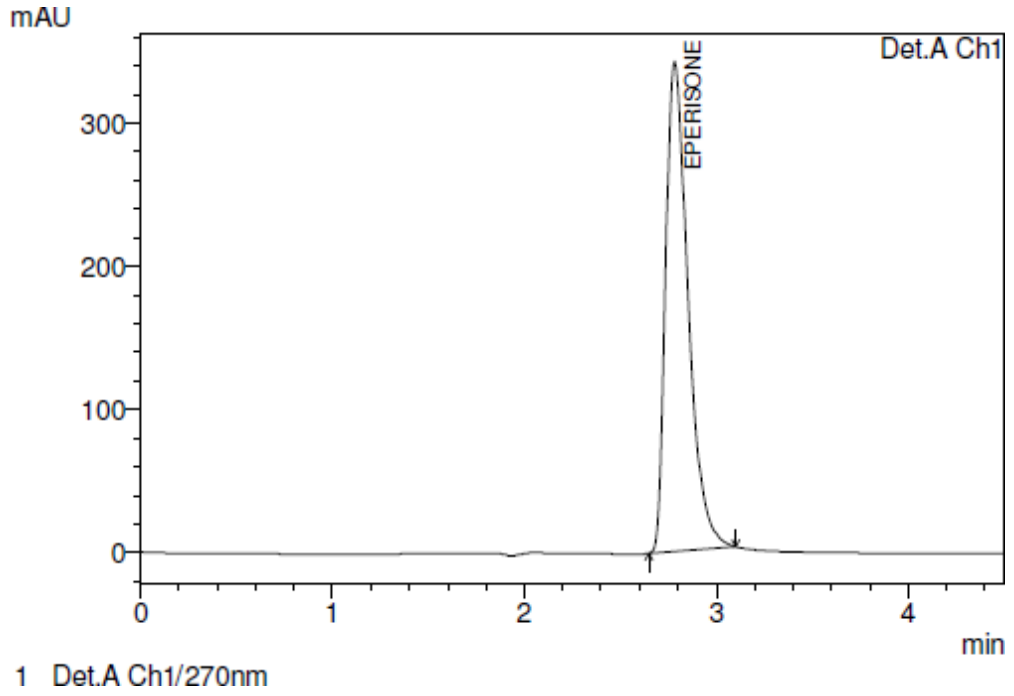


Fig 9: Chromatogram for Specificity Eperisone.

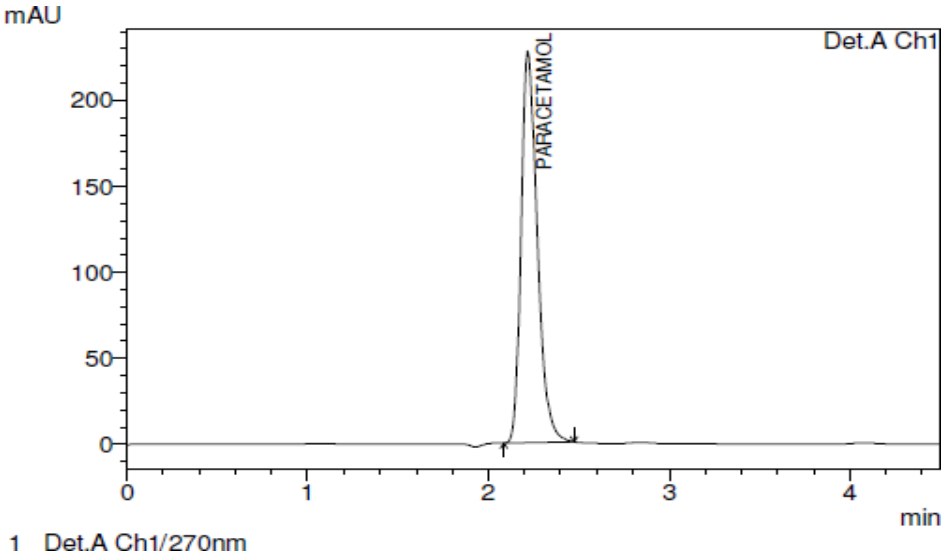


Fig 10. Chromatogram for Specificity Paracetamol.

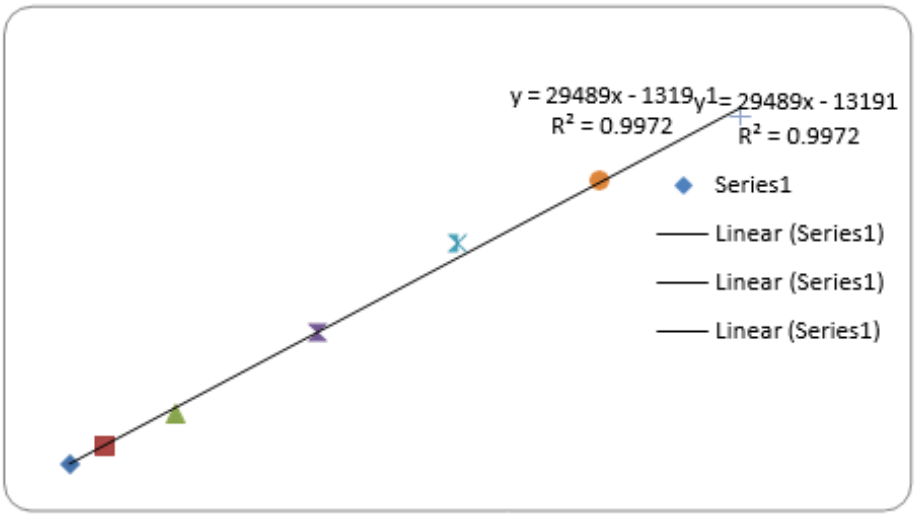


Fig 11: Linearity graph of Paracetamol.

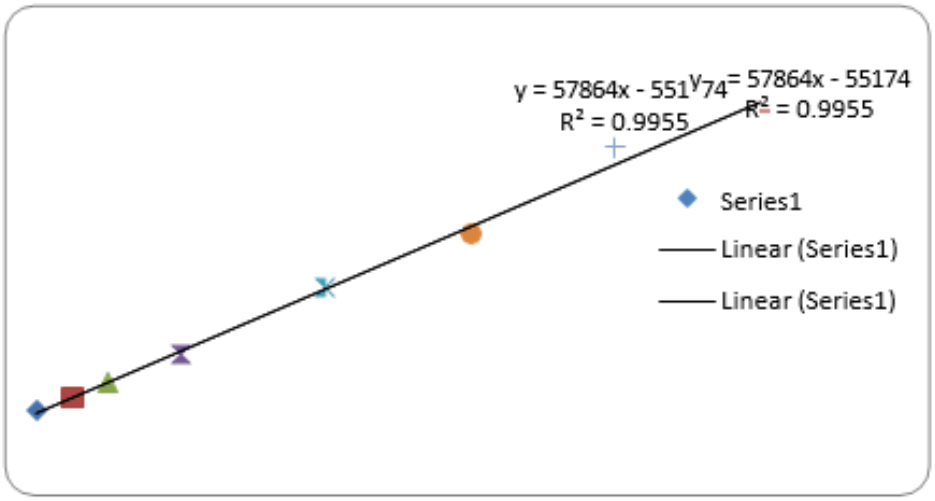


Fig 12: Linearity graph of Eperisone Hydrochloride.

Table 3: linearity data:

Parameters	Paracetamol	Eperisone hydrochloride
Slope	29489	57864
Intercept	13191	55174
Correlation coefficient	0.997	0.99

Accuracy and precision:

Accuracy and precision were calculated for the QC samples during the intra-day and inter-day run were given in Table 7.3 & 7.4. The results obtained from intermediate precision (inter-day) also indicated a good method precision. All the data were within the acceptance criteria of 5%.

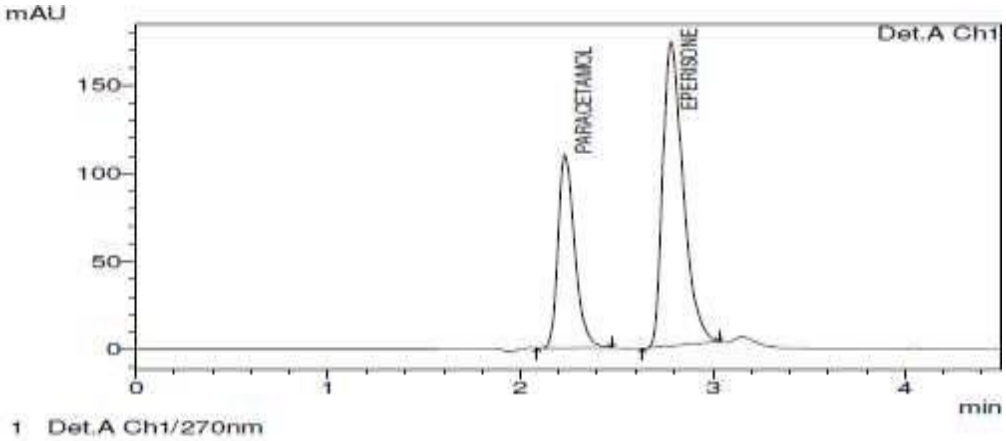


Fig 13: Chromatogram for LQC sample.

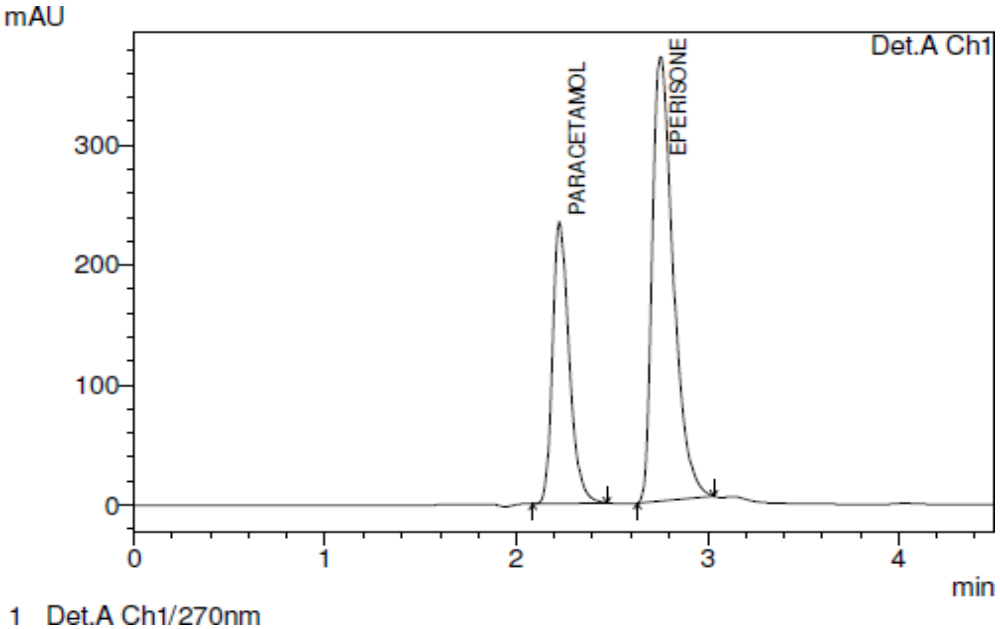


Fig 14: Chromatogram for MQC sample.

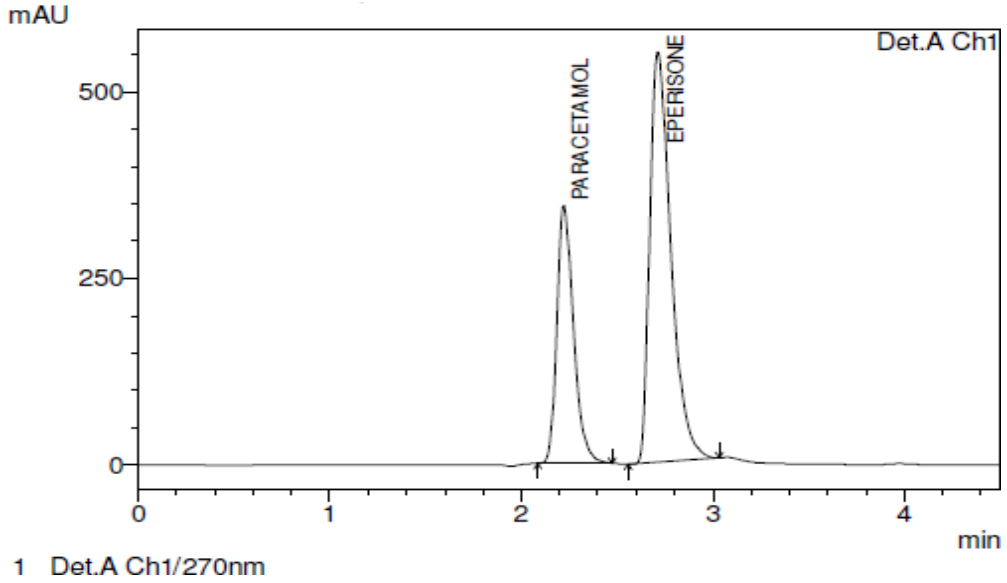


Fig 15: Chromatogram for HQC sample Table 4: Accuracy data of Paracetamol:

For LQC of Paracetamol:

PARACETAMOL

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	LQC 1	25.03	636306	2.23	22.03	87.99
2	LQC 2	25.03	665197	2.21	23.00	91.91
3	LQC 3	25.03	661564	2.23	22.88	91.42
MEAN					**22.64**	**90.44**
STDEV					**0.53**	**2.13**
% CV					**2.36**	**2.36**

For MQC of Paracetamol:

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	MQC 1	50.05	1429436	2.22	48.92	97.74
2	MQC 2	50.05	1410232	2.21	48.27	96.44
3	MQC 3	50.05	1463960	2.22	50.09	100.08
MEAN					**49.09**	**98.09**
STDEV					**0.92**	**1.84**
% CV					**1.88**	**1.88**

For HQC of Paracetamol:

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	HQC 1	75.08	2102206	2.22	71.74	95.54
2	HQC 2	75.08	2032332	2.20	69.37	92.39
3	HQC 3	75.08	1987645	2.19	67.85	90.37
MEAN					**69.65**	**92.77**
STDEV					**1.96**	**2.61**
% CV					**2.81**	**2.81**

Table 5: Accuracy data of Eperisone Hydrochloride: For LQC of Eperisone:

EPERISONE

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	LQC 1	25.21	1271657	2.80	22.93	90.96
2	LQC 2	25.21	1321400	2.76	23.79	94.37
3	LQC 3	25.21	1281873	2.78	23.11	91.66
MEAN					**23.28**	**92.33**
STDEV					**0.45**	**1.80**
% CV					**1.95**	**1.95**

For MQC of Eperisone:

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	MQC 1	50.41	2833438	2.75	49.92	99.03
2	MQC 2	50.41	2745088	2.74	48.39	96.00
3	MQC 3	50.41	2915417	2.78	51.34	101.84
MEAN					**49.88**	**98.96**
STDEV					**1.47**	**2.92**
% CV					**2.95**	**2.95**

For HQC of Eperisone:

SR NO	SAMPLE ID	Conc (µg/mL)	DRUG		Calculated Conc'n (µg/mL)	Accuracy (%)
			PEAK AREA	RETENTION TIME		
1	HQC 1	75.62	4226447	2.71	73.99	97.85
2	HQC 2	75.62	3995492	2.69	70.00	92.57
3	HQC 3	75.62	3913535	2.67	68.59	90.70
MEAN					**70.86**	**93.71**
STDEV					**2.80**	**3.71**
% CV					**3.96**	**3.96**

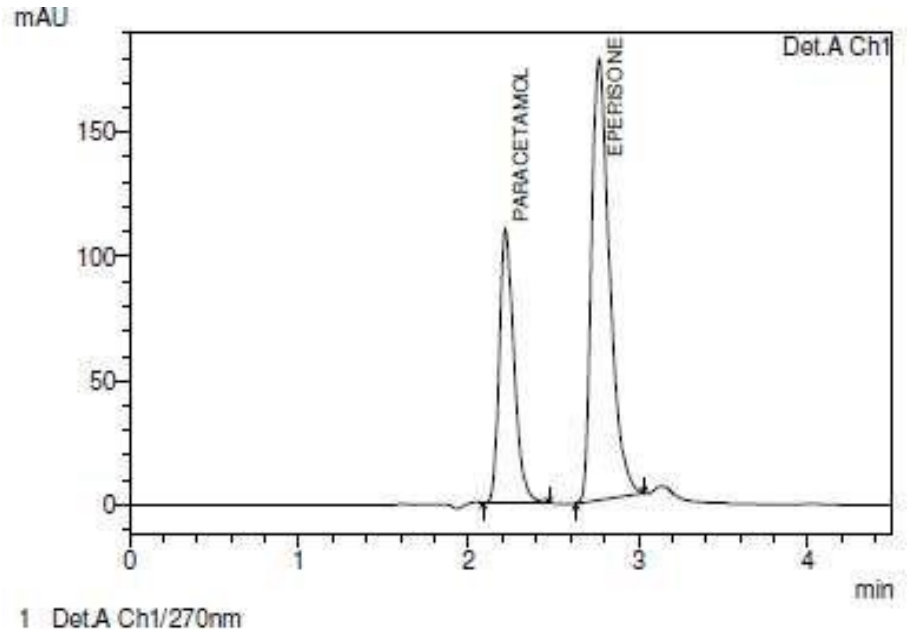


Fig 16: Chromatogram for LQC sample.

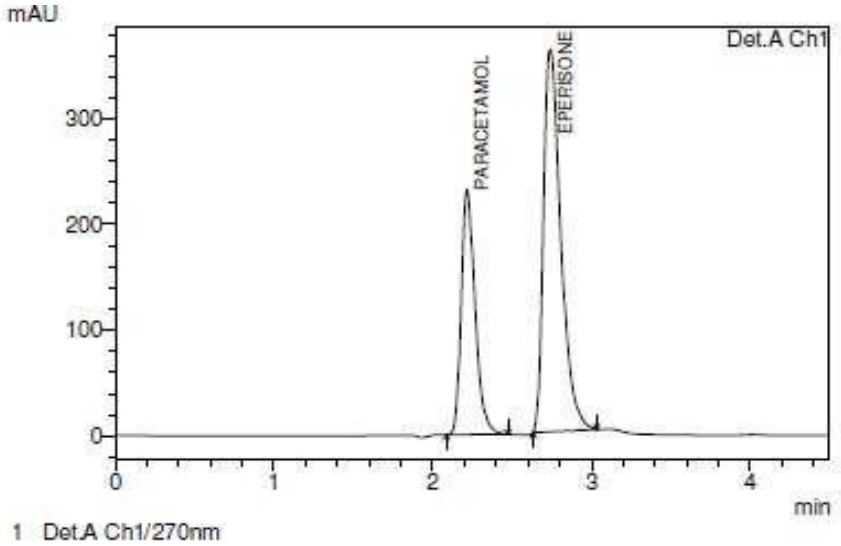


Fig 17: Chromatogram for MQC sample

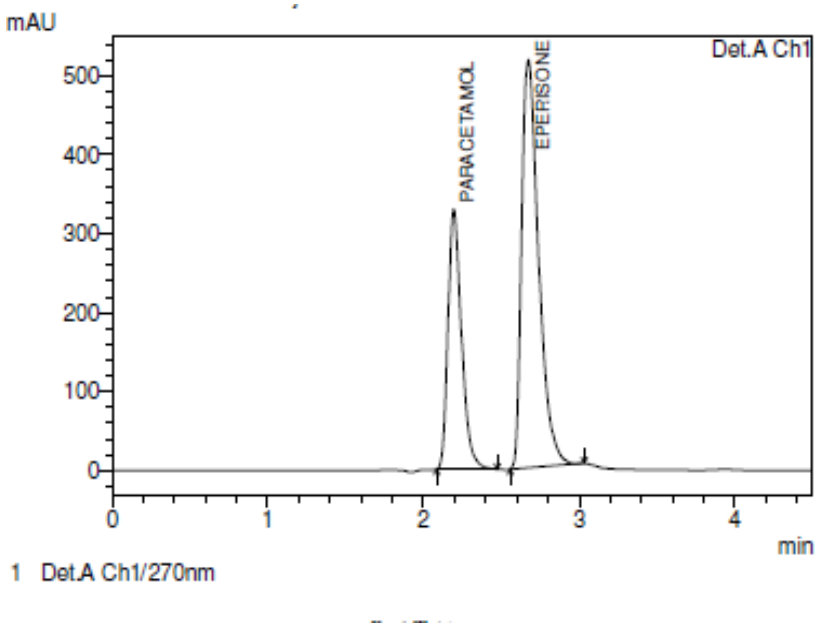


Fig 18: Chromatogram for HQC sample.

Table 6: Precision data of Paracetamol : Intra day Precision:

PARACETAMOL				
Sample ID	**Peak Retention Time**	**Peak Area**	**Theoretical Plates**	**Tailing Factor**
1	2.22	1441645	7365	1.35
2	2.21	1418834	7394	1.35
3	2.22	1435402	7310	1.35
4	2.21	1469153	7336	1.34
5	2.21	1473907	7531	1.33
6	2.21	1480977	7468	1.32
MEAN	**2.213**	**1453319.7**	**7400.7**	**1.340**
STDEV	**0.0052**	**24843.76**	**83.95**	**0.0126**
%CV	**0.23**	**1.71**	**1.13**	**0.94**

Table 7 Precision data of Paracetamol: Inter day precision:

EPERISONE				
Sample ID	**Peak Retention Time**	**Peak Area**	**Theoretical Plates**	**Tailing Factor**
1	2.78	2800463	7237	1.48
2	2.74	2760986	7308	1.47
3	2.74	2778492	7287	1.47
4	2.75	2825472	7240	1.47
5	2.75	2860443	7341	1.41
6	2.75	2842846	7381	1.41
MEAN	**2.752**	**2811450.3**	**7299.0**	**1.452**
STDEV	**0.0147**	**38304.57**	**56.64**	**0.03**
%CV	**0.53**	**1.36**	**0.78**	**2.24**

Table 8: Precision data of Eperisone Hydrochloride:

DAY 1	LQC	MQC	HQC
Mean	22.64	49.09	69.65
SD	0.53	0.92	1.96
%RSD	2.36	1.88	2.81
Recovery (%)	90.44	98.09	92.77
DAY 2			
Mean	22.71	49.34	69.77
SD	0.56	0.86	1.91
%RSD	2.46	1.74	2.73
Recovery (%)	90.84	98.68	93.02
DAY 3			
Mean	23.15	50.69	70.81
SD	0.63	0.99	1.94
%RSD	2.72	1.95	2.73
Recovery (%)	92.6	101.38	94.41
DAY 1	LQC	MQC	HQC
Mean	23.28	49.88	70.86
SD	0.45	1.47	2.80
%RSD	1.95	2.95	3.96
Recovery (%)	93.12	99.76	94.48
DAY 2			
Mean	23.36	50.01	70.79
SD	0.51	1.53	2.89
%RSD	2.1	3.05	4.08
Recovery (%)	93.44	100.02	94.38
DAY 3			
Mean	23.38	49.97	70.91
SD	0.57	1.59	2.96
%RSD	2.43	3.18	4.17
Recovery (%)	93.52	99.94	94.54

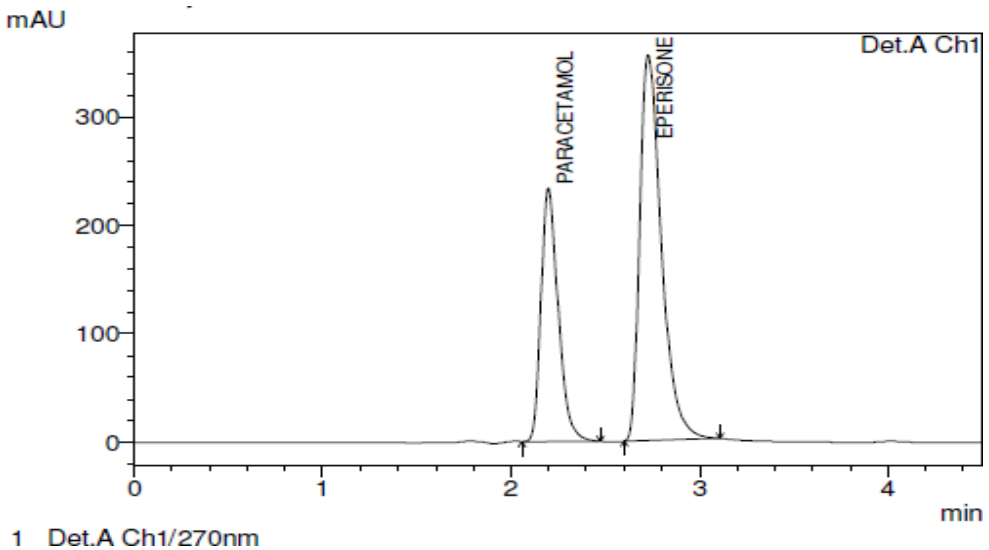


Fig 19: Chromatogram for ruggedness by analyst variation.

Table 9: Ruggedness data:

	Drug name	Rt	Tailing factor	Theoretical plates	Resolution
Analyst 1	Paracetamol	2.2	1.337	7394	-
	Eperisone Hcl	2.75	1.450	7308	5.08
Analyst 2	Paracetamol	2.2	1.333	7468	-
	Eperisone Hcl	2.7	1.403	7341	4.94

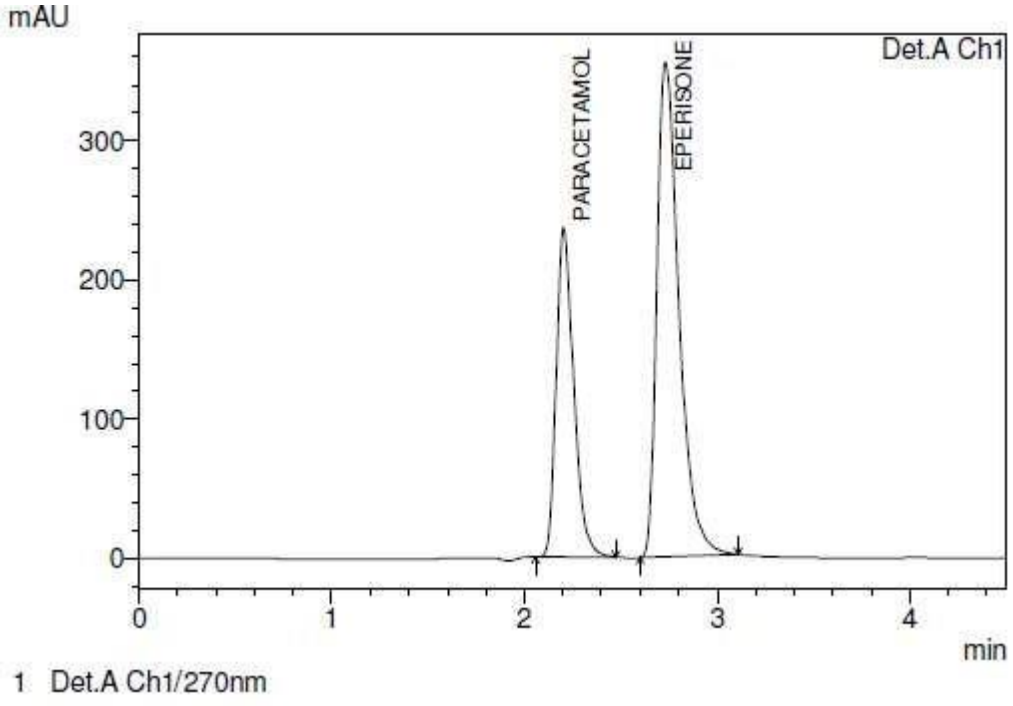


Fig 20: Chromatogram for ruggedness by Column Variation.

Forced degradation studies:

The stress studies involving acid, alkali, photolytic and oxidation revealed that Paracetamol and Eperisone hydrochloride were not fully degraded. However in alkaline conditions (1N NaOH) Paracetamol was degraded and there is slight change in peak area of Eperisone hydrochloride. Except for alkaline conditions, the drugs content were within 90-110 % for all stress conditions indicating the stability and specificity of the analytical method to differentiate the degradation peaks.

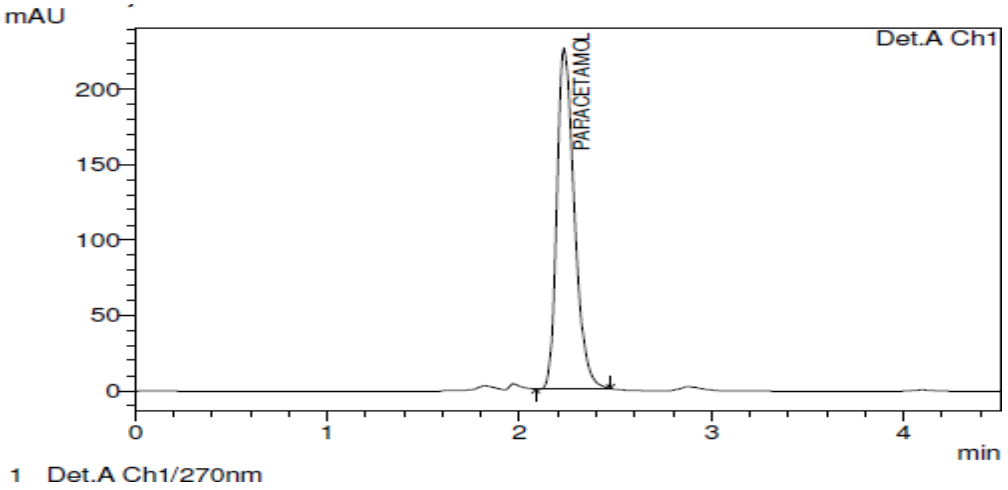


Fig 21: Chromatogram for Paracetamol oxidative degradation.

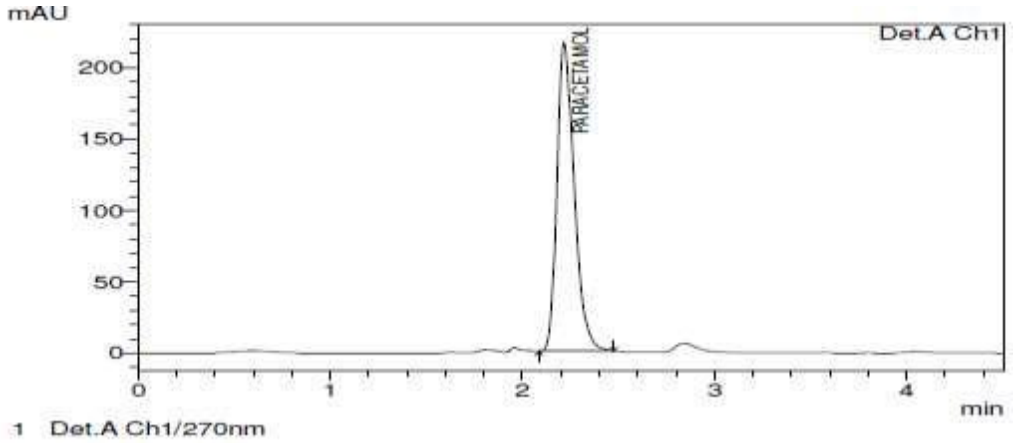


Fig 22: Chromatogram for Paracetamol photolytic degradation.

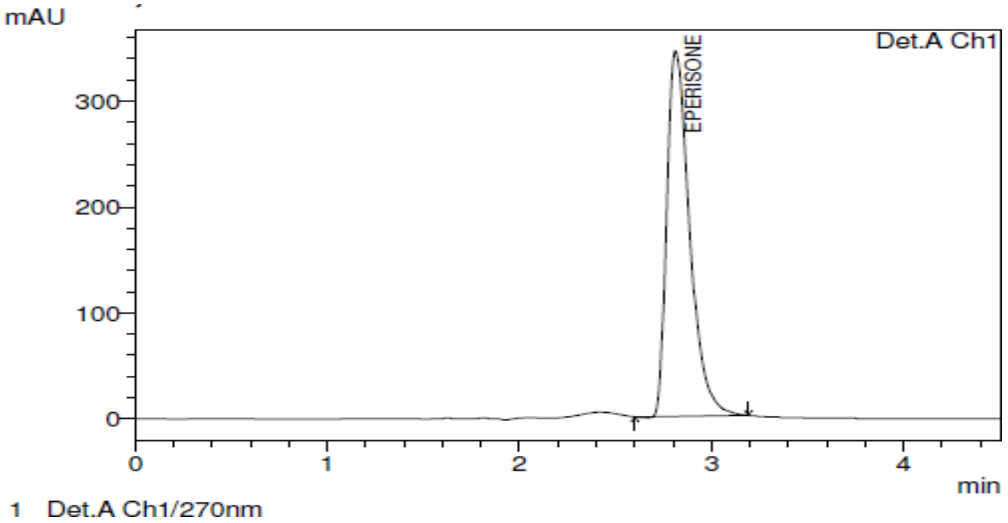


Fig 23: Chromatogram for Eperisone hydrochloride oxidative degradation.

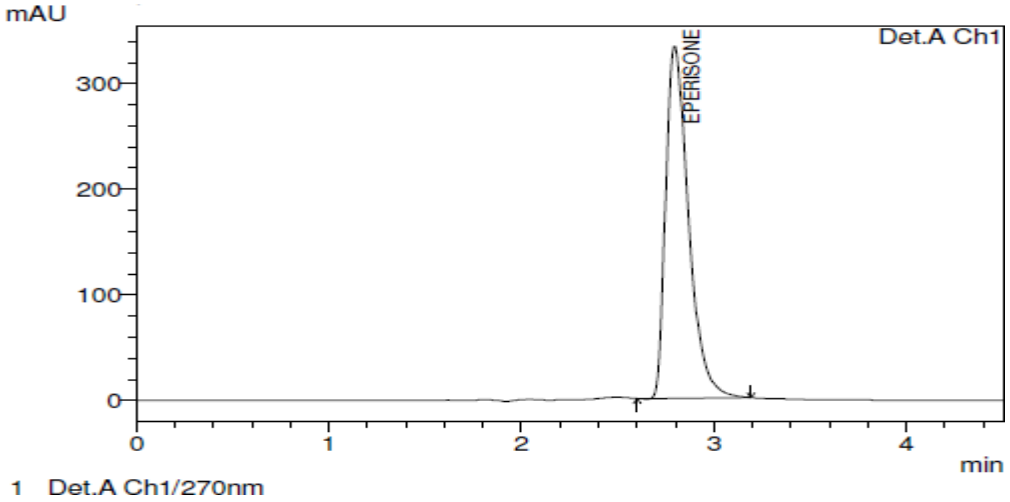


Fig 24: Chromatogram for Eperisone hydrochloride photolytic degradation Table 10: forced degradation studies:

Table 11: Results of Paracetamol and Eperisone hydrochloride in marketed product:

	Paracetamol			**Eperisone hydrochloride**		
	%stability	**SD**	**%RSD**	**%stability**	**SD**	**%RSD**
Oxidation	97.35	2.79	2.86	99.06	2.7	2.72
Light	100.05	2.3	2.29	101.17	3.1	3.06
Acid	98.89	1.95	1.97	99.93	3	3.00
Alkaline	82.16	1.64	1.99	88.13	1.56	1.77
Marketed formulation		**Drug**		**%Assay**	**SD**	**%RSD**
MYOSONE PLUS		**Eperisone hydrochloride - 50mg**		98.56	0.83	0.85
		Paracetamol - 325mg		99.36	0.60	0.61

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