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Development of Validated Stability Indicating HPTLC Method for Estimation of Trazodone in Bulk and Its Dosage Form

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ABSTRACT:
A new high-performance thin-layer chromatography (HPTLC) method has been created to identify the safety profile of Trazodone when it is in its bulk form. Studies were carried out to examine the effects of various stressors on Trazodone's chemical stability. The drug was subjected to conditions that mimic real-life degradation, including acidic and alkaline conditions, heat, oxidation and light.A toluene: methanol mobile phase (5:5 v/v) was combined with a silica gel 60 F254 stationary phase to create a chromatogram using HPTLC. Analysis of Trazodone at 255 nm revealed a distinct peak with an Rf value of 0.50 and clear separation of components.It was determined by chromatographic analysis and ultraviolet light that the drug in question decomposes significantly in acidic, alkaline, and oxidative environments. Two well-resolved peaks emerged as a result of oxidative degradation in conjunction with the parent compound, and distinct chromatographic patterns were isolated, with single peak appearances obtained in acidic and alkaline media. Rf values of noticeably different magnitudes were obtained from the subsequent separations of the parent drug and degradation products. Additionally, the well-established HPTLC method made it possible to quickly and reliably determine the amount of trazodone in pharmaceutical tablets. The accuracy of the suggested approach was confirmed by calibration analysis, which produced mean recoveries of 100.75%. Furthermore, the methodology's robustness, ruggedness, and specificity were evaluated. From the results, it can be concluded that the well-established High-Performance Thin-Layer Chromatography (HPTLC) method is effective at separating Trazodone from its breakdown products. As a result, pharmaceutical companies and regulatory bodies can use it to periodically analyze Trazodone in different bulk formulations.

INTRODUCTION:

Trazodone exhibits antidepressant properties, having demonstrated efficacy comparable to imipramine in clinical trials[1]. This compound, possessing the chemical structure 2-[3-{4-(3-chlorophenyl)-1-piperazinyl} propyl], [4,3-a] -1,2,4-triazolo Hydrochloride of pyridine-3-(2H)-one, is characterised as an off-white crystalline powder.

In compliance with USP and ICH criteria, a thorough evaluation that included specificity, system suitability, accuracy, linearity, precision, ruggedness, robustness, limit of quantification, and limit of detection necessitated the quantitative evaluation of trozoladone hydrochloride using the HPTLC technique.[2]

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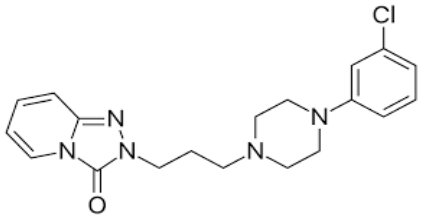

Fig 1: Trazodon

MATERIALS & METHODS:

Instruments and Equipment used:

A commercial electronic balance utilizing the Shimadzu ATX224R model is utilized. The Shimadzu 1780 spectrophotometer enables the measurement of absorbance within the ultra-violet and visible regions of the electromagnetic spectrum. Employing the CAMAG HPTLC SYSTEM, specifically designed by its Swiss-based company, has become an essential component of our research, including a Linomat-5 applicator, a Camag TLC scanner 3, and the accompanying WIN CATS software version 1.3.0. Photostability assessments are conducted within a controlled environment facilitated by the NEWTRONIC Model NEC103RSPI photostability chamber. Ultrasonic disruption is achieved using the Prama solutions for laboratory sonicator. Water purification is performed via the Lablink water purification system. Specimens are evaluated within the Biomedica UV Cabinet. Thermal dehydration of materials is carried out within the Kumar labs hot air oven.

Reagents and Chemicals:

Methanol of grade of analytical reagents. Grade N-hexane, analytical reagent, at a concentration of 99.8%. Ethyl acetate, analytical 99.5% concentration, reagent grade.Hydrochloric acid and sodium hydroxide, both of analytical reagent grade. Hydrogen peroxide, 30% v/v aqueous solution, of analytical reagent grade.

Preparation of Solution:

Due to the solubility of Trazodone in methanol, this solvent was selected for the preparation of various sample solutions.

a) Preparation of standard stock solution:

After weighing 10 milligrams of the Drug, it disintegrated in methanol to a volume of 5 ml and then up to 10 ml to achieve full solubilization, creating a Trazodone stock solution (Solution A) with a concentration of 1000 µg/ml.[7]

b) Preparation of working standard solution:

Pipette off 2.5 milligrams of the Trazodone stock solution standard (1000 µg/ml) or solution A, and then transfer it to a 10 ml volumetric flask to create solution B, which contains 250 µg/ml of Trazodone. Next, add 10 ml of methanol to the volume.[5]

Preparations of Reagents:

a) Making aA 100 ml volumetric flask containing a 1 N HCl solution, 8 ml of hydrochloric acid was diluted with 100 ml of water. Fill the entire volume with water to create a solution of 1 N hydrochloric acid.
b) Making a 1 N NaOH solution: Dissolve 4 g of sodium hydroxide pellets in 100 ml of water to create a 1 N sodium hydroxide solution.

Selection of Analytical wavelength:

Methanol was used to make additional dilutions of the stock standard solution (1000 µg/ml), which were then scanned across the 200–400 nm range to get the spectra. The medication was found to exhibit significant absorbance at 255 nm. Trazodone's representative UV spectrum is displayed in Fig.[8]

Fig 2 : UV Spectrum of Trazodone

Optimized Chromatographic Conditions:
Chromatographic parameters that were enhanced and compiled included saturation time, band length, detection wavelength, stationary phase, and mobile phase. and criteria for system suitability are gathered. Merck stationary phase silica gel 60 F254 (10 cm x 10 cm) precoated metal TLC plates Saturation time: 15 minutes, band length: 6 mm, measurement wavelength: 255 nm, and Rf value (mean ± RSD): 0.315 ± 1.14

Table 1: - Optimized chromatographic conditions

Sr. No.	Parameters	Conditions used for analysis
1	Stationary Phase	Merck's TLC aluminum plates precoated with silica gel 60 F254 (10 cm x 10 cm)
2	Mobile Phase	n-Hexane: Ethyl Acetate (8.5:1.5 v/v)
3	Band length	6 mm
4	Saturation time	15 min
5	Detection wavelength	255 nm
6	Rf value (Mean ± RSD)	0.315 ± 1.14

Method Validation: [13]
Analytical Validation procedures was performed by using the following parameters, the Trazodone technique was validated in accordance with ICH Q2(R1) guidelines.

Specificity:
The capacity to definitively evaluate the analyte in the presence of possibly predicted components is known as specificity. These usually include matrix, contaminants, and degradants. Other supporting analytical techniques can make up for an analytical method's lack of specificity.

Linearity:
To assess linearity, mixed standard solutions of multiple concentrations (three replicates each) were assessed within specified ranges for the analytes Trazodone. Linear relationships were observed for both compounds within the designated concentration ranges. A calibration curve was produced.by plotting peak area against the corresponding analyte concentration and a correlation coefficient was subsequently calculated to confirm the linearity of the relationships.

Accuracy:
Accuracy was assessed by injecting the solutions in triplicates at 50%, 100% and 150% level. Spiking the preanalysed sample with standard drug and mixture solutions were reanalysed. calculated the amount found and % recovery.

Precision:
Three distinct analyte concentrations, composed of 1000, 2000, and 3000 micrograms per milliliter of Trazodone were administered to the high- performance thin liquid chromatography (HPTLC) system at varying time intervals on the same an different days to assess intraday and interday variability, with relative standard deviation (%RSD) calculated as a measure of precision.

1.Repeatability:
Reliability is the capacity to convey accuracy across a brief period of time while maintaining the same operational circumstances. An alternative phrase for repeatability is intra-assay precision. The procedure's indicated range (e.g., 3 concentrations/3 replicates each) or at least six findings at full test concentration should be used to evaluate repeatability.

2.Intermediate precision:
The high- performance thin liquid chromatography (HPTLC) system at varying time intervals on the same an different days to assess intraday and interday variability, with relative standard deviation (%RSD) calculated as a measure of precision.

3.Reproducibility:
The precision between labs is expressed by reproducibility (collaborative investigations, typically used to standardization of methodology).

Robustness:

Four parameters from the optimal chromatographic condition were changed in order to confirm the method's robustness. After the detecting wavelength, saturation time, and time were The influence on the area was observed as the focus shifted from spotting to development and then to scanning.Determine the RSD as a percentage.

RESULTS AND DISCUSSION:

System suitability parameters for Trazodone

Table 2 : System suitability parameters

Drug	Concentration (ng/band)	Rf (Mean ± % RSD)	Area	Asymmetry
Trazodone	1000	0.315 ± 1.14	5167.46	1.23

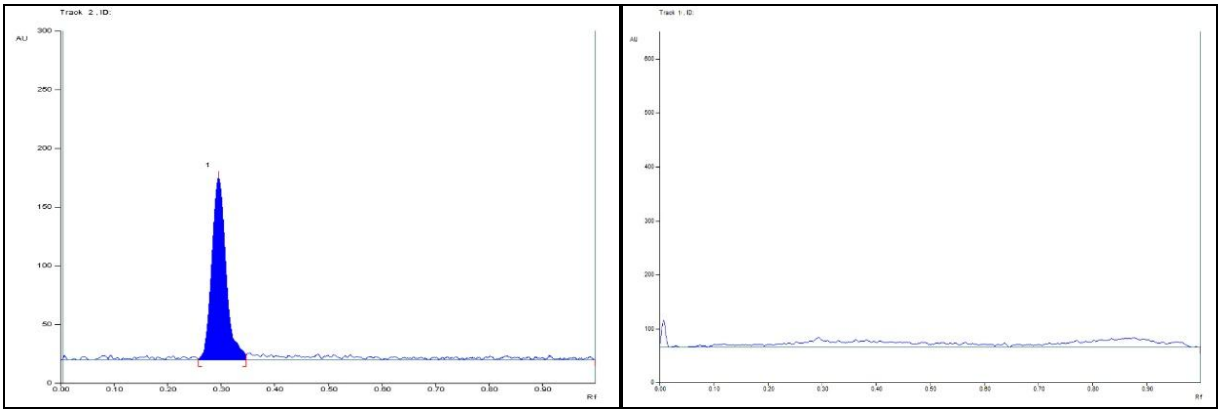

Fig3 :- Representative Densitogram of Blank and Standard Trazodone

Linearity and Calibration curve:

A solution containing 250 µg/ml of Trazodone was made from the standard stock solution, which had 1000 µg/ml of the drug. Additionally, the solution was employed for spotting. For each concentration, six replicates were identified. By examining six concentrations across the 500–3000 ng/band concentration range for Trazodone, The link between peak area and concentration, or linearity, was determined. The calibration curve was created by plotting the peak regions against the relevant concentrations. With a regression equation of y = 5.5198 – 181.31 and R2 = 0.9977, the findings were determined to be linear. Table 3 displays the Trazodone linearity research, and Figure 4 displays the calibration curve. Fig. 5 displays a three-dimensional densitogram.

Table 3: Linearity study of Trazodone

Replicates	Concentrations of Trazodone (ng/band)					
	500	**1000**	**1500**	**2000**	**2500**	**3000**
1	2557.44	5296.00	8500.00	10532.16	13885.12	16803.52
2	2470.06	5167.46	8305.35	10436.99	13538.88	16426.08
3	2529.12	5233.28	8528.32	10312.80	13975.78	16349.28
4	2504.48	5278.56	8474.56	10562.24	13683.20	16181.92
5	2552.64	5332.64	8565.76	10408.80	13527.04	16099.20
6	2512.80	5347.52	8493.44	10654.56	13979.20	16214.08
Average	2521.090	5275.909	8477.904	10484.591	13764.870	16345.679
SD	32.649	73.912	90.308	122.233	209.373	253.371
% RSD	1.295	1.401	1.065	1.166	1.521	1.550

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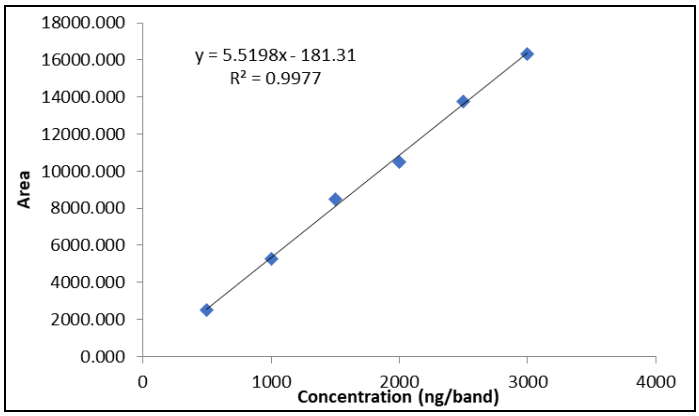

Fig 4: Calibration curve of Trazodone (500-3000 ng/band)

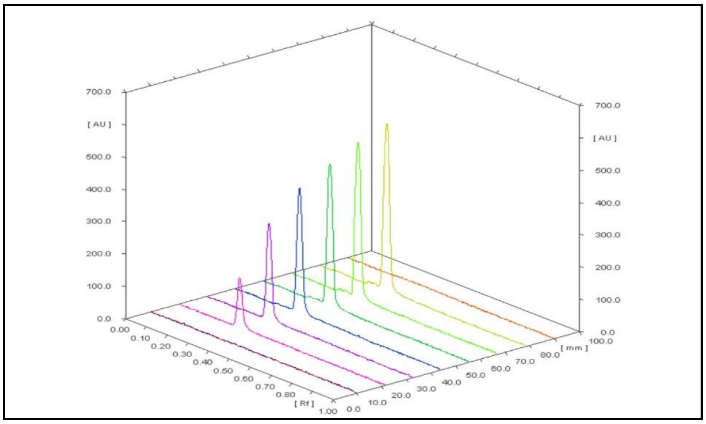

Fig 5: 3D densitogram of linearity of Trazodone

Range:

Trazodone= 500-3000 ng/band.

Precision:

Studies of fluctuation within and between days showed how accurate the system was. Three replicates of three concentrations were analyzed on the same day in the intra-day investigations, and the % RSD was computed. Three replicates of three concentrations were examined over three days in a row for the inter-day variation investigations, and the percentage RSD was computed. Table 4 displays the results for both intra-day and inter-day precision.

Table 4: Intra-day and inter-day variation studies data for Trazodone.

	Intra-day precision				**Inter-day precision**			
	Area	**Amount Recovered (ng/band)**	**% Recovery**	**Mean ± % RSD**	**Area**	**Amount Recovered (ng/band)**	**% Recovery**	**Mean ± % RSD**
1000	5343.52	1001.055	100.105	99.936 ± 0.335	5337.67	999.994	99.999	100.108 ± 0.199
	5346.08	1001.518	100.152		5336.96	999.866	99.987	
	5312.84	995.495	99.550		5356.39	1003.387	100.339	
2000	10822.18	1993.745	99.687	100.162 ± 0.430	10832.57	1995.629	99.781	98.890 ± 0.153
	10886.62	2005.422	100.271		10837.29	1996.483	99.824	
	10915.07	2010.576	100.529		10863.94	2001.312	100.066	
3000	16369.68	2998.910	99.964	99.994 ± 0.228	16429.14	3009.683	100.323	99.977 ± 0.417
	16339.92	2993.517	99.784		16295.32	2985.435	99.515	
	16414.76	3007.076	100.236		16391.28	3002.823	100.094	

Limit of Detection (LOD) and Limit of Quantitation (LOQ):
The following formula is utilized to determine LOD and LOQ: LOD is equal to 3.3 σ / S
LOQ is equal to 10 σ/S.
where σ is the linearity equation's y intercept standard deviation.
S is the analyte's calibration curve's slope.

LOD of Trazodone = 72.725 ng/ band.
LOQ of Trazodone = 220.379 ng/band.

Assay:
Label Claim: Twenty pills (Trazonil 100; Intas Pharmaceuticals Ltd.) Trazodone 100 mg is contained in each uncoated tablet, which was precisely weighed and ground into powder. After weighing and transferring the tablet powder containing 10 mg of Trazodone to a 10-milliliter It was dissolved in methanol in a volumetric flask and filtered to raise the volume to10 milliliters. To obtain 250 µg/ml of Trazodone solution, This solution was diluted to 10 ml from 2.5 ml. After applying this sample solution (4 µl), the area was noted. The sample's basic concentration was 1000 ng/band from the tablet solution. The process was carried out six times. The linearity equation was used to get the concentration and recovery percentage. Table 5 displays the results of the assay.

Table 5: Assay of Marketed Formulation.

Sr. No.	Peak area	Amount Recovered (ng/band)	% Recovery
1	5359.36	1003.925	100.392
2	5352.64	1002.707	100.271
3	5347.68	1001.808	100.181
4	5342.72	1000.910	100.091
5	5327.84	998.213	99.821
6	5348.02	1001.870	100.187
Mean	5346.377	1001.572	100.157
SD	10.669	1.933	0.193
%RSD	0.200	0.193	0.193

Accuracy:
Spiking the standard drug to the tablet (Sample) solution at three different levels 50, 100, and 150% was used to conduct recovery experiments.in order to verify the method's accuracy. The sample's basic concentration was 1000 ng/band. The linearity equation was used to determine recovery. The outcomes are displayed in Table 6.

Table 6: Accuracy studies of Trazodone.

Level	Amount of sample taken (ng/band)	Amount of standard spiked (ng/band)	Area	Recovered Conc. (ng/band)	% Recovery	Mean ± % RSD
50%	1000	500	8136.41	1507.105	100.474	100.206 ± 0.245
			8109.89	1502.299	100.153	
			8096.45	1499.863	99.991	
100%	1000	1000	10928.39	2012.989	100.649	100.306 ± 0.304
			10879.36	2004.106	100.205	
			10863.84	2001.294	100.065	
150%	1000	1500	13681.61	2511.851	100.474	100.329 ± 0.141
			13642.52	2504.769	100.191	
			13660.64	2508.053	100.322	

Robustness:
By doing the analysis under settings that included changing the detection wavelength, saturation time, and The robustness of the approach was determined by measuring the duration from spotting to development and development to scanning, as well as the influence on the region. The approach was proven to be robust because the percentage RSD value was less than 2. The outcomes are displayed in Table 7.

Table 7: Robustness Study.

% RSD Found for Robustness Study (Peak Area)	
	WAVELENGTH VARIATION

	224 nm	225 nm	226 nm
	5261.52	5226.39	5309.24
	5239.90	5147.51	5291.46
	5244.81	5246.94	5271.49
AVG	5248.746	5206.944	5290.731
S.D	11.333	52.489	18.887
% RSD	0.216	1.008	0.357
	SATURATION TIME VARIATION		
	9 min	10 min	11 min
	5227.47	5226.17	5191.90
	5183.38	5207.52	5194.66
	5317.47	5150.42	5152.04
AVG	5242.773	5194.704	5179.532
S.D	68.344	39.470	23.850
%RSD	1.304	0.760	0.460
	APPLICATION TO DEVOLOPMENT		
	Immediate	30 min	60 min
	5210.37	5249.82	5027.12
	5144.21	5275.08	5142.01
	5191.18	5159.69	5188.42
AVG	5181.920	5228.199	5119.183
S.D	34.038	60.658	83.042
%RSD	0.657	1.160	1.622
	DEVOLOPMENT TO SCANNING		
	Immediate	30 min	60 min
	5243.77	5154.37	5059.34
	5193.67	5179.17	5174.97
	5217.77	5159.69	5188.42
AVG	5218.404	5164.412	5140.912
S.D	25.054	13.057	70.962
%RSD	0.480	0.253	1.380

Forced Degradation Studies:

According to ICH recommendations Q1A (R2), the degradation conditions were met. To achieve 10–30% degradation, the reagent strength and exposure duration were adjusted. Table 8 provides a summary of the findings. The following are the optimal conditions:

a) Acid Degradation:

To make 10 milliliters, 2.5 milliliters of Trazodone standard solution at 1000 µg/ml were mixed with one milliliter of 1 N HCl. After a 24-hour period at room temperature, the resultant 250 µg/ml solution was transferred to a TLC plate and developed using an optimized mobile phase. The representative HPTLC densitogram is shown in Fig. 6.

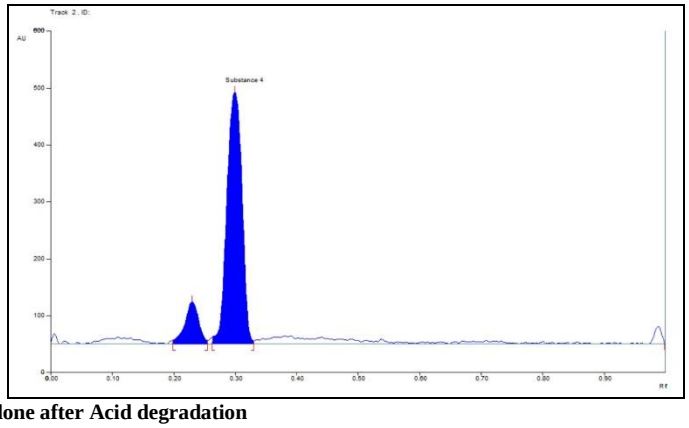

Fig. 6: Densitogram of Trazodone after Acid degradation

b) Alkali Degradation:
One milliliter of 1 N NaOH was combined with 2.5 milliliters of Trazodone standard solution (1000 µg/ml) to make a volume of 10 milliliters. The 250 ug/ml solution that was produced after 24 hours at room temperature was put onto a TLC plate and developed using an ideal mobile phase. Fig. 7 displays the representative HPTLC densitogram.

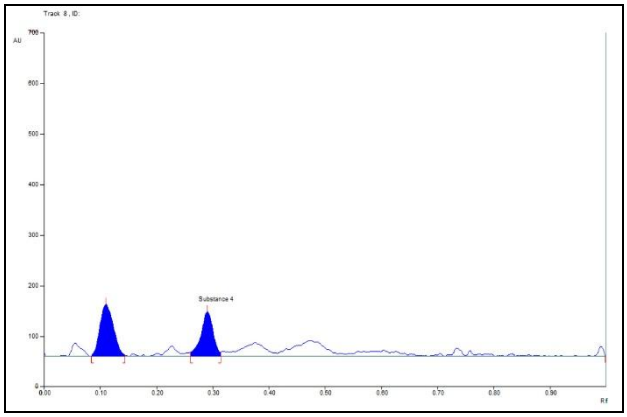

Fig.7: Densitogram of Trazodone after Alkali degradation

c) Oxidation Degradation:
To make 10 ml, combine 2.5 ml of an ug/ml Delamanid standard solution with 1 ml of 30% H2O2 v/v. The resulting solution, 250 ug/ml, was put to a TLC plate after being left at room temperature for 24 hours. Fig. 8 displays the representative HPTLC densitogram.

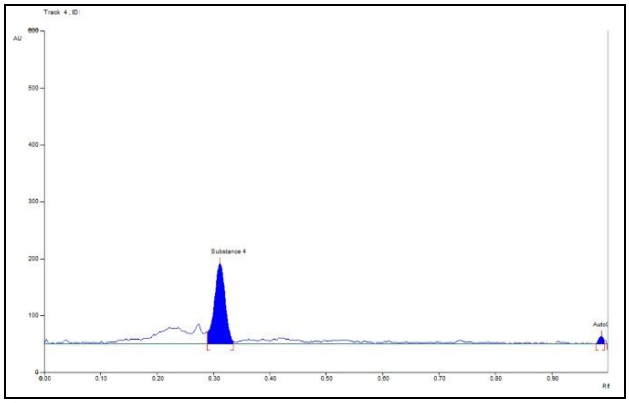

Fig.8: Densitogram of Trazodone after Oxidation degradation

e) Thermal Degradation:
The bulk medication was solidified and baked at 100°C for eight hours in order to carry out the thermal degradation. A sample was taken out of the oven, allowed to cool to room temperature, weighed, and diluted in methanol to reach a final 250 µg/ml concentration before being subjected to TLC and evaluated under optimal chromatographic conditions. The representative HPTLC densitogram is shown in Fig. 9.

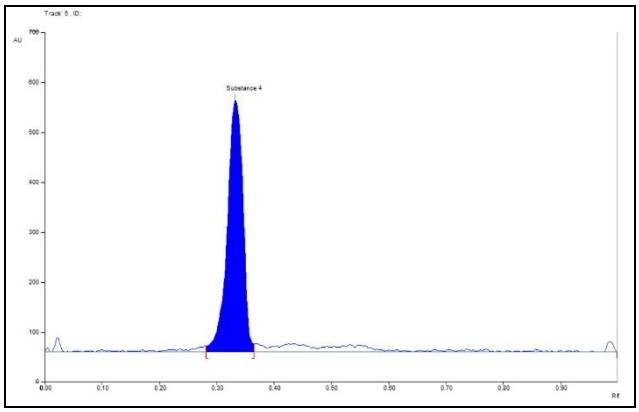

Fig. 9: Densitogram of Trazodone after Thermal degradation

d) Photolytic Degradation:

UV Degradation:

In accordance with ICH Q1B Guidelines, a photo stability chamber was used. By subjecting a solid state powdered sample of trazodone to UV radiation of at least 200 watt hours/square meter, photolytic breakdown was accomplished. After weighing the sample, it was diluted in methanol to achieve a concentration of 250 µg/ml. TLC was used to apply the solution, and optimal chromatographic conditions were used for analysis. Fig. 10 displays the representative HPTLC densitogram.

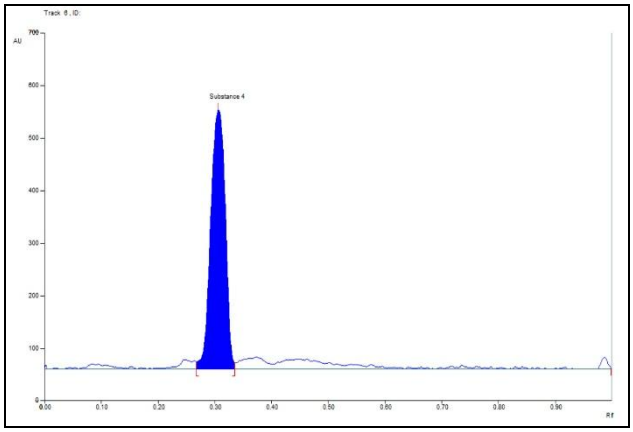

Fig.10: Densitogram of Trazodone after UV light degradation

Fluoresces Degradation:

The process involved subjecting a solid state powdered Trazodone sample to cool white fluorescent light at an intensity of at least 1.2 million Lux hours. After weighing the sample, it was diluted in methanol to achieve a concentration of 250 µg/ml. TLC was used to apply the solution, and optimal chromatographic conditions were used for analysis. Fig. 11 displays the representative HPTLC densitogram.

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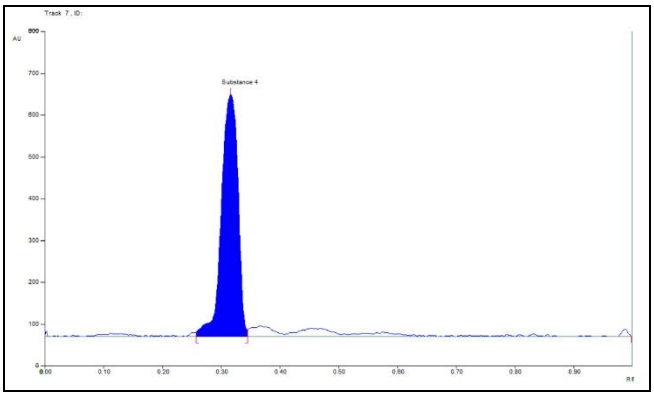

Fig. 11: Densitogram of Trazodone after Fluorescence degradation

Table 8: Summary of force degradation studies

SN	Parameters	Conditions	% Recovery	% Degradation	Purity front	Purity tail
1	Acid hydrolysis	1 N HCl at 24 hr.	84.48	15.52	0.997117	0.999469
2	Alkaline hydrolysis	1N NaOH at 24 hr.	62.95	37.05	0.999423	0.999698
3	Oxidative degradation	30 % $H_2O_{2\ at}$ 24 hr.	54.38	45.62	0.998962	0.999496
4	Thermal degradation	100°C for at 8 hr.	98.43	1.57	0.999184	0.999412
5	UV degradation	200-Watt Hr./ m^2	99.48	0.52	0.998759	0.999665
6	Florescence degradation	1.2 million Lux Hrs.	97.86	2.14	0.999906	0.999517

Table 9: Summary of Results

Sr. No.	Validation parameters	Trazodone
1.	Linearity equation R^2	y = 5.5198x - 181.31 R^2= 0.9977
2.	Range	500-3000 ng/band
3.	Precision	(% RSD)
	Intra-day	0.228 – 0.430
	Inter-day	0.153 – 0.417
4.	% Assay (Mean ± %RSD)	100.157 ± 0.193
5.	Accuracy	Mean ± % RSD
	50	100.206 ± 0.245
	100	100.306 ± 0.304
	150	100.329 ± 0.141
6.	Limit of detection	72.725 ng/band
7.	Limit of quantitation	220.379 ng/band
8.	Specificity	Specific
9.	Robustness	Robust

DISCUSSION:

For Trazodone, a High-Performance Thin Layer Chromatographic technique has been created. Trazodone was optimized utilizing a straightforward and accurate process that used n-Hexane: Ethyl Acetate as a mobile phase in an 8.5:1.5 v/v ratio. The results showed that the retardation factor was 0.315 ± 1.14. 319 nm was used as the detection wavelength. The 500–3000 ng/band linear range was chosen for examination. The recovery studies established the method's accuracy. 72.725 ng/band was the LOD, while 220.379 ng/band was the LOQ. According to ICH Q1A(R2) and Q1B guidelines, stress degradation conditions such as Degradation processes including acid, alkali, photolytic, thermal, and oxidative were used.It was discovered that the medication was vulnerable to oxidative stress, acid, and alkali environments.

CONCLUSION:

Trazodone is found to susceptible in Acid, Akaline and Oxidative stress condition so drug should be protected from these conditions during manufacturing, transporting and storage.

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