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STABILITY-INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF LULICONAZOLE AND SALICYLIC ACID IN ITS TOPICAL DOSAGE FORM

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ABSTARCT

A simple, rapid, precise, and stability-indicating RP-HPLC method was developed and validated for the simultaneous estimation of Luliconazole and Salicylic Acid in pharmaceutical dosage form. Separation was achieved on a YMC Pack ODS-A column (150 mm × 4.6 mm, 5 µm) using Buffer: Methanol (30:70 % v/v) as mobile phase at a flow rate of 1.0 mL/min, with detection at 226 nm. The method showed excellent linearity in the range of 10–30 µg/mL for Luliconazole and 30–90 µg/mL for Salicylic Acid ($R^2 > 0.998$). Accuracy studies showed recoveries of 98% and 99.6%, respectively. LOD and LOQ values indicated good sensitivity. Forced degradation studies under various stress conditions confirmed the stability-indicating nature of the method, with clear separation of degradation products. The method is suitable for routine quality control analysis.

KEYWORDS: Luliconazole; Salicylic Acid; RP-HPLC; Stability-indicating method; Method validation; Forced degradation; Pharmaceutical dosage form; Linearity; Accuracy; Precision; LOD; LOQ.

I. INTRODUCTION

Dermatophytic infections are common superficial fungal infections affecting the skin, hair, and nails, often caused by keratinophilic fungi such as *Trichophyton*, *Microsporum*, and *Epidermophyton*, which can lead to itching, scaling, and discomfort if untreated.[1-3] Luliconazole is a novel topical imidazole antifungal agent that demonstrates potent activity against dermatophytes, yeasts, and other pathogenic fungi.[4-5] Salicylic Acid is a keratolytic agent widely used in dermatological formulations to treat hyperkeratosis conditions, warts, psoriasis, and acne.[6-7] A stability-indicating method is a validated analytical procedure capable of detecting changes in the chemical and physical properties of a drug substance and drug product over time, including separation of degradation products from the intact drug.[8-9]

II. MATERIALS AND METHODS

- **Materials**

Luliconazole (1% w/w) and Salicylic Acid IP (3% w/w) cream was used as the pharmaceutical dosage form. HPLC grade Methanol, Acetonitrile, and Milli-Q water were procured from Merck Life Science Pvt. Ltd., India. All other reagents were of analytical grade.

- **Buffer Preparation**

A 0.02 M Potassium Dihydrogen Phosphate buffer was prepared by dissolving 2.72 g of potassium dihydrogen orthophosphate in 1 L of Milli-Q water using sonication. The pH was adjusted to 2.5 with diluted orthophosphoric acid.

- **Instrumentation**

Chromatographic analysis was carried out using a Shimadzu HPLC system (LC-2010 CHT) equipped with a 100 µL fixed loop injector and LC Solution software. Spectral analysis was performed using a Shimadzu UV-1800 double-beam UV–Visible spectrophotometer with UV Probe software. Additional instruments included a Sartorius analytical balance, Lab India digital pH meter, ultrasonic bath (Athena Technology), hot air oven (Patel Scientific), and micropipettes (Eppendorf).

- **Chromatographic Conditions**

Separation was achieved on a YMC Pack ODS-A column (150 mm × 4.6 mm, 5 µm) using a mobile phase of Buffer: Methanol (30:70 % v/v) at a flow rate of 1.0 mL/min. Detection was

performed at 226 nm, the injection volume was 10 µL, and the column temperature was maintained at 25 °C.

- **Method Validation and Forced Degradation Studies**

The method was validated according to ICH guidelines for linearity, accuracy, precision, LOD, and LOQ. Forced degradation studies were conducted under acidic, alkaline, oxidative, thermal, and photolytic conditions to assess the stability-indicating nature of the method.

- **IR identification and wavelength selection**

The individual standard drugs, Luliconazole & Salicylic Acid were mixed with KBr and KBr pallets were prepared. These KBrs pallets of drugs were used for FTIR analysis. And then FTIR spectra were interpreted and results were co-related with M.P., UV spectra and solubility to confirm identity of individual drugs. Wavelength was selected from the overlay spectra of above solutions.

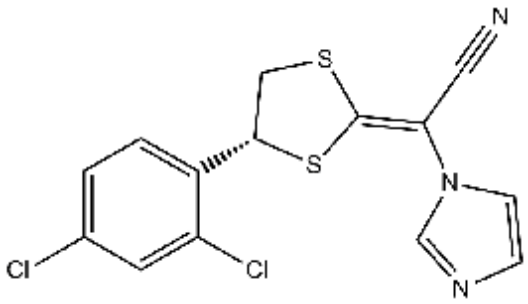


Fig. 1: Structure of Luliconazole.

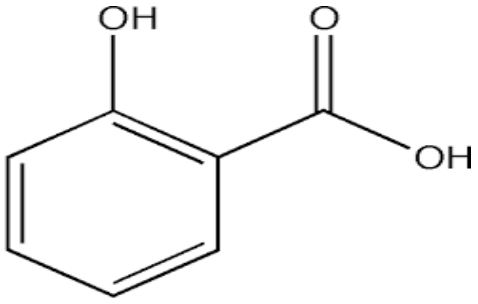


Fig. 2: Structure of Salicylic acid.

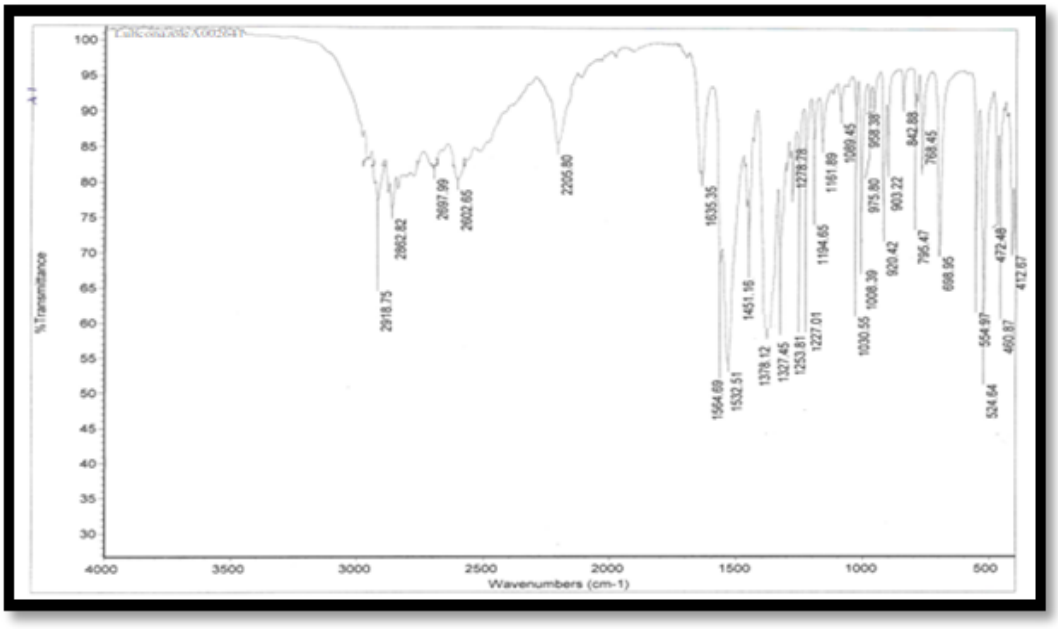


Fig. 3: IR spectrum of Luliconazole (API).

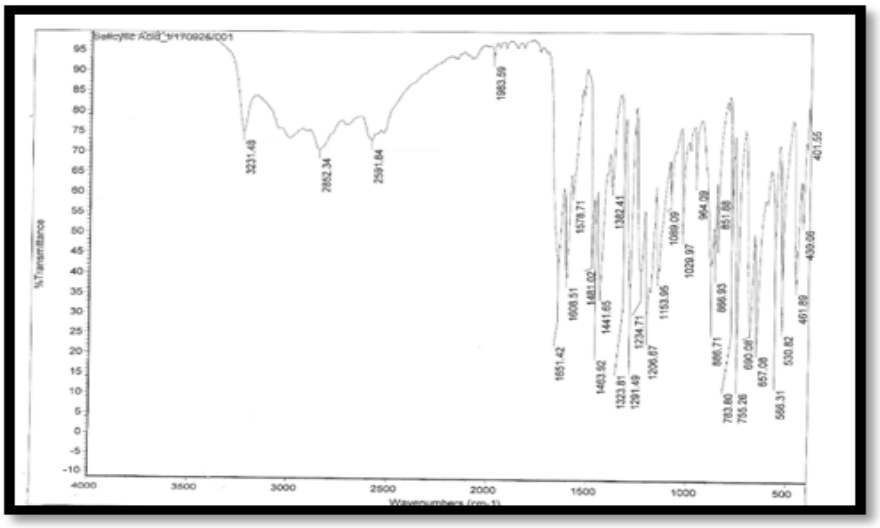


Fig. 4: IR Spectrum of salicylic Acid (API).

Table 1: IR spectrum of Luliconazole.

SR. NO.	Functional group	Observed value	Standard value
1	Aliphatic C–H stretching	2918.75, 2862.82	3000–2800
2	C≡N stretch	2205.80	2400–2100
3	C=N stretch	1653.35, 1584.69	1650–1580
4	C-H bending	842.88	860–800
5	C–Cl stretch	795.47	600-800

Table 2: IR spectrum of Salicylic acid.

Sr. No.	Functional group	Observed value	Standard value
1	O-H stretch	3231.48	3600-3200
2	C–H stretch	2852.34	2960-2850
3	C=O stretching	1651.42	1750-1600
4	Aromatic C=C stretches	1608.51, 1578.71, 1463.92, 1441.65	1600-1450

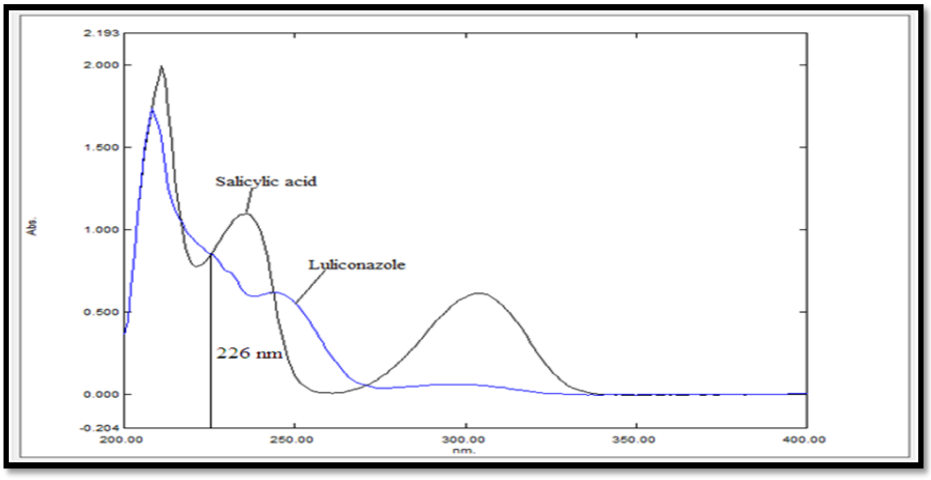


Fig. 5: Determination of wavelength maximum (226nm).

- **Preparation of Solutions**

Luliconazole Standard Solutions

A stock solution (200 µg/mL) was prepared by dissolving 10 mg of Luliconazole in methanol in a 50 mL volumetric flask with sonication for 15 minutes, followed by dilution to volume. A working standard solution (20µg/mL) was prepared by diluting 1.0 mL of the stock solution to 10 mL with diluent.

Salicylic Acid Standard Solutions

A stock solution (600 µg/mL) was prepared by dissolving 30 mg of salicylic acid in methanol in a 50 mL volumetric flask with sonication for 15 minutes, followed by dilution to volume. A working standard solution (60 µg/mL) was prepared by diluting 1.0 mL of the stock solution to 10 mL with diluent.

Mixed Standard Solution

A mixed standard solution containing 60 µg/mL of salicylic acid and 20 µg/mL of Luliconazole was prepared by transferring 1.0 mL each of their respective stock solutions into a 10 mL volumetric flask and diluting to volume with diluent.

Sample Solution

A sample stock solution containing 600 µg/mL of salicylic acid and 200 µg/mL of Luliconazole was prepared by dissolving cream equivalent to 30 mg salicylic acid and 10 mg Luliconazole in a 50 mL volumetric flask using 10% sodium chloride solution and diluent, followed by sonication for 20 minutes. The solution was diluted to volume, centrifuged at 3500 rpm for 15 minutes, and filtered through a 0.45 µm PVDF filter. A working sample solution (60 µg/mL salicylic acid and 20 µg/mL Luliconazole) was prepared by diluting 1.0 mL of the sample stock solution to 10 mL with diluent.

- **METHOD DEVELOPMENT**

Trial 1.

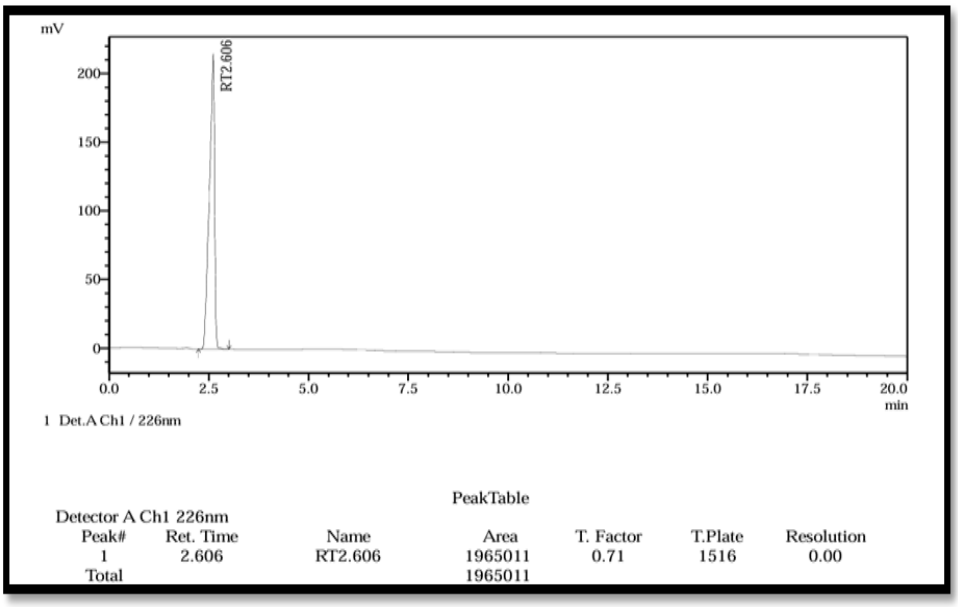


Fig. 6: chromatogram of Luliconazole and salicylic acid (water: methanol, 50:50 % v/v).

Trial-2

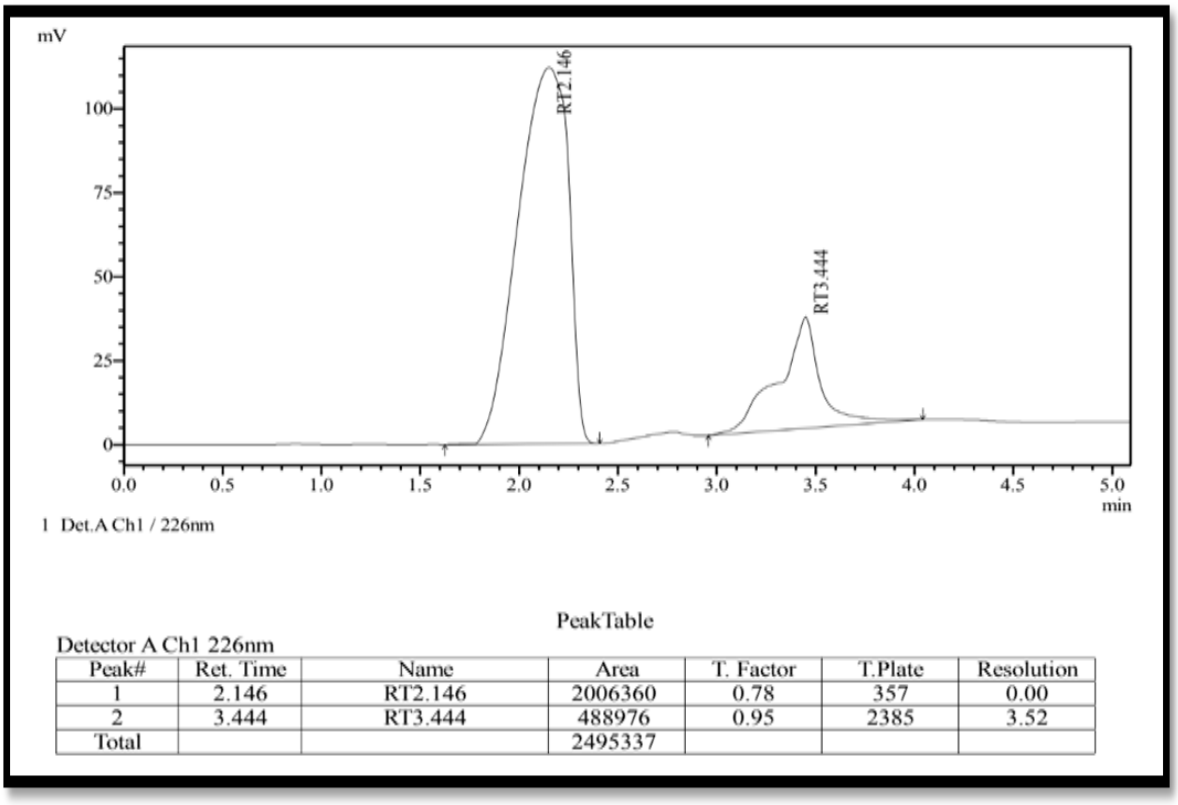
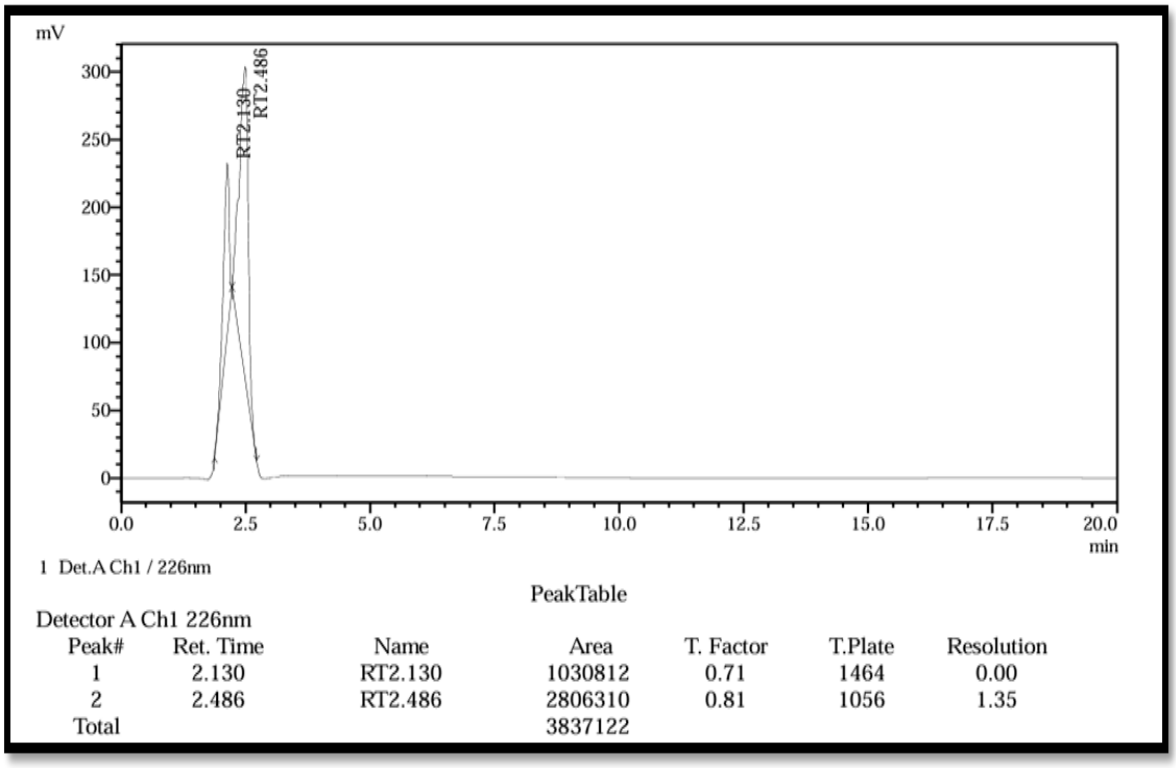


Fig. 7: Chromatogram of Luliconazole and salicylic acid (Water: Methanol 40:60 % v/v)

Trial 3



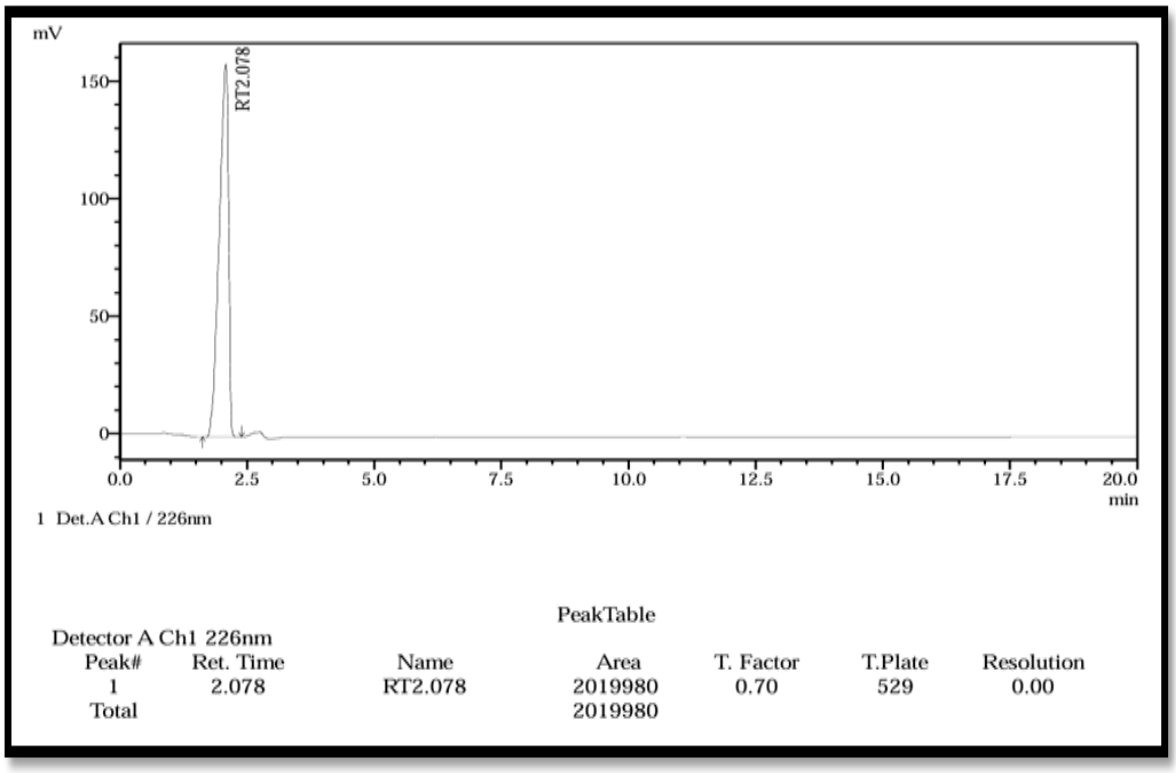
PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	2.130	RT2.130	1030812	0.71	1464	0.00
2	2.486	RT2.486	2806310	0.81	1056	1.35
Total			3837122			

Fig. 8: Chromatogram of Luliconazole and salicylic acid (Water: ACN (50: 50 % v/v)).

Trial-4



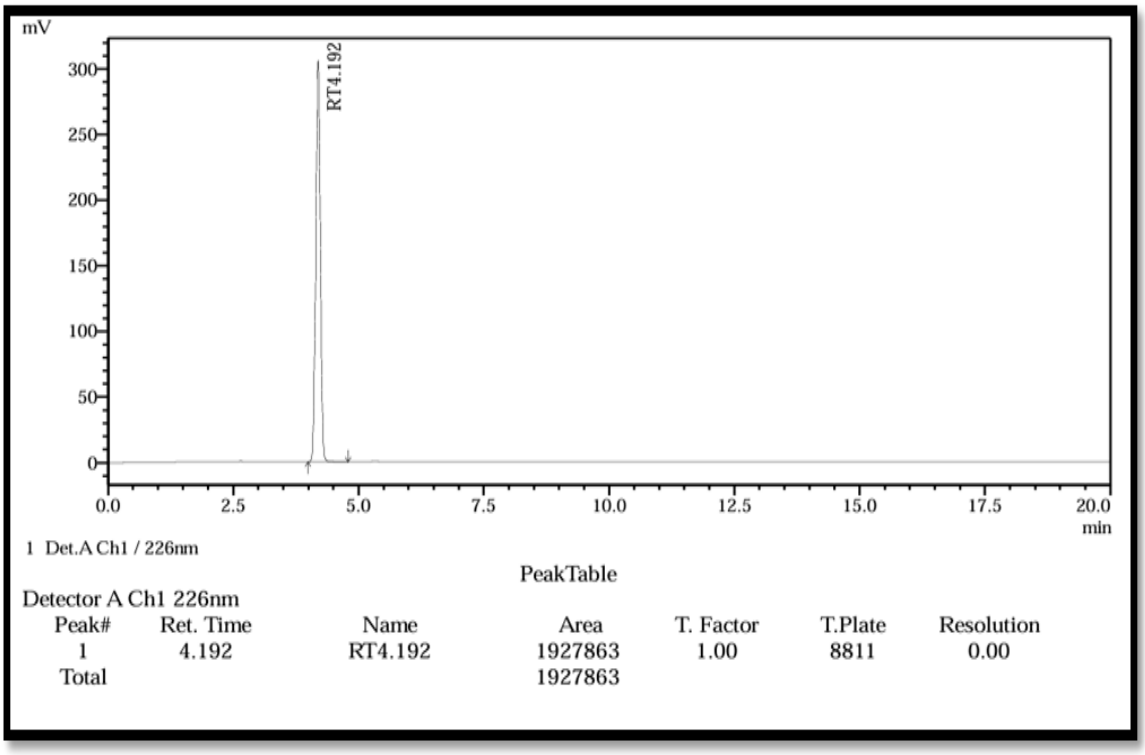
PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	2.078	RT2.078	2019980	0.70	529	0.00
Total			2019980			

Fig. 9: Chromatogram of Luliconazole and salicylic acid (Water: ACN (60 : 40 % v/v)).

Trial-5



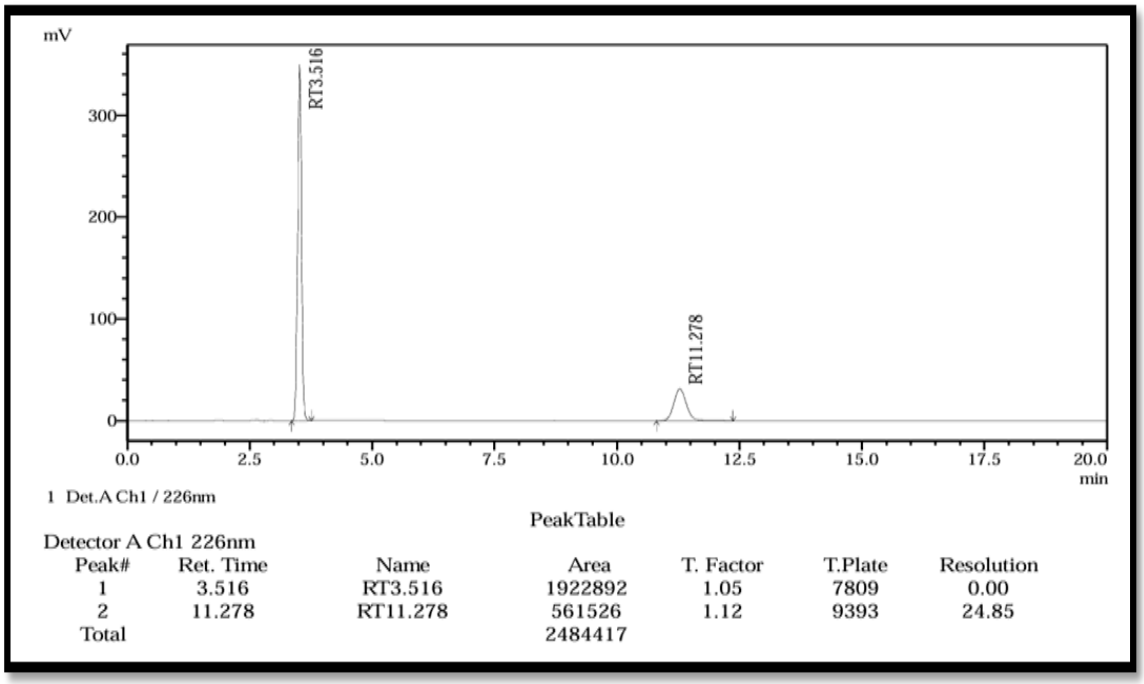
PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	4.192	RT4.192	1927863	1.00	8811	0.00
Total			1927863			

Fig. 10: chromatogram of Luliconazole and salicylic acid (Buffer: Methanol 50:50% v/v)).

Trial 6



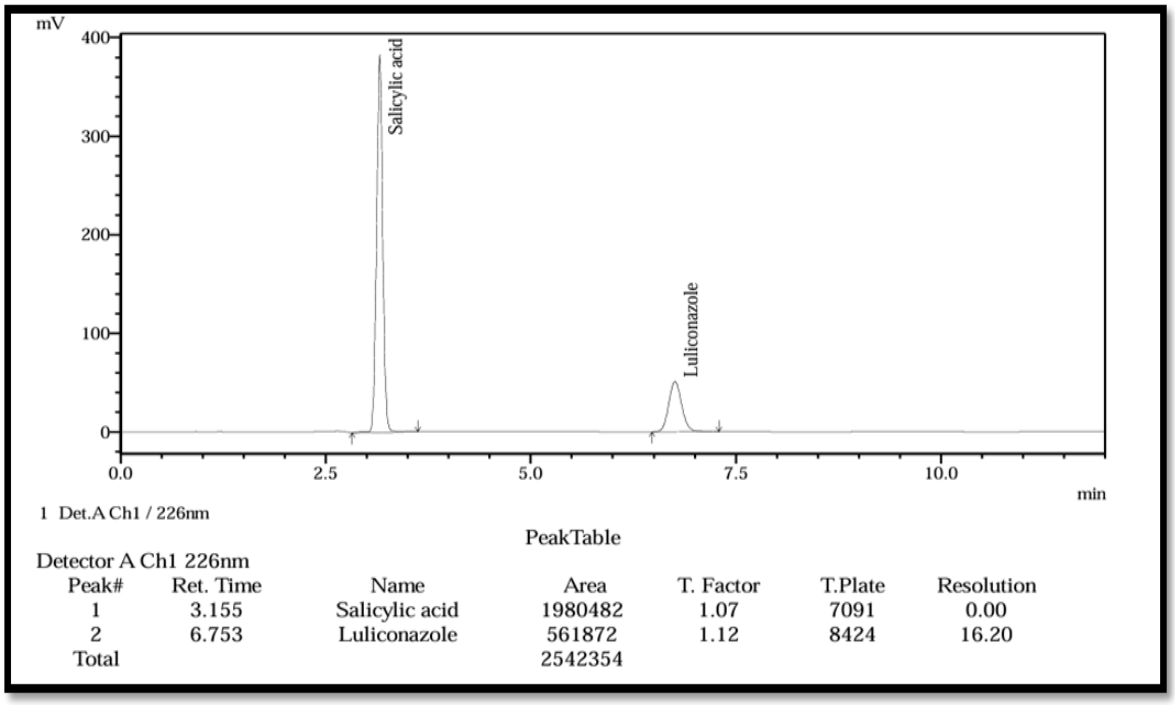
PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	3.516	RT3.516	1922892	1.05	7809	0.00
2	11.278	RT11.278	561526	1.12	9393	24.85
Total			2484417			

Fig. 11: chromatogram of Luliconazole and salicylic acid (Buffer: Methanol 40:60% v/v)).

Trial -7

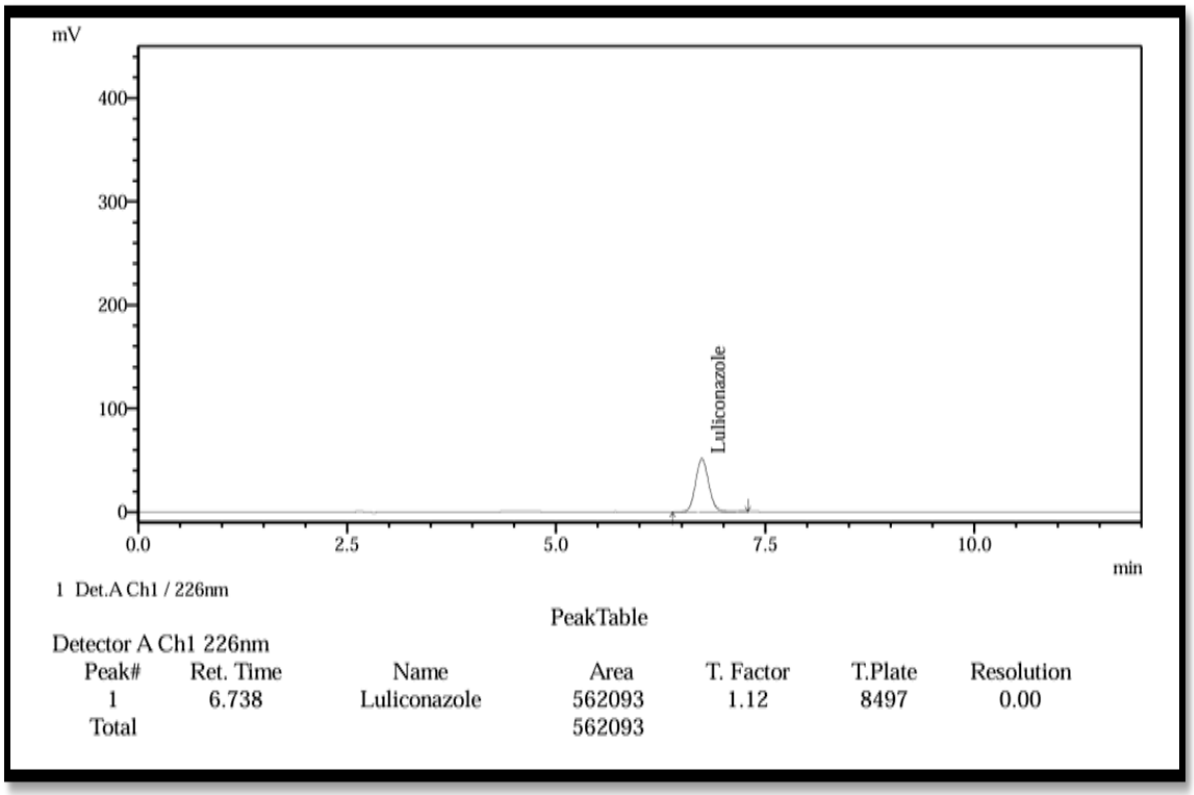


PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	3.155	Salicylic acid	1980482	1.07	7091	0.00
2	6.753	Luliconazole	561872	1.12	8424	16.20
Total			2542354			

Fig. 12: Chromatogram of Luliconazole and salicylic acid (Buffer: Methanol 30:70% v/v)).



PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	6.738	Luliconazole	562093	1.12	8497	0.00
Total			562093			

Fig. 13: Peak Identification (20 µg/mL Luliconazole).

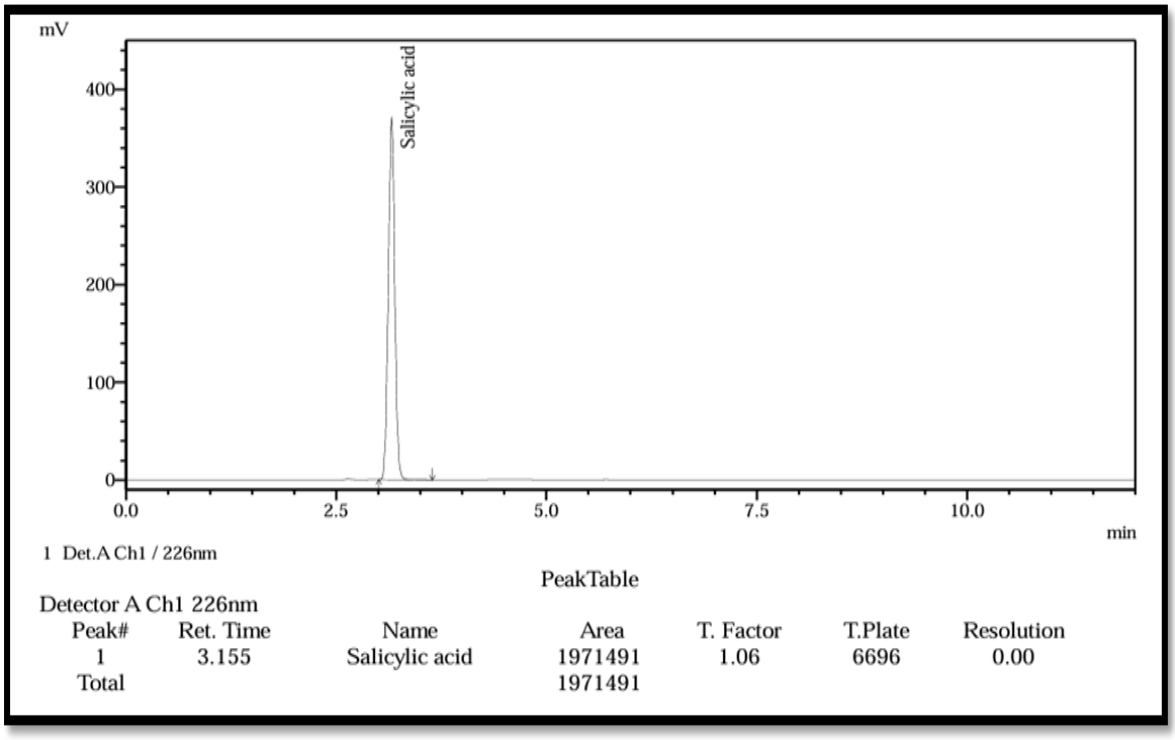


Fig. 14: Peak identification (60 µg/mL Salicylic Acid).

Table 3: Mobile phase selection.

Sr. No	Mobile Phase Composition	Ratio (%V/V)	Observation
1	Water: Methanol	50:50	The first analyte eluted at 2.60 min; the second showed no elution up to 20 min.
2	Water: Methanol	40:60	Upon changing the organic modifier ratio, both analytes eluted; however, the peaks were distorted.
3	Water: Acetonitrile	50:50	When acetonitrile was used instead of methanol, both peaks co-eluted.
4	Water: Acetonitrile	60:40	Lowering the solvent ratio improved separation; first analyte eluted near dead volume with low N, second analyte retained longer.
5	Buffer: Methanol	50:50	Replacing water with buffer resulted in a single sharp peak.
6	Buffer: Methanol	40:60	Increasing methanol resulted in symmetrical peaks for both analytes, but with a longer run time.
7	Buffer: Methanol	30:70	Higher methanol reduced run time; system suitability confirmed with retention times of 3.1 min (salicylic acid) and 6.7 min (Luliconazole).

IV. METHOD VALIDATION

1. System Suitability

System suitability was assessed by six replicate injections of standard solution (20 µg/mL Luliconazole, 60 µg/mL salicylic acid), recording retention time, theoretical plates, tailing factor, and %RSD of peak areas.

Sr. No.	Parameter	Luliconazole (Mean ± SD)	%RSD	Salicylic Acid (Mean ± SD)	%RSD
1	Retention Time (min)	6.753 ± 0.007	0.10	3.155 ± 0.006	0.19
2	Peak Area	561872 ± 842.8	0.15	1980482 ± 2772.7	0.14
3	Tailing Factor	1.12 ± 0.008	0.71	1.07 ± 0.007	0.65
4	Theoretical Plates (N)	8424 ± 32.6	0.39	7091 ± 28.4	0.40
5	Resolution	16.20 ± 0.04	0.25	—	—

2. Specificity

Specificity was confirmed by injecting blank, standard, and sample solutions; no interfering peaks were observed at the retention times of Luliconazole and salicylic acid.

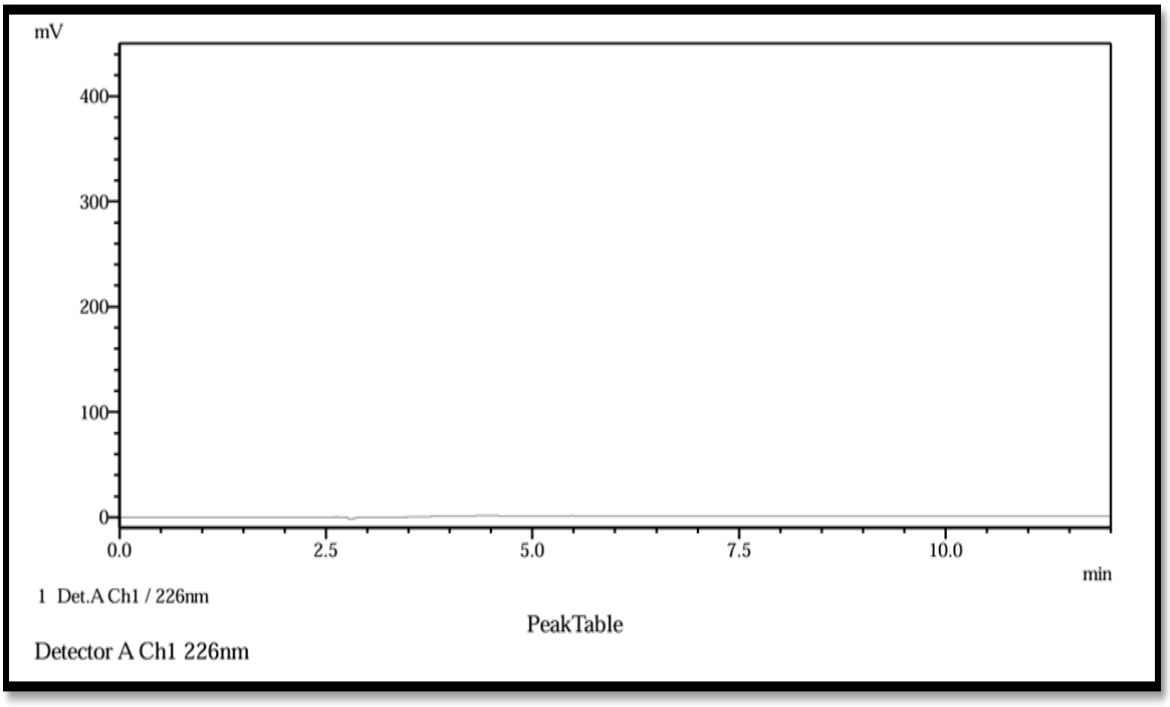
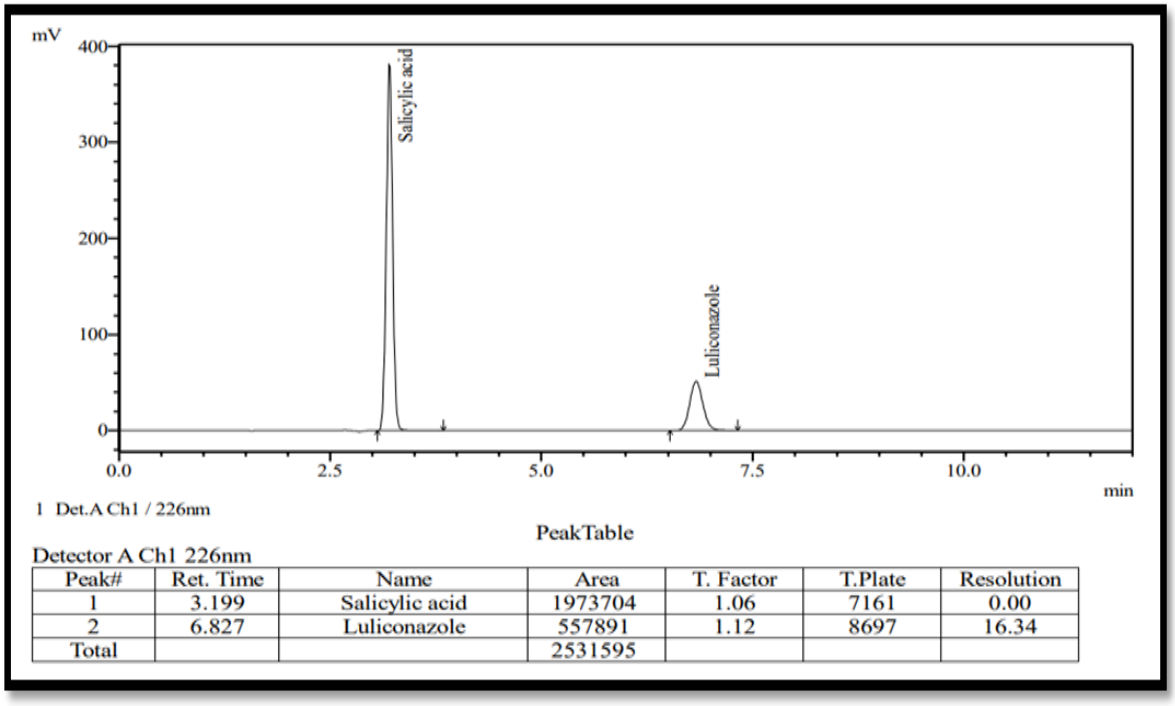


Fig. 15: Chromatogram of Diluent.

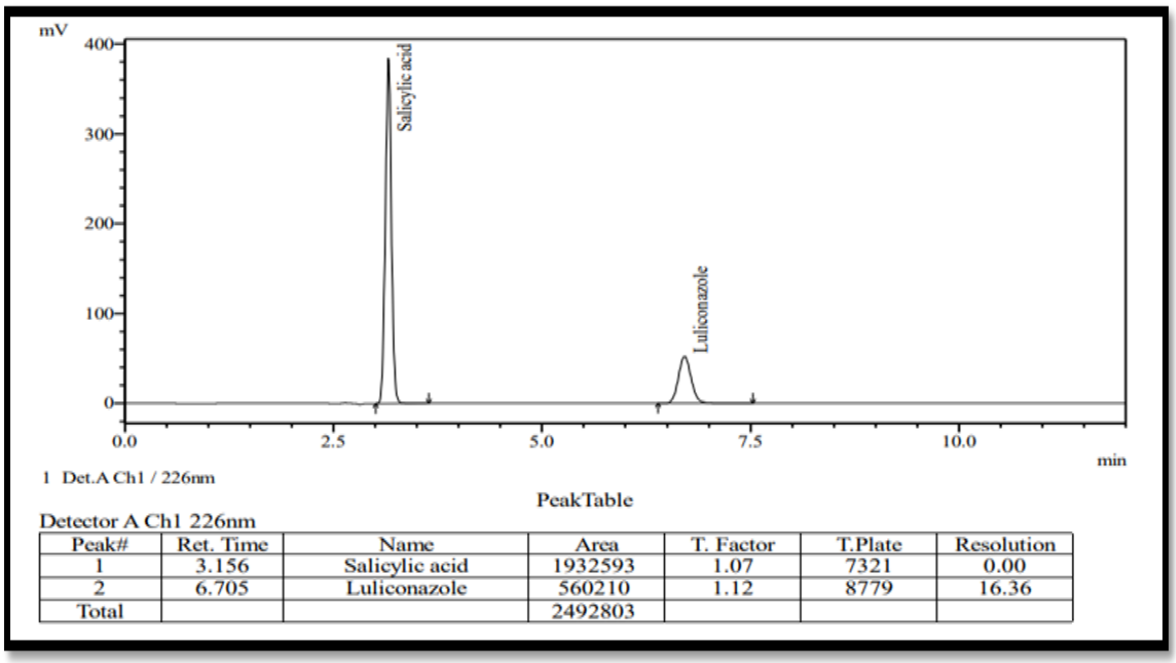


PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	3.199	Salicylic acid	1973704	1.06	7161	0.00
2	6.827	Luliconazole	557891	1.12	8697	16.34
Total			2531595			

Fig. 16: Spectra of Standard of Luliconazole And Salicylic Acid.



PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	3.156	Salicylic acid	1932593	1.07	7321	0.00
2	6.705	Luliconazole	560210	1.12	8779	16.36
Total			2492803			

Fig. 17: Spectra for Sample Of Luliconazole And Salicylic Acid.

3. Linearity

Linearity was established by preparing standard solutions at different concentration levels.

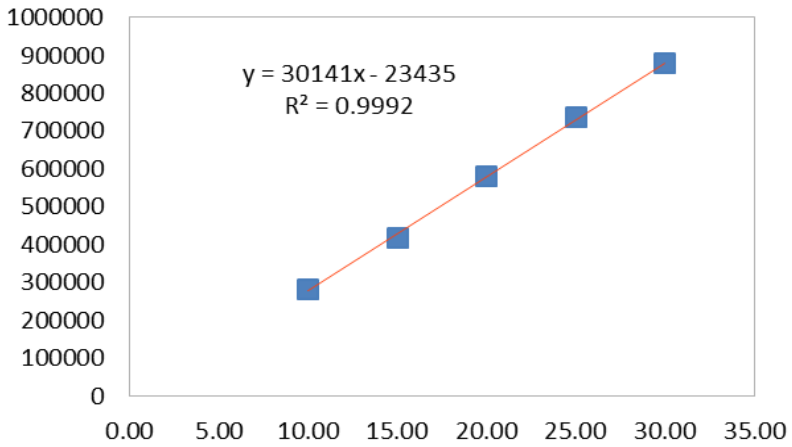


Fig. 18: Calibration Curve of Luliconazole.

Table 4: Linearity Data for Luliconazole.

Sr. No.	Concentration (µg/ml)	Mean Peak Area	SD	% RSD
1	10.00	283098	3836.761	1.35
2	15.00	419071	852.7708	0.20
3	20.00	580271	2112.128	0.36
4	25.00	736701	2223.851	0.30
5	30.00	877817	2137.584	0.24

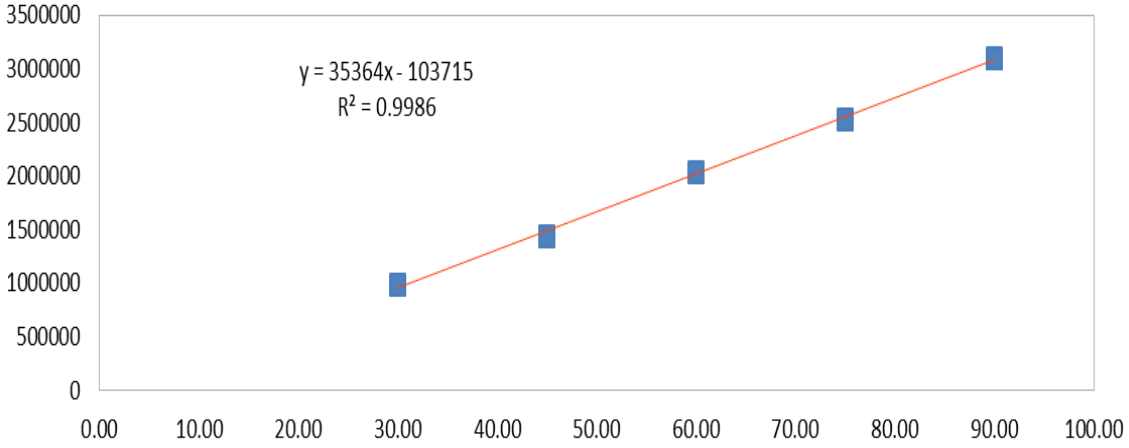


Fig. 19: Calibration Curve of Salicylic acid.

Table 5: Linearity Data for Salicylic acid.

Sr. No.	Concentration (µg/ml)	Mean Peak Area	SD	% RSD
1.	30.00	985582	501.3387	0.05
2.	45.00	1441963	873.2769	0.06
3.	60.00	2039197	1856.155	0.09
4.	75.00	2530027	4626.6	0.18
5.	**90.00**	3093847	708.521	0.02

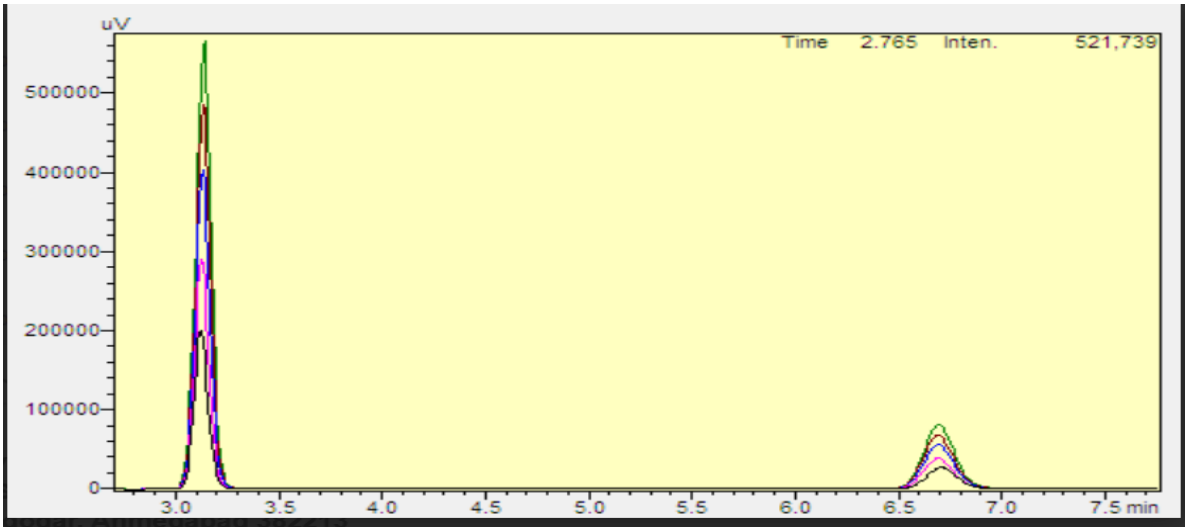


Fig. 20: Overlain Linearity Chromatogram of Luliconazole and Salicylic Acid.

4. PRECISION

4.1 Repeatability: Repeatability was confirmed by six consecutive injections of mixed standard (20 µg/mL Luliconazole, 60 µg/mL salicylic acid); %RSD for both peaks was <2%, indicating consistent response.

Table 6: Repeatability study of Luliconazole & Salicylic acid.

Conc. of Luliconazole	Peak area		Conc. of Salicylic acid	Peak area	
20 µg/ml	1) 561872	4) 553317	60 µg/ml	1) 1980482	4) 1951436
	2) 557891	5) 558907		2) 1973704	5) 1946612
	3) 560801	6) 573163		3) 1974214	6) 1983580
Mean (n = 6)	**560992**		Mean (n = 6)	**1968338**	
SD	6660.53		SD	15497.18	
%RSD	1.18		%RSD	0.78	

4.2.* Intraday*: It was assessed at three concentrations of Luliconazole (10, 20, 30 µg/mL) and Salicylic Acid (30, 60, 90 µg/mL) in triplicate. %RSD values were below 2%, demonstrating excellent precision and repeatability within a single day.

Table 1: Intra Day Precision Data of Luliconazole and Salicylic Acid.

Luliconazole			Salicylic acid		
Concentration (µg/mL)	Mean Peak Area ± SD	%RSD	Concentration (µg/mL)	Mean Peak Area ± SD	%RSD
10	285084 ± 582.67	0.20	30	977072 ± 4150.24	0.42
20	557322 ± 2699.91	0.48	60	1935238 ± 9138.41	0.47
30	861046 ± 8467.84	0.98	90	2944225 ± 21091.41	0.72

4.3 Interday Precision: It was evaluated at three concentrations of Luliconazole (10–30 µg/mL) and Salicylic Acid (30–90 µg/mL) over three days in triplicate. %RSD values were below 2%, indicating good reproducibility and intermediate precision.

Table 2: Inter Day Precision Data of Luliconazole and Salicylic Acid.

Luliconazole			Salicylic acid		
Concentration (µg/mL)	**Mean Peak Area ± SD**	**%RSD**	**Concentration (µg/mL)**	**Mean Peak Area ± SD**	**%RSD**
10	287087 ± 354.34	0.12	30	983720 ± 2622.82	0.27
20	565389 ± 5821.53	1.03	60	1947944 ± 20062.87	1.03
30	865896 ± 8278.48	0.96	90	3006178 ± 8713.99	0.29

5. Accuracy

Table 9: Accuracy Data Luliconazole & Salicylic Acid.

Level%	Set	Luliconazole					Salicylic Acid				
		Amount Added (µg)	Amount Found (µg)	%Recovery	Mean % Recovery	%RSD	Amount Added (µg)	Amount Found (µg)	%Recovery	Mean % Recovery	%RSD
50	1	10	10.100	**101.0**	100.7	0.3	30.000	30.030	**100.1**	100.0	0.3
50	2	10	10.070	**100.7**			30.000	30.050	**100.2**		
50	3	10	10.030	**100.3**			30.000	29.870	**99.6**		
100	1	20	19.890	**99.5**	100.3	1.8	60.000	60.450	**100.8**	98.9	1.7
100	2	20	19.810	**99.1**			60.000	58.620	**97.7**		
100	3	20	20.480	**102.4**			60.000	58.910	**98.2**		
150	1	30	30.490	**101.6**	101.4	0.2	90.000	90.710	**100.8**	100.4	0.9
150	2	30	30.340	**101.1**			90.000	90.880	**101.0**		
150	3	30	30.410	**101.4**			90.000	89.490	**99.4**		

6. Robustness

Following parameters were changed one by one and their effect was observed on system suitability for standard preparation.

1. Flow rate of was changed (± 1%).
2. Temp of Mobile phase was changed (± 5°C).
3. Ratio of Mobile phase was changed (± 2 %). The results are shown in table.

Table 10: Robustness Data of Luliconazole and Salicylic Acid.

Parameter	Drug	Area at Tem. (-5°C)	Area at Tem. (+5°C)	Area at Flow (-1% ml/min)	Area at Flow (+1% ml/min)	Area at Organic Phase -2%	Area at Organic Phase +2%
Mean Peak Area	**Luliconazole**	563924	564094	618966	517013	566355	567095
	Salicylic Acid	1955574	1965174	2150206	1786220	1972076	1957481
% RSD	**Luliconazole**	0.83	1.17	0.13	1.95	0.55	0.74
	Salicylic Acid	1.13	0.24	0.26	0.14	0.72	0.61
Theoretical Plates	**Luliconazole**	8231	9244	9438	8230	8821	8550
	Salicylic Acid	7464	7168	7716	6742	7348	7064
Tailing Fator	**Luliconazole**	1.12	1.13	1.12	111	1.12	1.12
	Salicylic Acid	1.07	1.06	1.05	1.08	1.06	1.06

7. LOD and LOQ

Calibration curve was repeated for three times and the standard deviation (SD) of the intercepts was calculated. Then LOD and LOQ were calculated as follows:

LOD = 3.3 * SD/slope of calibration curve LOQ = 10 * SD/slope of calibration curve

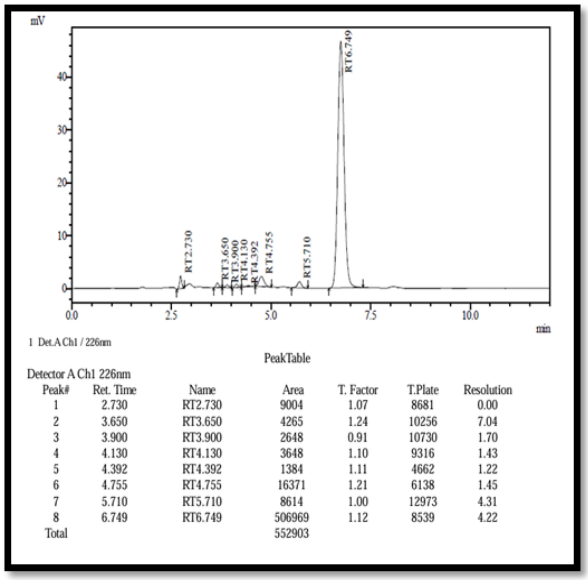
Where, SD = Standard deviation of intercepts. The results are shown in table.

Table Error! No text of specified style in document.**.3 Limit of Detection and Limit of Quantitation data for Luliconazole and Salicylic Acid.**

Parameters	LOD (µg/ml)	LOQ (µg/ml)
Luliconazole	1.85	5.61
Salicylic Acid	7.52	22.8

V. Forced Degradation Condition

1. **Acid Degradation:** 1 mL of standard or sample stock was treated with 1 mL of 1 N HCl for 6 h, neutralized with 1 mL of 1 N NaOH, diluted with diluent, filtered, and analyzed by HPLC.

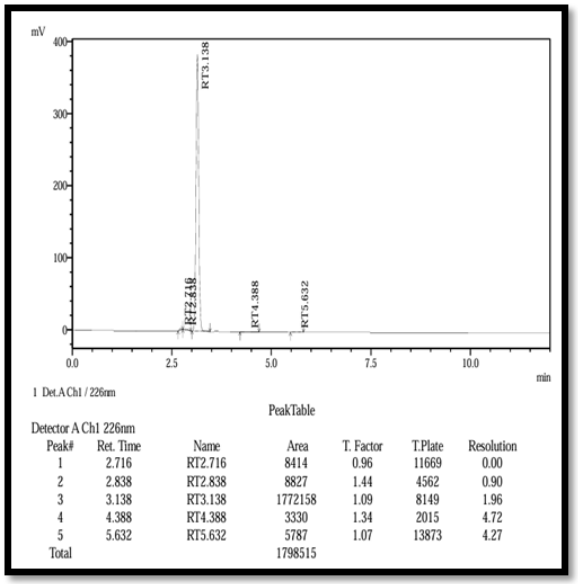


PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	2.730	RT2.730	9004	1.07	8681	0.00
2	3.650	RT3.650	4265	1.24	10256	7.04
3	3.900	RT3.900	2648	0.91	10730	1.70
4	4.130	RT4.130	3648	1.10	9316	1.43
5	4.392	RT4.392	1384	1.11	4662	1.22
6	4.755	RT4.755	16371	1.21	6138	1.45
7	5.710	RT5.710	8614	1.00	12973	4.31
8	6.749	RT6.749	506969	1.12	8539	4.22
Total			552903			

Fig. 21: Acid Degradation Luliconazole (API)

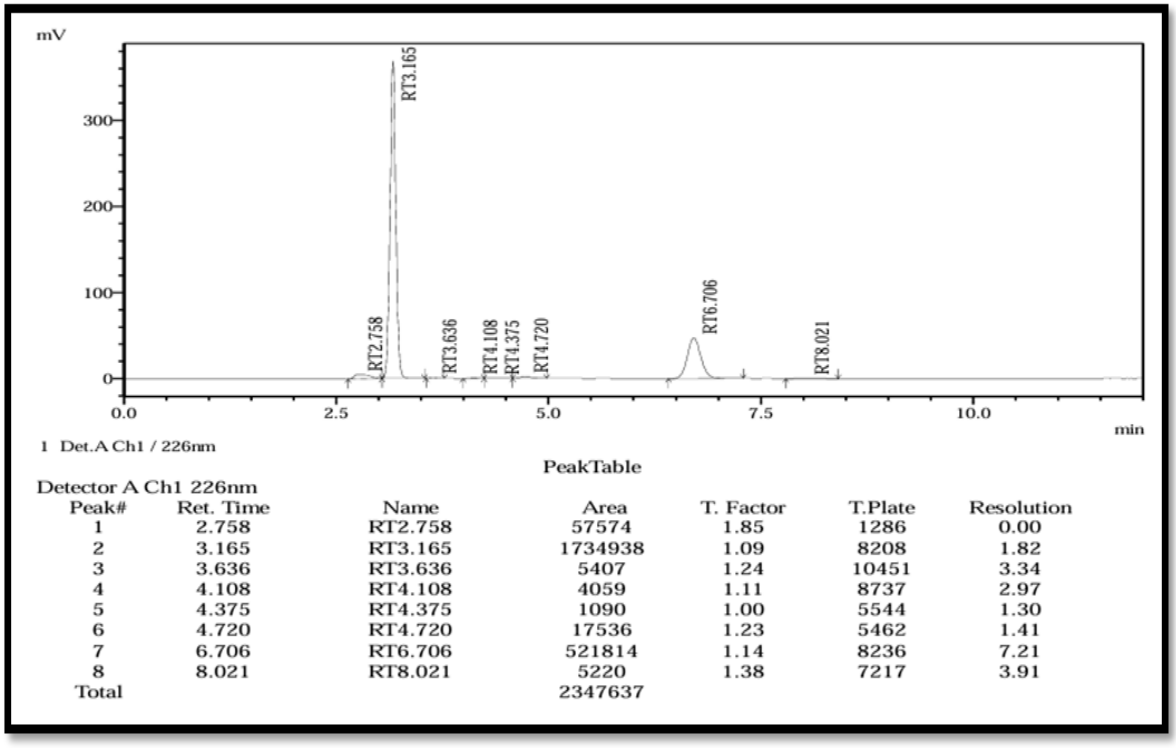


PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	2.716	RT2.716	8414	0.96	11669	0.00
2	2.838	RT2.838	8827	1.44	4562	0.90
3	3.138	RT3.138	1772158	1.09	8149	1.96
4	4.388	RT4.388	3330	1.34	2015	4.72
5	5.632	RT5.632	5787	1.07	13873	4.27
Total			1798515			

Fig. 22: Acid Degradation Salicylic Acid (API)



PeakTable

Detector A Ch1 226nm

Peak#	Ret. Time	Name	Area	T. Factor	T.Plate	Resolution
1	2.758	RT2.758	57574	1.85	1286	0.00
2	3.165	RT3.165	1734938	1.09	8208	1.82
3	3.636	RT3.636	5407	1.24	10451	3.34
4	4.108	RT4.108	4059	1.11	8737	2.97
5	4.375	RT4.375	1090	1.00	5544	1.30
6	4.720	RT4.720	17536	1.23	5462	1.41
7	6.706	RT6.706	521814	1.14	8236	7.21
8	8.021	RT8.021	5220	1.38	7217	3.91
Total			2347637			

Fig. 23: Acid Degradation (Sample).

2.Base Degradation:1 mL of standard or sample stock solution was treated with 1 mL of 1 N NaOH for 6 h at room temperature, neutralized with 1 mL of 1 N HCl, diluted with diluent, filtered, and analyzed by HPLC.

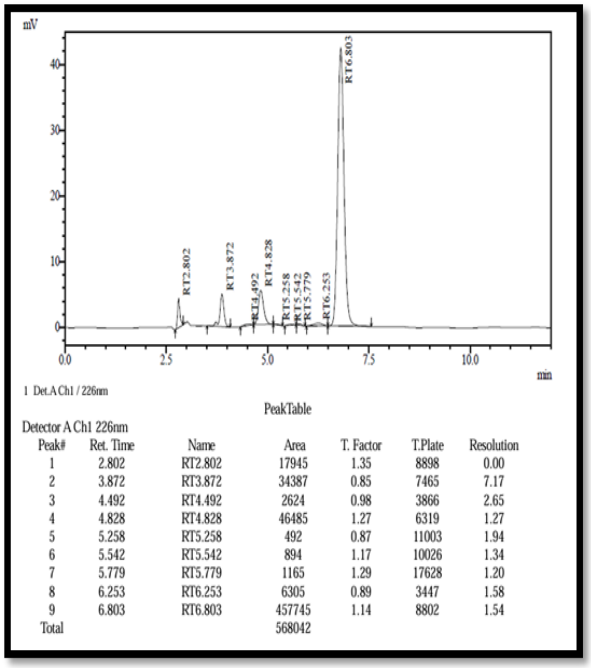


Fig. 24: Base Degradation Luliconazole (API)

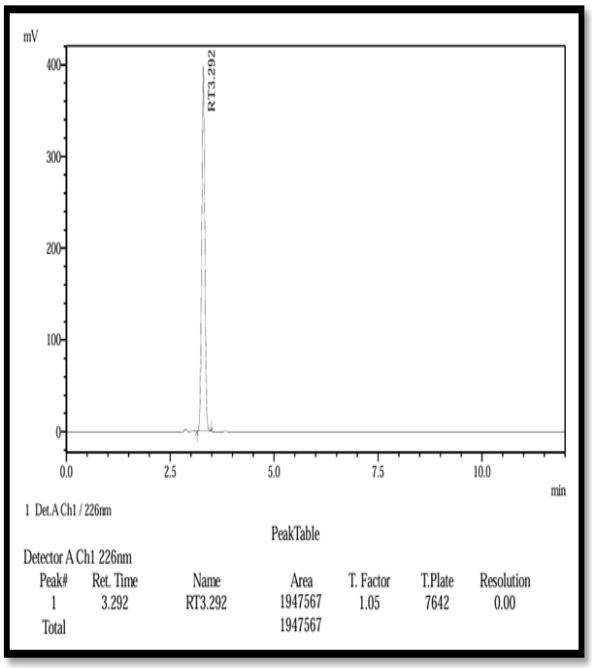


Fig. 25: Base Degradation Salicylic Acid (API)

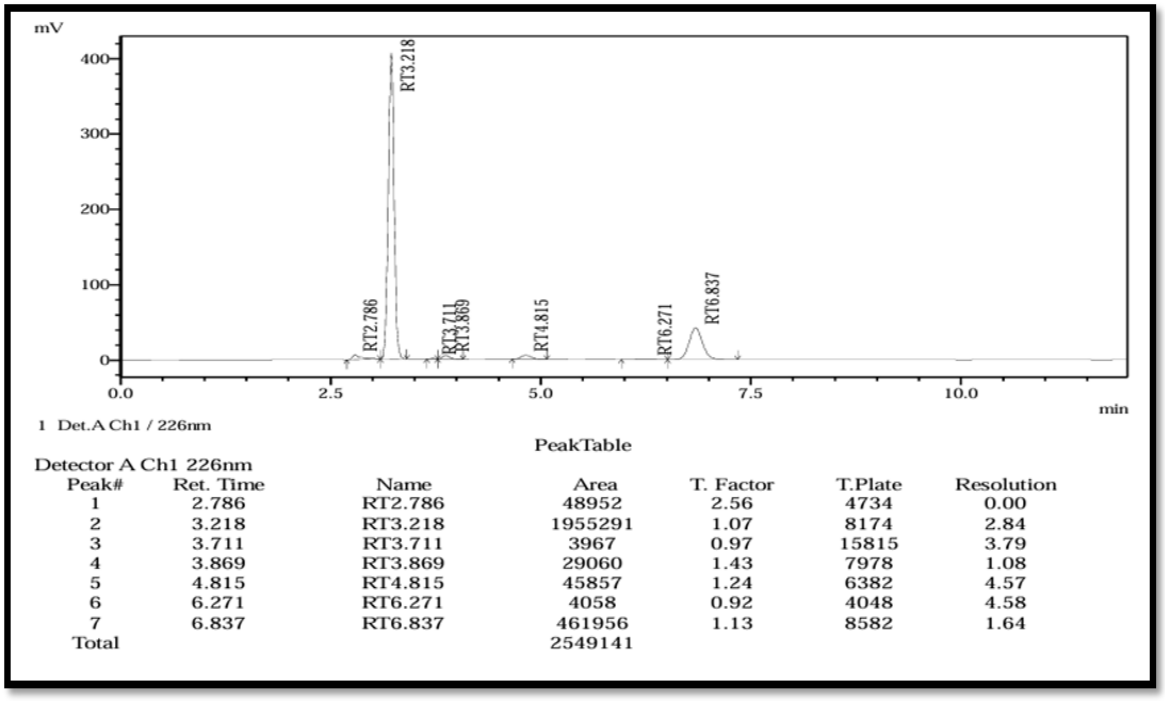


Fig. 26: Base Degradation (Sample).

3. Oxidation Degradation: 1 mL of standard or sample stock solution was treated with 1 mL of 3% H_2O_2 for 6 h at room temperature, diluted to volume with diluent, filtered, and analyzed by HPLC.

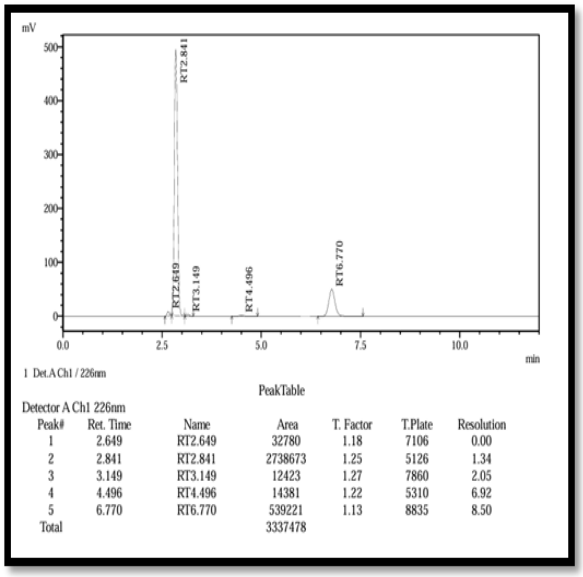


Fig. 27: Oxidation Degradation Luliconazole (API)

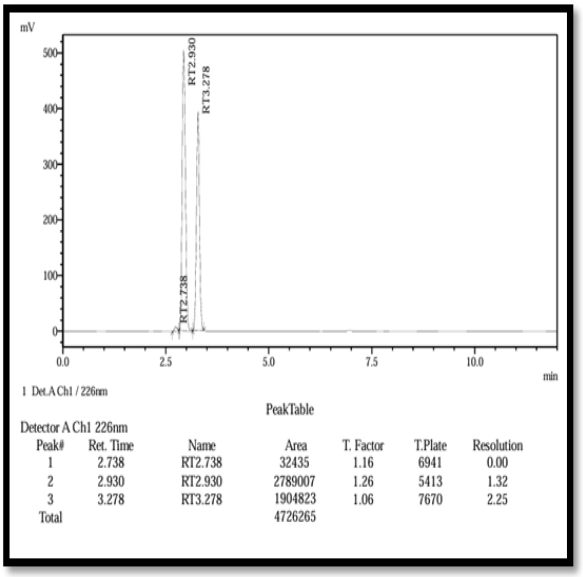


Fig. 28: Oxidation Degradation Salicylic Acid (API)

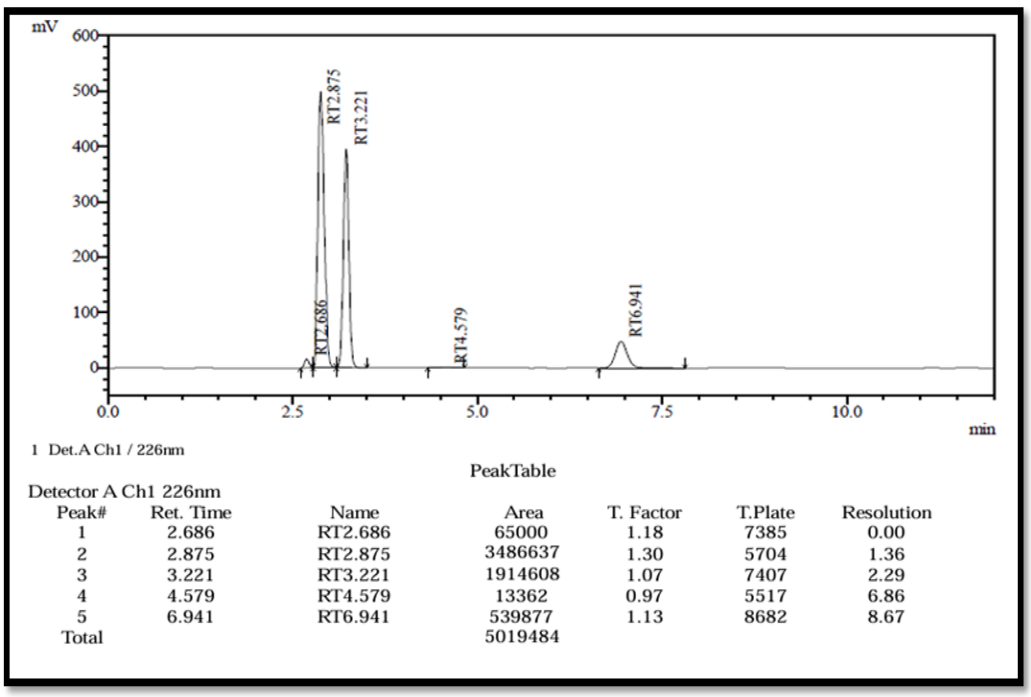


Fig. 29: Oxidation Degradation (Sample).

4. **Photolytic Degradation:** Standard and sample solutions were exposed to direct sunlight for 48 h, then diluted with diluent, filtered, and analyzed by HPLC.

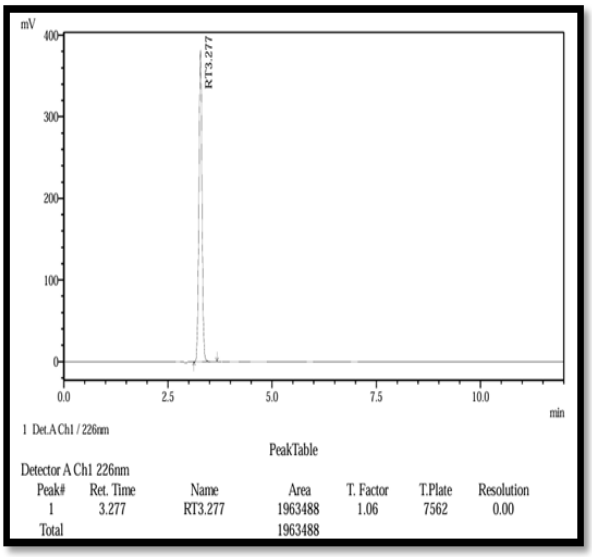


Fig. 30: Photolytic Degradation Salicylic acid (API)

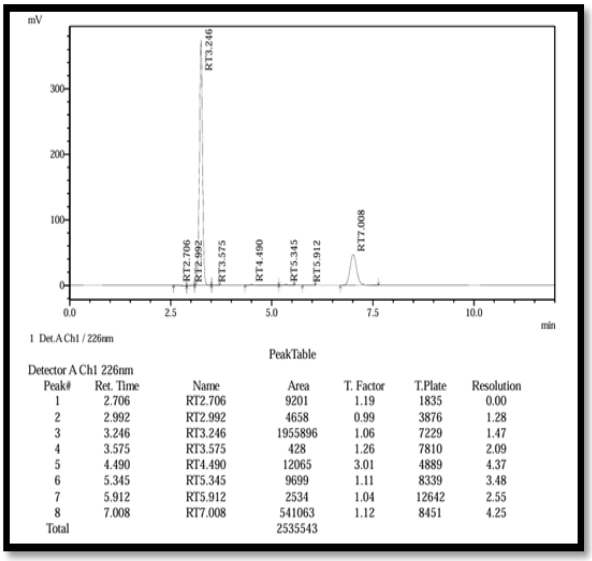


Fig. 31: Photolytic Degradation Luliconazole (API)

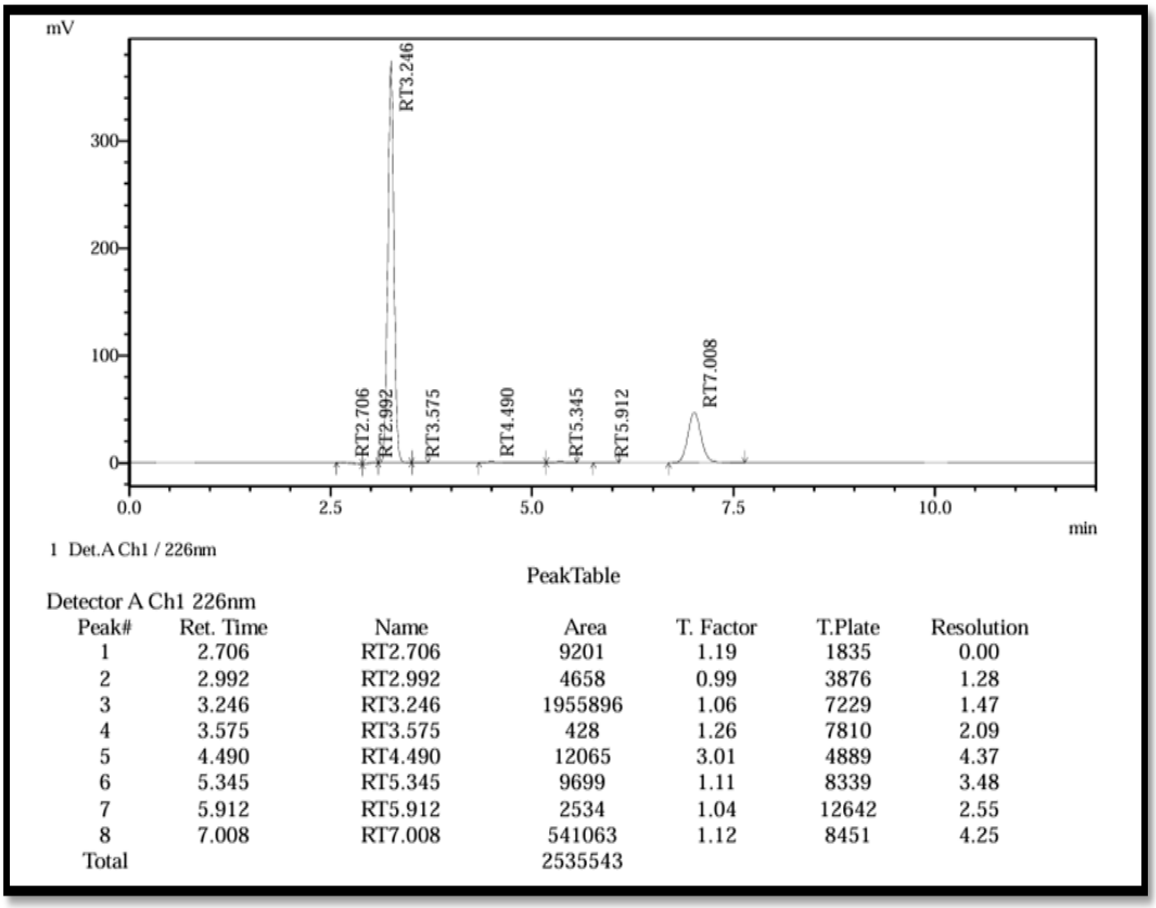


Fig. 32: Photolytic Degradation (Sample).

5. Thermal Degradation: API and sample solutions were exposed to 100 °C for 24 h, cooled, diluted with diluent, filtered, and analyzed by HPLC.

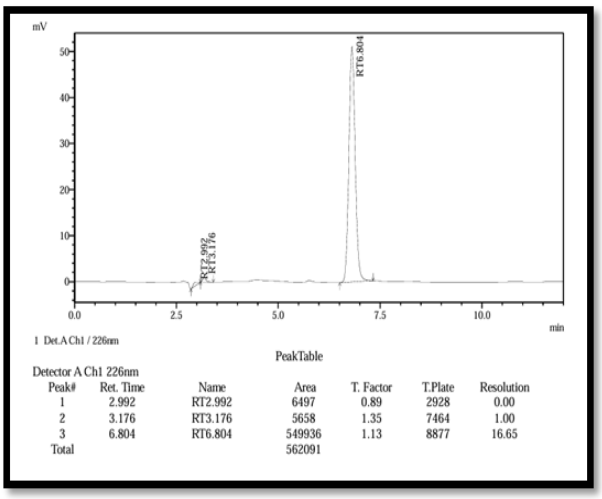


Fig. 33: Thermal Degradation Luliconazole (API)

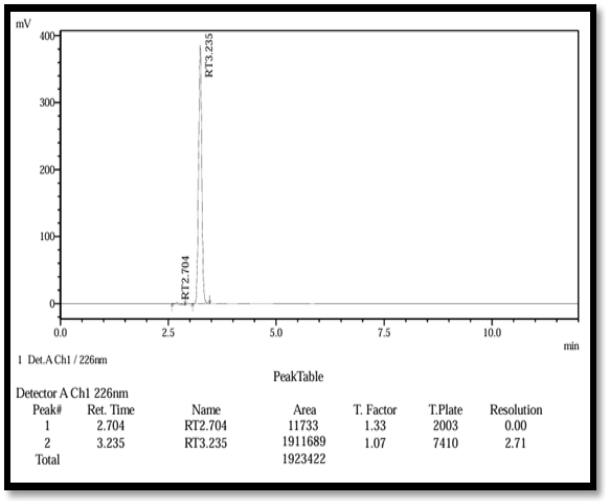


Fig. 34: Thermal Degradation Salicylic acid (API)

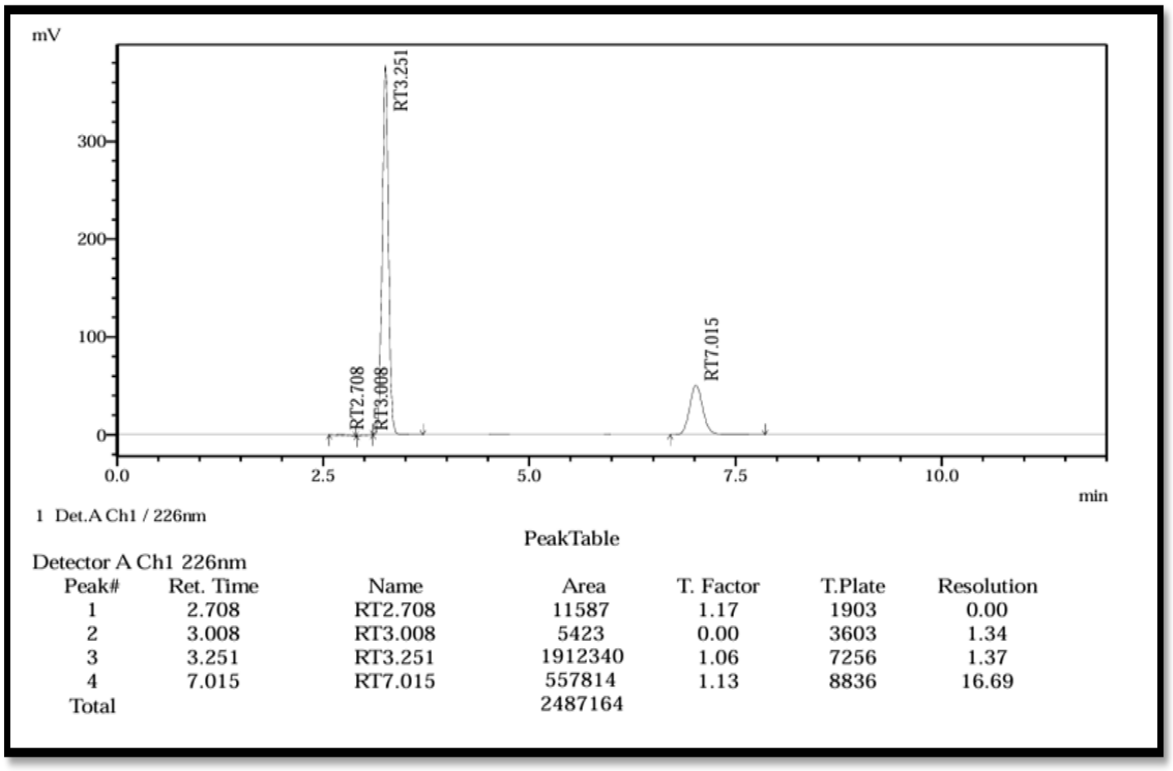


Fig. 35: Thermal Degradation (Sample).

RESULTS OF DEGARADATION

% Degradation Sample and Standard of Luliconazole and Salicylic acid

Drug	Sample Area	API Area
Luliconazole	567215	562093
Salicylic acid	1961269	1971491

Table 11: Result of stability study of Luiconazole and salicylic acid.

Condition	Luliconazole				Salicylic acid			
	Standard	% Degradation	Sample	% Degradation	Standard	% Degradation	Sample	% Degradation
Acid	506969	9.8	521814	8.0	1772158	10.1	1734938	11.5
Base	457745	18.6	461956	18.6	1947567	1.2	1955291	0.3
Oxidation	539221	4.1	539877	4.8	1904823	3.4	1914608	2.4
Photo	548601	2.4	541063	4.6	1963488	0.4	1955896	0.3
Thermal	549936	2.2	557814	1.7	1911689	3.0	1912340	2.5

CONCLUSION

The developed RP-HPLC method is simple, precise, accurate, sensitive, and reproducible for the simultaneous determination of Luliconazole and Salicylic Acid in pharmaceutical dosage forms. The method showed excellent linearity, satisfactory LOD and LOQ values, and high recovery, confirming its reliability. Furthermore, the forced degradation study demonstrated that the method is stability-indicating, as it effectively separates the drugs from their degradation products. Therefore, the method can be successfully applied for routine quality control analysis and stability studies of formulations containing Luliconazole and Salicylic Acid.

REFERENCES

1. Petrucelli MF, Naidu K, Shapiro H. Epidemiology and Diagnostic Perspectives of Dermatophytoses. *PMCID: PMC7712040.* 2020. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7712040/
2. Chanyachailert P, Leeyaphan C, Bunyaratavej S. Cutaneous Fungal Infections: An Updated Comprehensive Review of Epidemiology, Clinical Presentations, and Diagnostic Testing. *J Fungi (Basel),* 2023; 9(6): 669. Available from: https://www.mdpi.com/2309-608X/9/6/669
3. Ameen M. Epidemiology of superficial fungal infections. *Clin Dermatol,* 2010; 28(2): 197-201. Available from: https://www.sciencedirect.com/science/article/abs/pii/S0738081X09002478
4. Khanna D, Bharti S. Luliconazole for the treatment of fungal infections: an evidence-based review. *PMCID: PMC4181444.* 2014. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4181444/
5. Feng X, Huang Y, Chen M, et al. Efficacy and tolerability of Luliconazole cream 1% for dermatophytoses. *PubMed.,* 2014. Available from: https://pubmed.ncbi.nlm.nih.gov/25156082/

6. Arif T. Salicylic acid as a peeling agent: a comprehensive review. *PMCID: PMC4554394*. 2015. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC4554394/
7. Bashir SJ, Dreher F, Chew AL, et al. Cutaneous bioassay of salicylic acid as a keratolytic. *Int J Pharm.*, 2005; 294(1-2): 23-31. Available from: https://pubmed.ncbi.nlm.nih.gov/15725565/
8. ICH Q1A(R2) Guidelines. Stability Testing of New Drug Substances and Products, 2003. Available from: https://www.ich.org/page/quality-guidelines
9. Snyder LR, Kirkland JJ, Dolan JW. Practical HPLC Method Development. 3rd ed. Hoboken: Wiley, 2012.