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STABILITY INDICATING HPTLC METHOD DEVELOPMENT AND VALIDATION FOR COMBINED DOSAGE FORM OF TOLPERISONE HYDROCHLORIDE AND DICLOFENAC SODIUM

PareshBavaliya*[1], Vijay Kalkani[2], Raval Kashyap[3]
[1]Department of QA, Saurashtra University, Gujarat
[2]Asst. Proff., Department of Pharmacology, Noble Pharmacy College, Junagadh
[3]Asst. Proff.& Head, Department of QA, Noble Pharmacy College, Junagadh

ABSTRACT

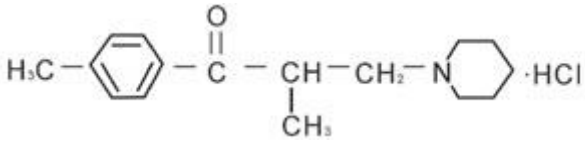
A simple HPTLC method has been developed and subsequently validated for tablet dosage form. The method employed TLC aluminum plates precoated with silica gel $60F_{254}$ as the stationary phase. The solvent system consist of Methanol: Toluene: Ethyl Acetate (2.5:7:0.5 v/v/v) and saturation time was 25 min.This system was found to give compact spots for diclofenac sodium (R_f =0.7±) and tolperisone hydrochloride (R_f 0.5).Analysis of tolperisone hydrochloride, diclofenac sodium was carried out at 275nm. Linearity of diclofenac sodium and tolperisone hydrochloride was found to be y = 5.3727x + 4514.2, R^2=0.998, y = 9.376x + 2635.6, R^2=0.995 respectively in concentration range of 300-1500 µg/bandand 100-300 µg/band. %Assay of tolperisone hydrochloride and diclofenac sodium was found to be 99.16%w/v and 99.60 %w/v.Results of all other experiments for method validation were found within the specified criteria of ICH guideline.

Key words: Tolperisone, HCL,Diclofenac Sodium, Validation Parameter

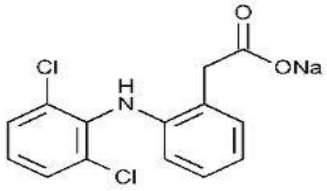
INTRODUCTION

Tolperisone Hydrochloride is approved by FDA as a generic drug manufacturing for regulatory market and non-regulated market to Taj Pharmaceuticals, Mumbai on 7th October 2010.It is piperidine derivative centrally acting muscle relaxant drug.Generic formulations of this drug are available in market now.Tolperisone acts at the level of spinal cord by blocking sodium channels and calcium channels. It exerts spinal reflex inhibitory action predominantly via a pre synaptic inhibition of the transmitter release from the primary afferent endings via a combined action on voltage-gated sodium and calcium channels. It causes preferential antinociceptive activity against thermal

stimulation that is likely to be attributed to its local anestheticaction. It Well absorbed in the stomach, duodenum and jejunum. It contain below structure:



Its IUPAC name is 1-(4-methyl-phenyl)-2-methyl-3-(1-piperidino)-1-propanone hydrochloride. Its molecular weight and molecular weight are C_{16} H_{23} NO · HCl& 281.82 g/mole respectively. It is Very soluble in acetic acid, Freely soluble in acetone and water, Soluble in acetic anhydride, Slightly soluble in acetone, Partially insoluble in diethyl ether. IUPAC name of Diclofenac sodium is Sodium{2-[(2,6-dichlorophenyl) amino]phenyl}acetate& it structure is define as below:



Its molecular formula and molecular weight are $C_{14}H_{10}Cl_2NNaO_2$& 318.13 g/mole.
It is Very slightly soluble in cold water, considerably more soluble in hot water soluble in ethanol and ethyl acetate, very slightly soluble in chloroform, slightly soluble in ether, practically insoluble in petroleum ether, pentane and benzene.[1-2]Up to now some analytical methods developed on Tolperisone, HCL &Diclofenac Sodium. But no stability indicting method developed by HPTLC & here developed method was validated by ICH guideline.[3-25]

MATERIALS & METHODS:

Selection of Solvent:

Tolperisone HCl and Diclofenac sodium is freely soluble in the methanol. Hence, methanol is selected as solvent for both the drug.

Selection of Wavelength for Detection:

The wavelength for detection was selected by tacking UV spectra of drug. The wavelength which gives the best result for proposed method was found to be 255nm forTolperisone HCl and 275 nm for Diclofenac sodium. These wavelengths were used for detection during whole method development.

Optimization of Mobile Phase:

Mobile phase was selected based on the review of literature and theoretical aspects. Various combinations of Methanol, Toluene, Acetone, Chloroform, Ethyl acetate, ammonia and Triethylamine (TEA) etc… were tried.

Table no1:List of Mobile Phase Trials in HPTLC

Sr. No.	Mobile phase composition	Result
1	Methanol	Tolperisone HCl was retained only
2	Toluene	Tolperisone HCl was retained only
3	Ethyl acetate	Drug spot was not found for Diclofenac sodium
4	Chloroform	Drug spot was not found Diclofenac sodium
5	Acetone	Drug spot was not found for Diclofenac Sodium
6	Methanol: Toluene (5:5 v/v)	Rf was more for Tolperisone HCl
7	Methanol: Toluene (8:2 v/v)	Rf was more for Diclofenac sodium
8	Methanol : Toluene (2:8 v/v)	Rf was proper but smiling effect was observed for both drugs
9	Methanol : Toluene: Ethyl Acetate (2:7:1 v/v/v)	Rf was proper but tailing was observed for Tolperisone HCl
10	Methanol : Toluene: Ethyl Acetate (3:6:1 v/v/v)	Rf was proper but tailing was observedforTolperisone HCl
11	Methanol : Toluene: Ethyl Acetate (3:6.5:0.5 v/v/v)	Rf was more for Diclofenac sodium
12	Methanol : Toluene: Ethyl Acetate (2.5:7:0.5 v/v/v)	Rf value was proper for both the drugs

Sharp peak were appeared with $R_f$value of 0.5 for Tolperisone HCl and 0.7 for Diclofenac sodium by using Methanol: Toluene: Ethyl Acetate (2.5:7:0.5 v/v/v)and was selected as a mobile phase for the method

Optimization of Saturation Time:

Saturation time was optimized at five different time intervals that are 10 min, 15 min, 20min, 25min and 30 min the best results was obtained at 25 min.

PREPARATION OF SOLUTIONS:

Preparation of Mobile Phase:

Mobile phase was prepared by mixing the components ofMethanol: Toluene: Ethyl Acetate (2.5:7:0.5 v/v/v).

Preparation of Standard Stock Solution:

Weigh accurately 15mg of Tolperisone HCl and 5mg of Diclofenac sodium and transferred to 10 ml volumetric flask. Methanol (HPLC GRADE) was added to dissolve the drug and final volume was made with the same solvent to obtain a concentration 1500 µg/ml for Tolperisone HCl and 500 µg/ml for Diclofenac sodium, this solutions were used for analysis.

Preparation of Sample Solution:

Weigh powder equivalent to 15 mg of Tolperisone HCl and 5mg Diclofenac sodium transferred to 10 ml volumetric flask. Methanol (HPLC GRADE) was added to dissolve the drug and final volume was made with the same solvent to obtain a concentration 1500 µg/ml for Tolperisone HCl and 500 µg/ml for Diclofenac sodium and this solution was used for analysis.

HPTLC METHOD VALIDATION PARAMETERS:

Linearity:

Linearity of Tolperisone HCl and Diclofenac sodium were performed over a concentration range of 300-1500µg/band and 100-500 µg/band for Tolperisone HCl and Diclofenac sodium respectively. 0.2, 0.4, 0.6, 0.8 and 1.0 µl of standard stock solution was applied to each band on TLC plate using Hamilton syringe by Linomat V Applicator. The detection was done at 255nm for Tolperisone HCl and Diclofenac sodium and the R_f value for Tolperisone HCl and Diclofenac sodium was found to be 0.5 and 0.7 respectively.

Accuracy:

Accuracy may often be expressed as % Recovery by the assay of known, added amount of analyte. It's measure of the exactness of the analytical method. The recovery experiments were carried out in triplicate by spiking previously analyzed samples of the Tolperisone HCl (300 µg/band) and Diclofenac sodium (100 µg/band)with three different concentrations of standards at 80%, 100% and 120% respectively.

Precision:

Repeatability:

The final solution containing600 µg/band of Tolperisone HCland200 µg/band of DiclofenacSodiumwas prepared and injected 6 times into the column to get the densitogram. The peak area were measured of the densitograms and % RSD was calculated.

Intraday Precision:

For Intraday Precision, The final solution containing600 µg/band of Tolperisone HCland 200 µg/band of DiclofenacSodiumwas prepared and injected 6 times into the column at 1hr, 2hr and 3hr to get the densitogram. The peak area were measured of the densitograms and % RSD was calculated.

Interday Precision:

For Interday Precision, The final solution containing600 µg/band of Tolperisone HCland 200 µg/band of Diclofenac sodiumwas prepared and injected 6 times into the column on different time interval; 1st day, 2nd day and 3rd day to get the densitogram. The peak area were measured of the densitograms and % RSD was calculated.

Assay:

Assay of dosage form is the one of critical quality parameter to assure the quality of dosage form. Some interference of the excipients with the peaks of interest appeared; hence the proposed is applicable for the routine estimation of Tolperisone HCl and Diclofenac sodium in pharmaceutical dosage forms. The method was successfully applied for the estimation of contents in the tablet. 600µg/band ofTolperisone HCl and 200 µg/band of Diclofenacsodiun test sample were used for measurement of peak area and that was compare with peak area of standard.

Specificity:

The specificity of the method was determined by checking the interference of placebo with analyte. The densitograms of blank, mobile phase and placebo do not show any interference at the R_f of Tolperisone HCl and Diclofenac Sodium as it can be seen from respective densotigrams. Only one peak of Tolperisone HCl and Diclofenac Sodium were obtained in the spectral evaluation which indicates that there was no interference from excipients in the proposed method. Further, peak purity data clearly shows that there is no any other interference in the developed method.

Robustness:

It means some deliberate changes have been made to the method parameter and check any significant changes obtained in the results or not. If not than the method is robust. Here, in this HPTLC method chamber saturation time and wavelength were changed to check the robustness of the developed method. Results are expressed in terms of %RSD.

LOD & LOQ

It is the lowest amount of analyte in a sample that can be detected but not necessarily quantities under the stated experimental conditions. Limit of detection can be calculated using following equation as per ICH guidelines.

$$LOD=3.3\times N/S$$

It is the lowest concentration of analyte in a sample that can be determined with the acceptable precision and accuracy under stated experimental conditions. Limit of quantification can be calculated using following equation asper ICH guidelines.

$$LOQ=10\times N/S$$

Where, N is the standard deviation of the peak areas of the drug and S is the slope of the corresponding calibration curve.

DEGRADATION STUDIES:

All degradation studies were done at a drug concentration of900 µg/band for Tolperisone HCl and 300µg/band for DiclofeancSodium.

Forced Degradation under Acidic Condition:

To 1 ml of stock solution, 1 ml of 1.0 N HCl was added in a 10 ml of volumetric flask and volume was brought up to the mark with methanol. The volumetric flask was kept under normal condition for 24 hours for degradation. After 24 hours, 1 ml of solution was withdrawn and neutralize with 1.0 N NaOH. Resulting solution was analyzed for acid degradation study.

Forced Degradation underAlkaline Condition:

To 1 ml of stock solution, 1 ml of 1 N NaOH was added in a 10 ml of volumetric flask and volume was brought up to the mark with methanol. The volumetric flask was kept under normal condition for 24 hours for degradation. After 24 hours, 1 ml of

solution was withdrawn and neutralize with 1 N HCl. Resulting solution was analyzed for alkaline degradation study.

Forced Degradation underOxidative Condition:

To 1 ml of stock solution, 1 ml of 3 % hydrogen peroxide was added in a 10 ml of volumetric flask and volume was brought up to the mark with methanol. The volumetric flask was kept under normal condition for 24 hours for degradation. After 24 hours, solution was heated in a boiling water bath to remove excess hydrogen peroxide.Resulting solution was analyzed for oxidative degradation study.

Forced Degradation underNeutral Condition:

To 1 ml of stock solution, 1 ml of water (distilled) was added in a 10 ml of volumetric flask and volume was brought up to the mark with methanol. The volumetric flask was kept under normal condition for 24 hours for degradation. After 24 hours, Resulting solution was analyzed for neutral degradation study.

Forced Degradation under Thermal Condition:

For thermal decomposition drug powders were kept at 60°C for 48 hours. From that powder solution having concentration of 900µg/band for Tolperisone HCl and 300 µg/band for Diclofenac sodium were prepared and analyzed for thermal degradation study.

Forced Degradation underDirect Sunlight:

A samples of drug were exposed to a direct sunlight. Drug were kept in petridis for time period of 48 hours. From that powder solution having concentration 900 µg/band for Tolperisone HCL and 300 µg/band for Diclofenac sodium were prepared and analyzed for thermal degradation study.

RESULT & DISCUSSION:

METHOD DEVELOPMENT (HPTLC)

Table no2: Optimized Chromatographic Condition for HPTLC

Chromatographic Parameters	Optimized Condition
Stationary phase	Precoated silica gel 60 F 254 aluminum sheets

Mobile phase composition	Methanol: Toluene: Ethyl Acetate (2.5:7:0.5 v/v/v)
Saturation time	25 minutes
Migration distance	80mm
Temperature	25-30 ^{o}C
Detection	255 nm for Tolperisone HCl and 275 nm for Diclofenac sodium
Band width	6mm
R_f value	For Tolperisone HCl=0.5 For Diclofenac Sodium=0.7

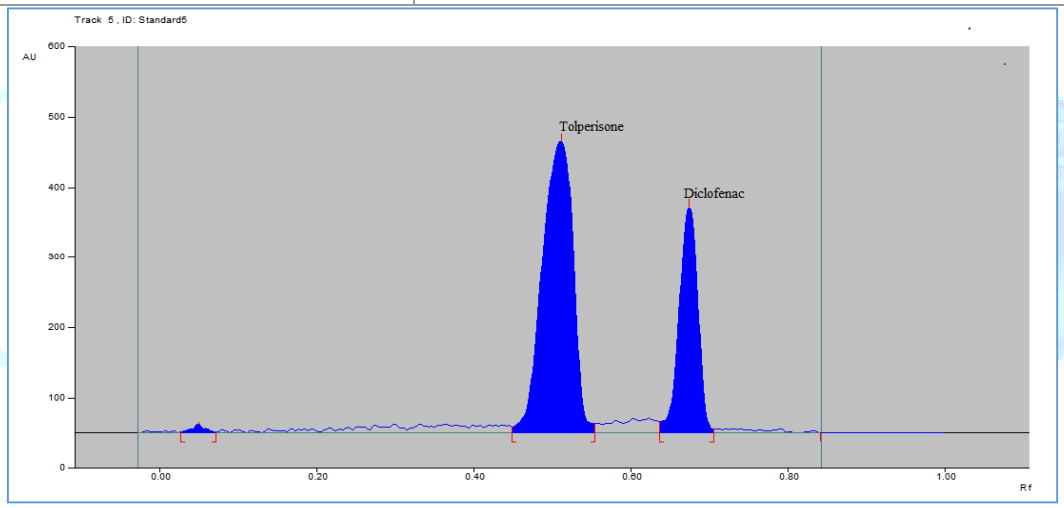


Figure no 1: HPTLC densitogram of Tolperisone HCl (600 µg/band) and Diclofenac Sodium (200 µg/band)

Method validation

Linearity

Linear response was obtained in concentration range of 300-1500 µg/ml for Tolperisone HCl and 100-500 µg/ml for Diclofenac Sodium by plotting calibration curve peak area versus concentration. The regration equation was found to be y = 5.3727x + 4514.2 and R^2 = 0.9983 andy = 9.376x + 2635.6 and R^2 = 0.9956. For Tolperisone HCl and Diclofenac Sodium respectively. The data for linearity clearly indicates that proposed method is Linear.

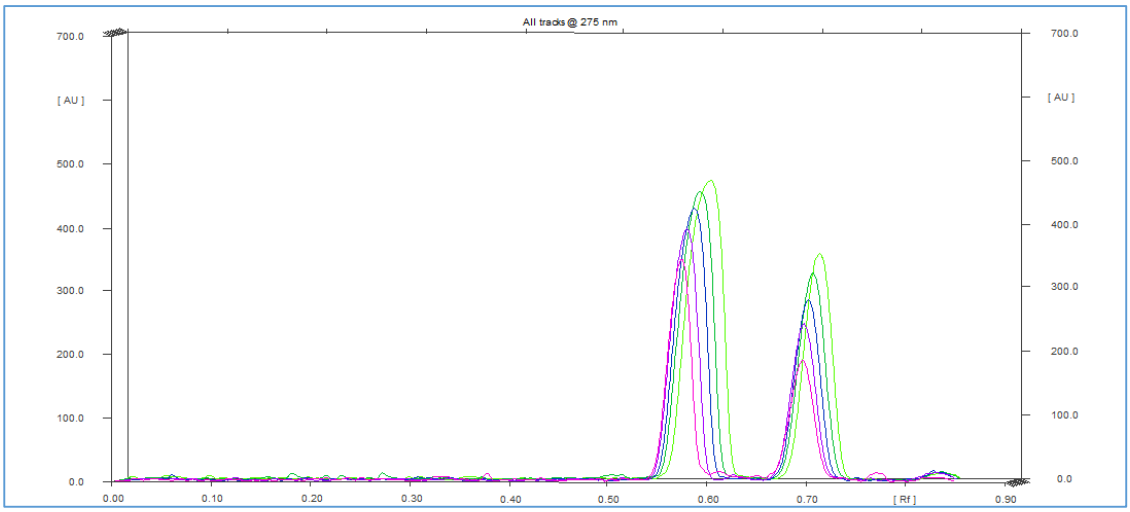


Fig. no 2: HPTLC Densitogram showing linearity of Tolperisone HCl and Diclofenac Sodium

Table no: 3 Linearity data of Tolperisone HCl by HPTLC

Sr.no.	Concentration(µg/band)	Area			Average.	SD
		L1	L2	L3		
1	300	6004	6001	6015	6006.66	7.37
2	600	7812	7910	7781	7834.33	67.33
3	900	9479	9423	9521	9474.33	49.16
4	1200	10965	10895	10854	10904.66	56.12
5	1500	12511	12458	12632	12533.66	89.18

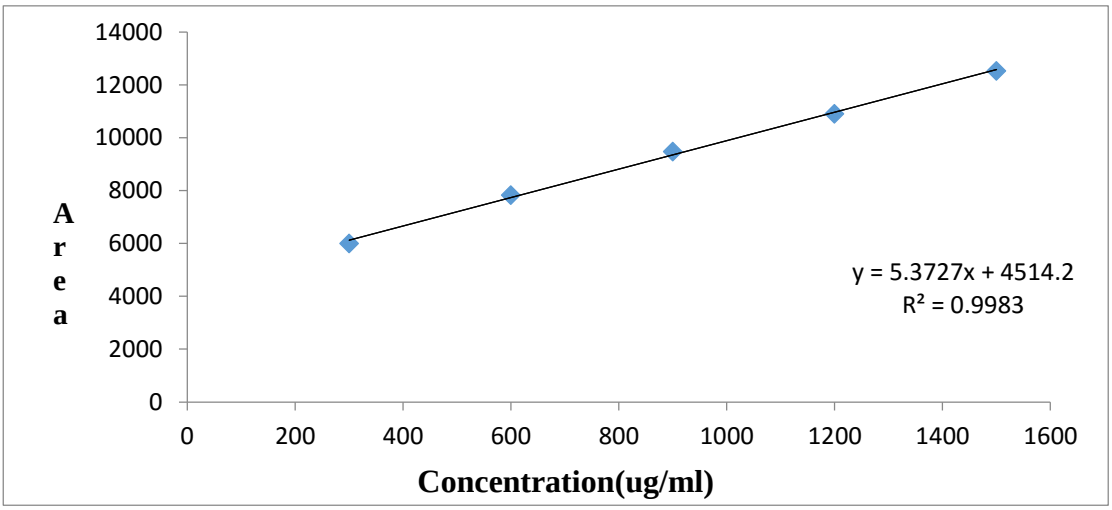


Figure no 3: Calibration curve of Tolperisone HCl.

Table no 4: Linearity data of Diclofenac Sodium by HPTLC

Sr.no.	Concentration(µg/band)	Area			Average	SD
		L1	L2	L3		
1	100	3495	3480	3475	3483.33	10.40
2	200	4585	4512	4610	4569.00	50.92
3	300	5469	5510	5480	5486.33	21.22
4	400	6471	6541	6480	6497.33	38.08
5	500	7265	7135	7221	7207.00	66.12

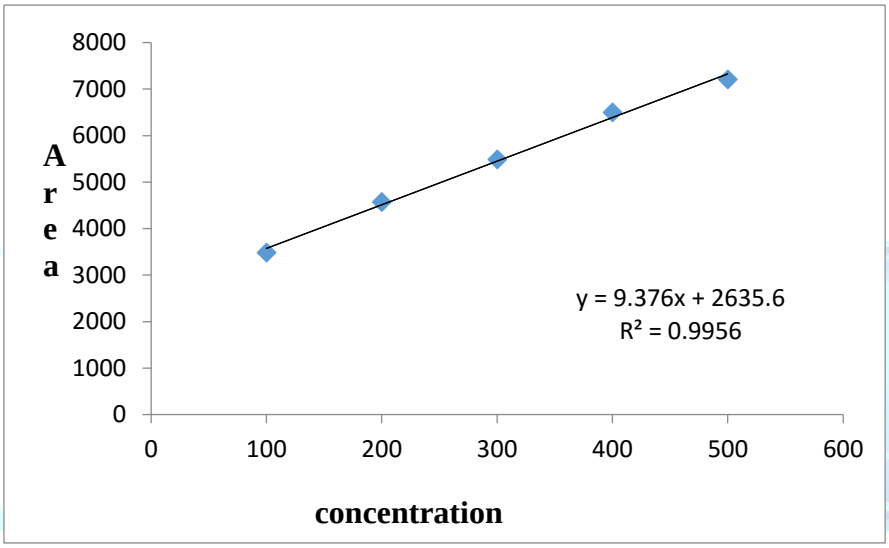


Figure no 4: Calibration curve for Dicloenac NA Precision

Repeatability

Repeatability was done to check the difference between results under the same chromatographic condition. %RSD of Tolperisone HCl and DiclofenacSidium was found to be **0.89** and **0.80**. All parameters are less than 2. This clearly indicates that proposed method is precise.

Table No 5: Repeatabilitydata of Tolperisone HCl by HPTLC

Sr,No.	Concentration (µg/band)	Area
1	600	7732.66 ±69.24

*n=6

Table no 6: Repeatability data of Diclofenac Sodium by HPTLC

Sr,No.	Concentration (µg/band)	Area
1	200	4592.83±36.74

***n=6**

Intraday Precision

% RSD for interday precision was found to be **1.35, 1.37, and 0.1.48** for Tolperisone HCl.and**1.17, 1.81** and **1.55** for Diclofenac Sodium. All parameters of % RSD are less than 2. This clearly indicates that proposed method is precise.

Table no 7: Intraday Precision of Tolperisone HCl by HPTLC

Sr. No.	Time Duration		
	1st Hour (AU)	**2nd Hour (AU)**	**3rd Hour (AU)**
1	7711.66±104.59	7710.33±105.85	7681±113.78

***n=6**

Table no 8: Intraday Precision of Diclofenac Sodium by HPTLC

Sr No.	Time Duration		
	1stHour (AU)	**2ndHour (AU)**	**3rdHour (AU)**
1	4662.33±54.81	4588.16±83.11	4621.66±71.94

***n=6**

Interday Precision

% RSD for in interday precision was found to be **1.41, 1.18, and 1.45** for Tolperisone HCl.and**1.18, 1.42** and **1.16** for Diclofenac Sodium. All parameters are less than 2. This clearly indicates that proposed method is precise.

Table no 9: Interday precision data of Tolperisone HCl by HPTLC

Sr. No.	Time Duration		
	1st Day (AU)	**2nd Day(AU)**	**3rd Day (AU)**
1	7831.33±111.16	7758.33±92.11	7772.83±112.90

*n=6

Table no 10:Interday precision data of Diclofenac Sodium by HPTLC

Sr. No.	Time Duration		
	1st Day (AU)	**2nd Day (AU)**	**3rd Day (AU)**
1	4567.16±54.23	4593.66±65.67	4567±53.34

*n=6

Accuracy

Accuracy of method is express in terms of %recovery study at 80%,100 and 120% level of recovery of three replicate of each of both drug were determine and data of recovery was given in following table. Table 5.13 shows recovery from the synthetic mixture. The data shows that proposed method is accurate.

Table no 11: Accuracy data of Tolperisone HCl by HPTLC

Level of Recovery	Concentration(µg/band)		Total amt.	Area	Amount Recovered	% Recovery	Mean Recovery	Standerd Deviation of area	%RSD of area
	Standard	test							
80%	240	300	540	7409	538.83	99.78	99.47	9.53	0.12
	240	300	540	7390	535.29	99.12			
	240	300	540	7401	537.34	99.50			
100%	600	300	900	7727	598.02	99.67	99.45	6.55	0.08
	600	300	900	7719	596.53	99.42			
	600	300	900	7714	595.60	99.26			
120%	360	300	660	8045	657.21	99.57	99.42	5.03	0.06
	360	300	660	8035	655.35	99.29			
	360	300	660	8039	656.09	99.40			

Table no 12: Accuracy data of Diclofenac Sodium by HPTLC

Level of	Concentration	Total amt.	Area	Amou-nt	% Recove	Mean	Standerd	%RSD of

Recovery	(µg/band)				Recovered	ry	Recovery	Deviation of area	area
	Standard	test							
80%	80	100	180	28025	178.12	98.95	98.61	8.38	0.029
	80	100	180	28010	176.40	98.00			
	80	100	180	28024	178.01	98.89			
100%	100	100	200	28225	199.46	99.73	99.37	7.63	0.027
	100	100	200	28220	198.93	99.46			
	100	100	200	28210	197.86	98.93			
120%	120	100	220	28405	218.67	99.39	99.60	3.78	0.017
	120	100	220	28412	219.42	99.73			
	120	100	220	28411	219.31	99.68			

LOD and LOQ

LOD and LOQ are calculated based on standard deviation and slope method and following result are found.

Table no 13: Data of LOD and LOQ by HPTLC

Drug	LOD(µg/band)	LOQ(µg/band)
Tolperisone HCl	19.22	57.66
Diclofenac Sodium	13.33	40.00

Robustness

Following data proves that proposed method is robustatsmall but deliberate change.

Table no 14: Data of robustness of Tolperisone HCl by HPTLC

Concentration (600 µg/band)	Wavelength (275±2)			Saturation time		
	275	273	277	25min	20min	30 min
1	7792.33±125.23	7648±84.65	7625.66±119.08	7792.33±125.23	7455.66±75.40	7482.33±78.21

***n=3**

Table no 15: Data of robustness of Diclofenac Sodium by HPTLC

Concentration (200 µg/band)	Wavelength(275±2)			Saturation time		
	275	**273**	**277**	**25min**	**20min**	**30 min**

1	4565.33 ±69.51	4270±73 .13	4238.66± 72.39	4565.33 ±69.51	4279.66 ±73.38	4203±71 .33

***n=3**

Application of proposed method to the tablet dosage form

No interference of the excipients with the peaks of interest appeared; hence the proposed method is applicable for the routine estimation of Tolperisone HCl and Diclofenac Sodium in tablet dosage forms. Results obtained are shown in following table.

Table no 16: Assay of Tolperisone HCl and Diclofenac sodium in tablet dosage form by HPLTC

Formulation	Label claimed (mg)	Amount found(mg) per tablet	% Label claim
Tolperisone HCl	150	148.99±0.5	99.16±0.80
Diclofenac Sodium	50	49.58±0.3	99.6±0.62

Degradation study

Acidic decomposition

Tolperisone HCl is known to be acid liable drug, and undergoes 5.94% degradation by stress acidic condition. While on the other hand Diclofenac Sodium is stable under stress acidic condition because there is little decrease in intensity of standard drug area. Thedegradation peak was not found within 24 hrs.

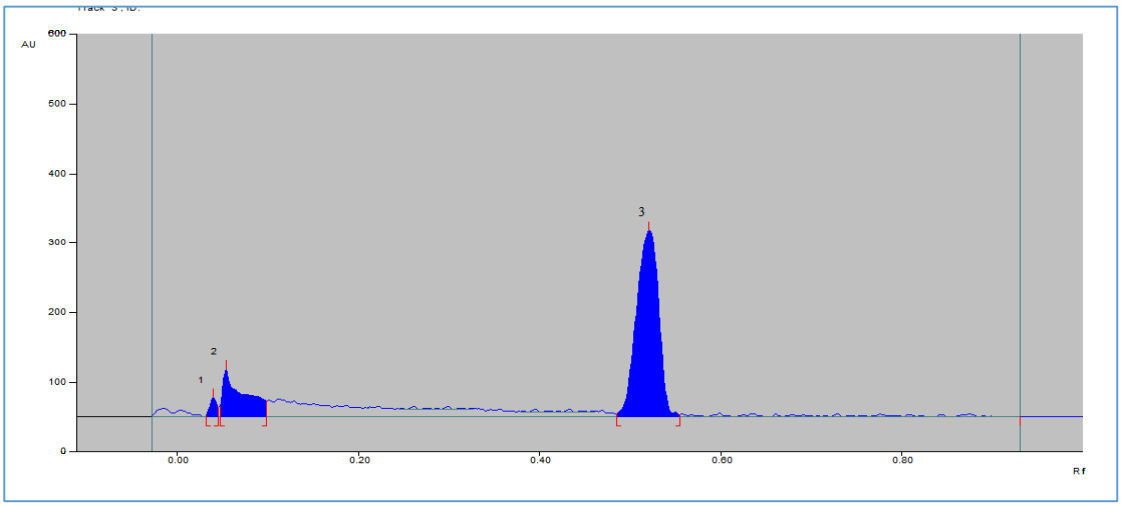


Fig.no 5: HPTLC densitogram of Diclofenac sodium by acid degradation (24 hrs.)

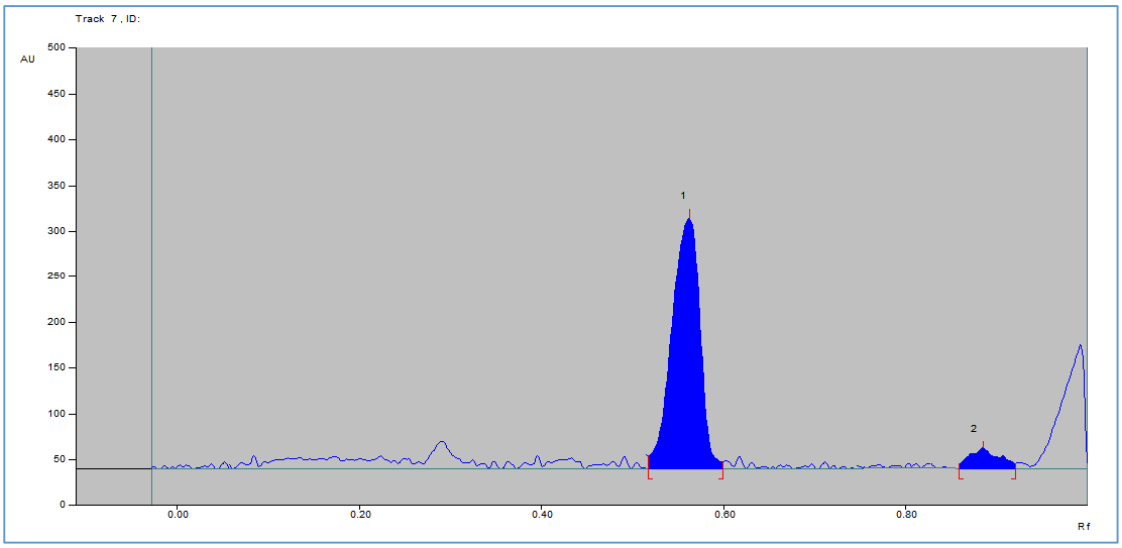


Fig.no 6: HPTLC densitogram of Tolperisone HCl by acid degradation (24 hrs.)

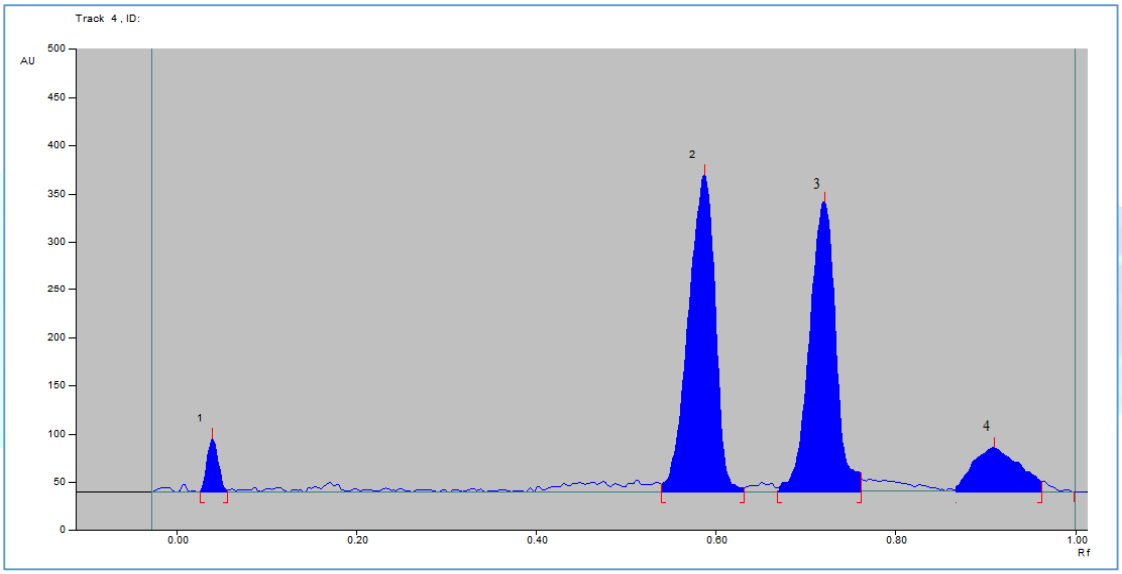


Fig. no 7:. HPTLC densitogram of Tolperisone HCl and Diclofenac sodium by acid degradation (24 hrs.)

Alkaline decomposition

Tolperisone HCl is known to be acid liable drug, and undergoes 10.11% degradation by stress alkali condition. While on the other hand Diclofenac Sodium is stable under stress alkali condition because there is little decrease in intensity of standard drug area. The degradation peak was not found within 24 hrs.

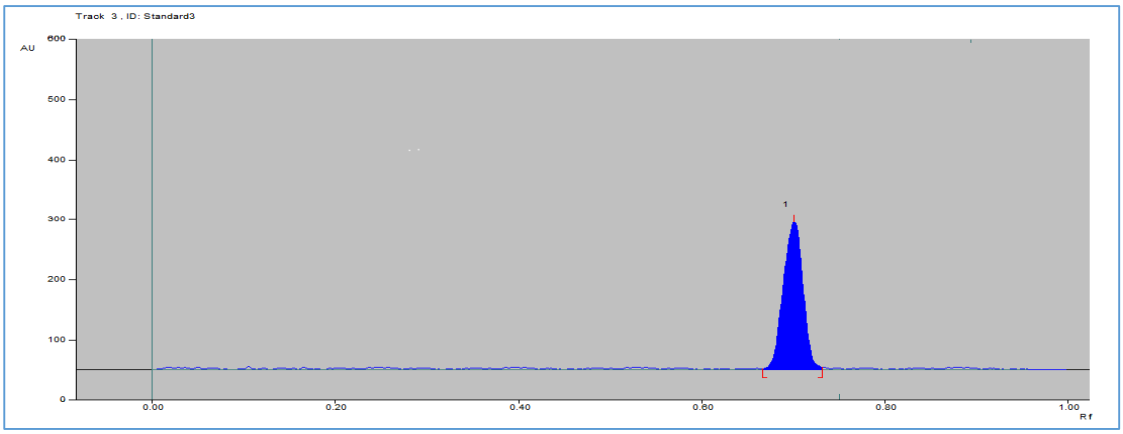


Fig. no 8: HPTLC densitogram of Diclofenac sodium by alkali degradation (24 hrs.)

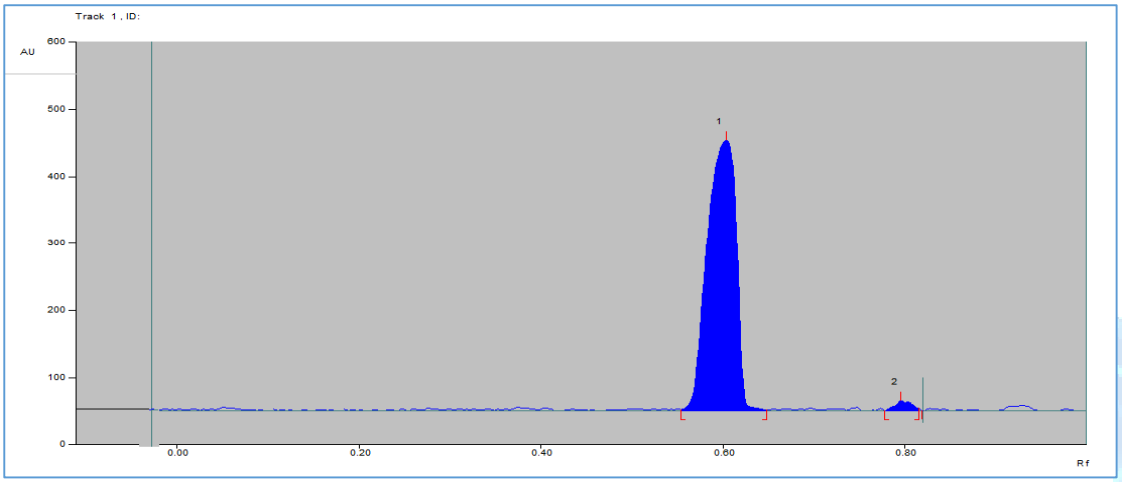


Fig.no 9: HPTLC densitogram of Tolperisone HCl by alkali degradation (24 hrs.)

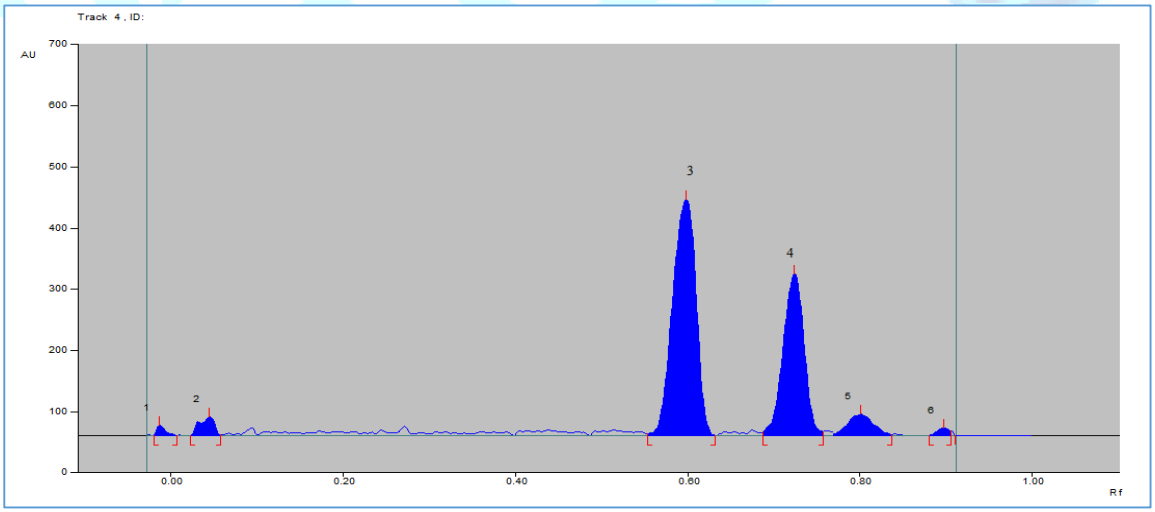


Fig. no 10: HPTLC densitogram of Tolperisone HCl and Diclofenac sodium by alkali degradation (24 hrs.)

Oxidatative degradation

Tolperisone HCl is known to be acid liable drug, and undergoes 4.35% degradation by stress oxidation condition. While on the other hand Diclofenac Sodium is stable

under stress oxidation condition because there is little decrease in intensity of standard drug area. The degradation peak was not found within 24 hrs.

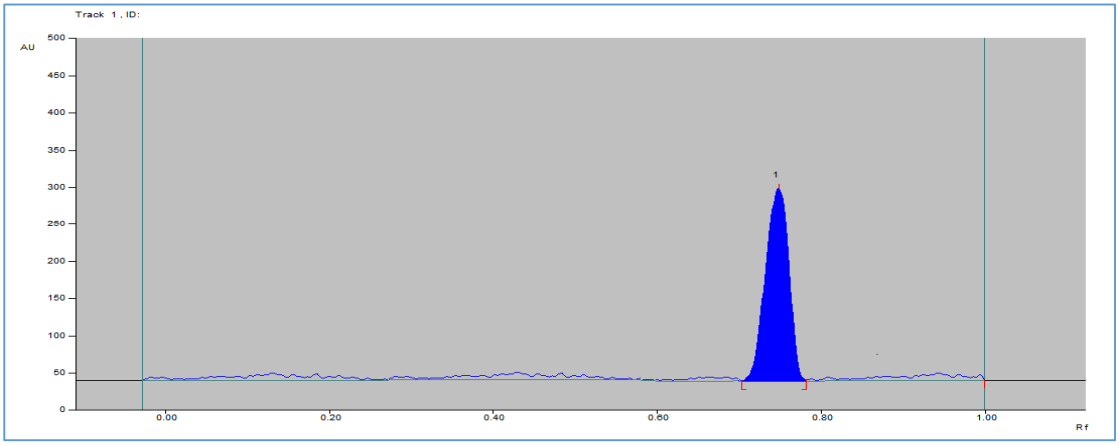


Fig. no 11:. HPTLC densitogram of Diclofenac sodium by oxidation degradation (24 hrs.)

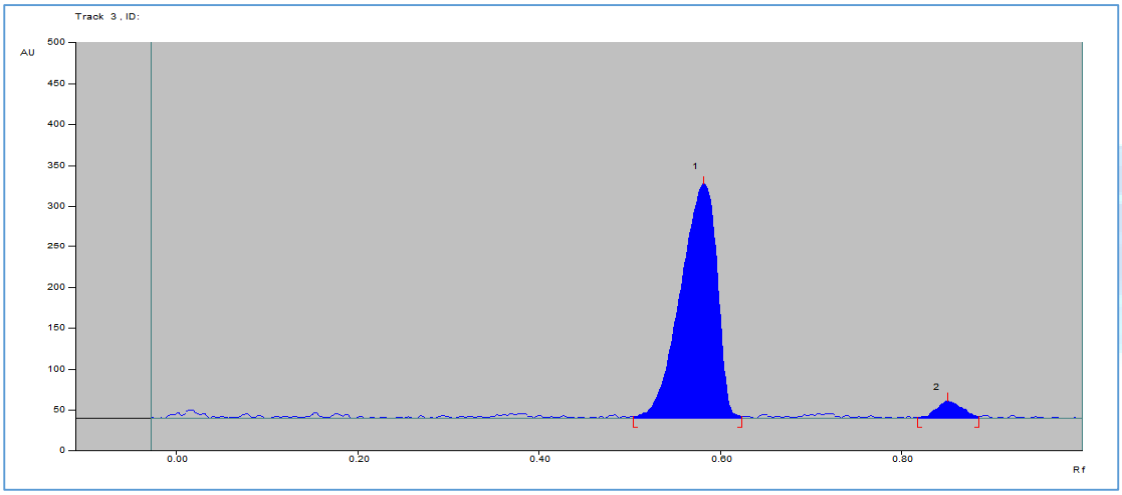


Fig. no 12: HPTLC densitogram of Tolperisone HCl by oxidation degradation (24 hrs.)

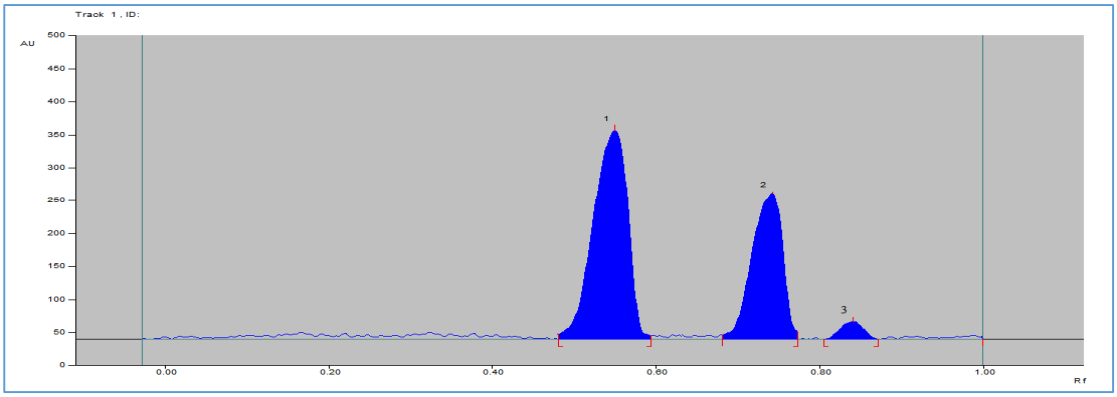


Fig. no 13: HPTLC densitogram of Tolperisone HCl and Diclofenac sodium by oxidation degradation (24 hrs.)

Thermal decomposition

Tolperisone HCl is known to be acid liable drug, and undergoes 2.93% degradation by stress oxidation condition. While on the other hand Diclofenac Sodium is stable under stress oxidation condition because there is little decrease in intensity of standard drug area. The degradation peak was not found within 24 hrs.

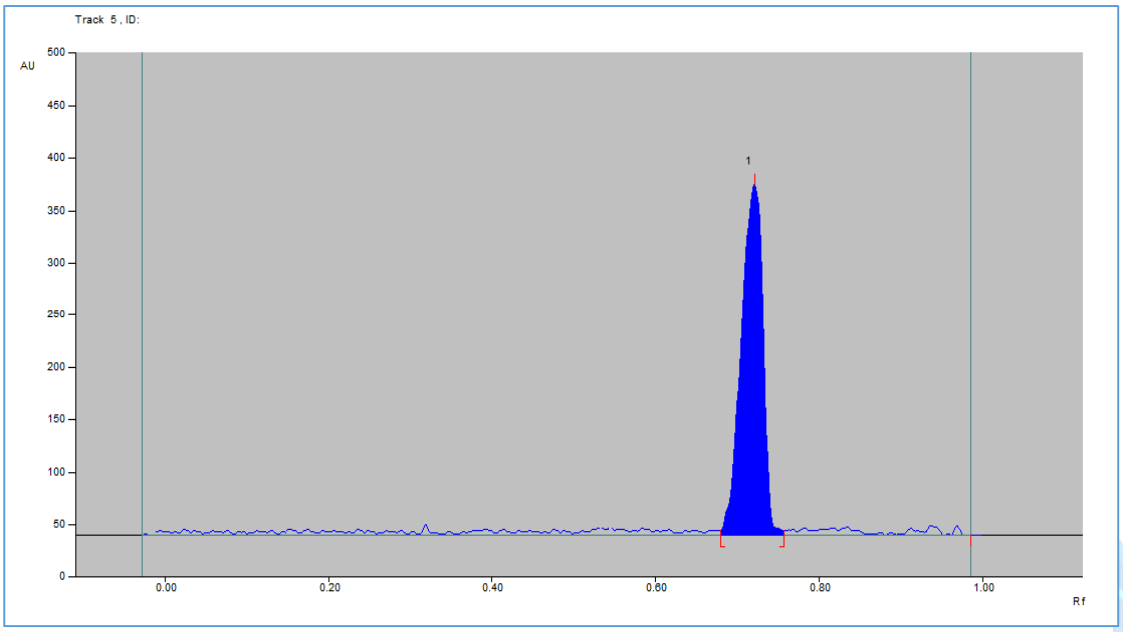


Fig. no 14: HPTLC densitogram of Diclofenac sodium by thermal degradation (24 hrs.)

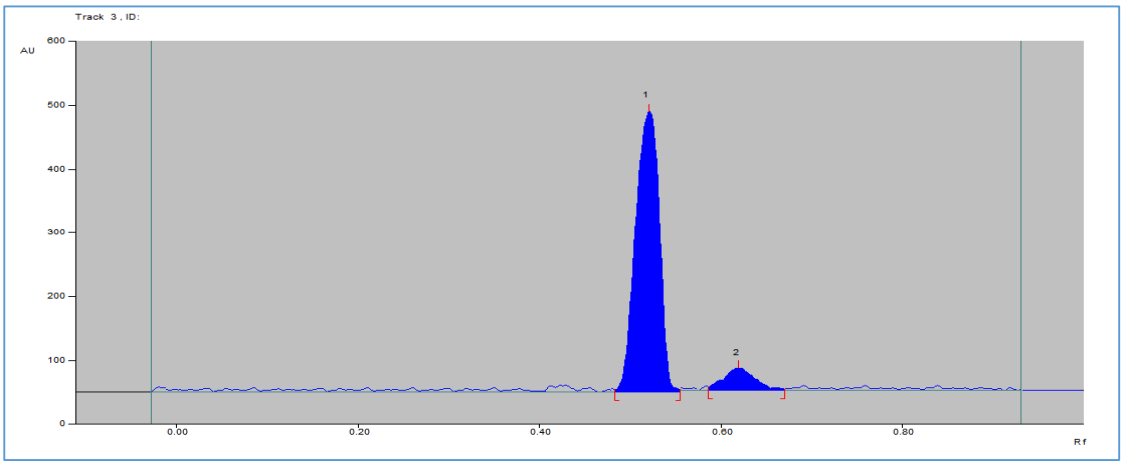


Fig. no 15: HPTLC densitogram of Tolperisone HCl by thermal degradation (24 hrs.)

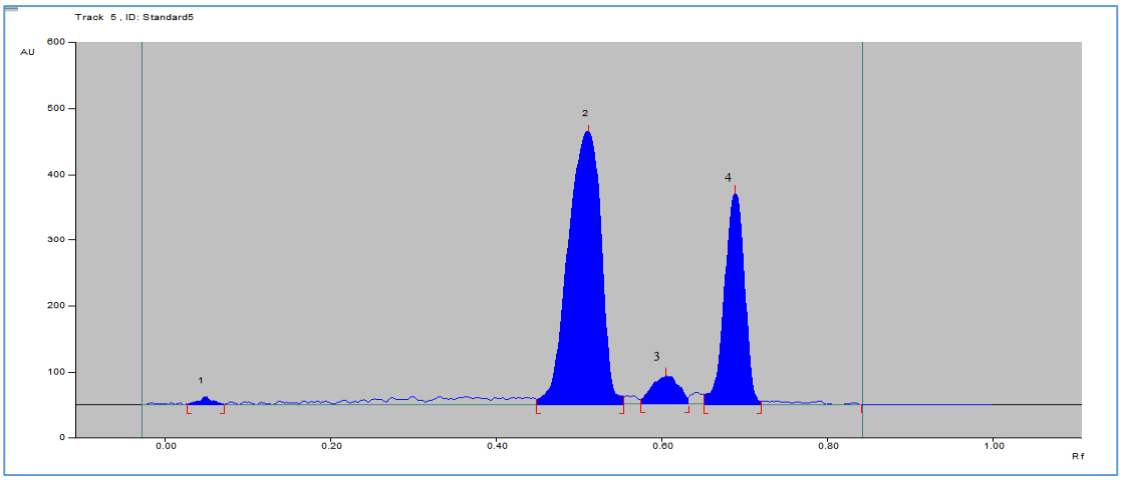


Fig. no 16: HPTLC densitogram of Tolperisone HCl and Diclofenac sodium by thermal degradation (24 hrs.)

Sunlight degradation

Both drugs are very stable under direct sunlight condition. There is no degradant peak in direct sunlight condition even after 24 hrs

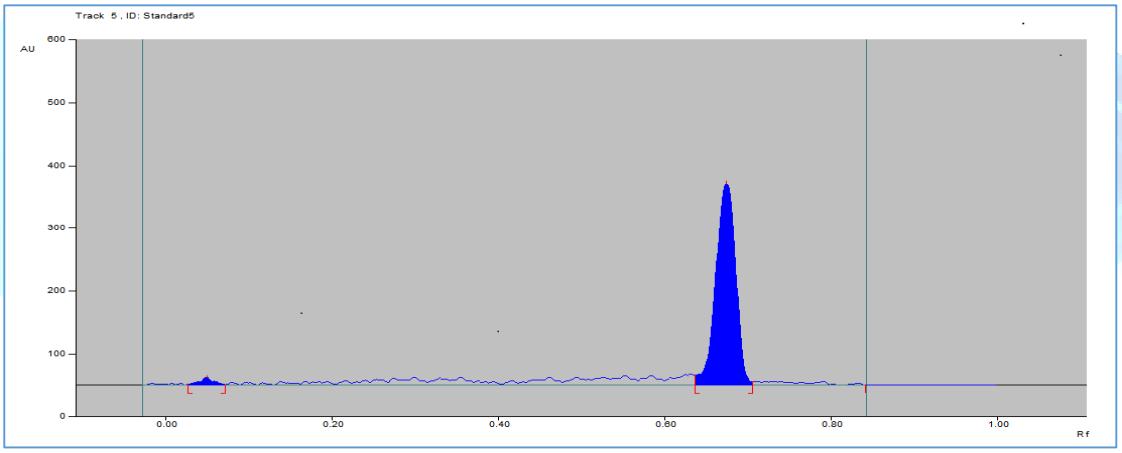


Fig. no 17: HPTLC densitogram of Diclofenac sodium by sun light degradation (24 hrs.)

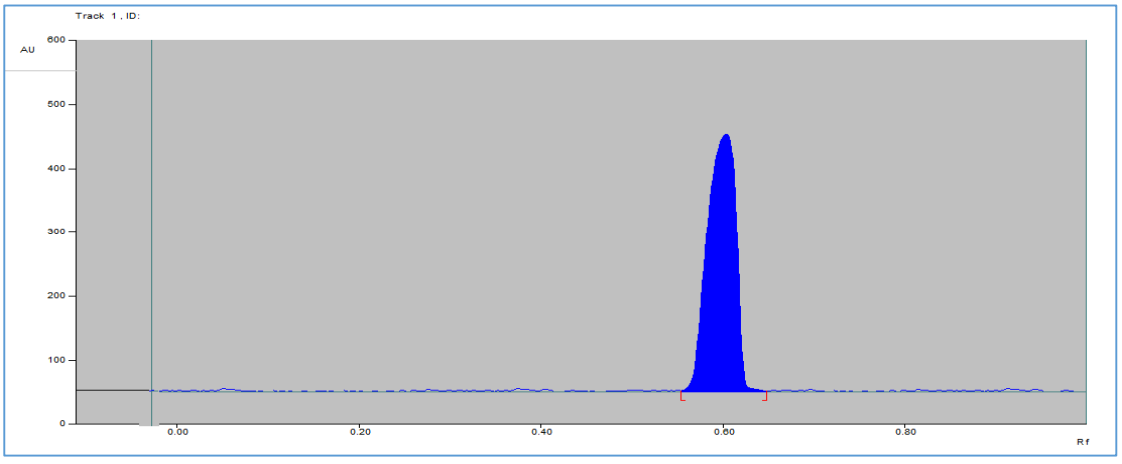


Fig. no 18:. HPTLC densitogram of Tolperisone HCl by sun light degradation (24 hrs.)

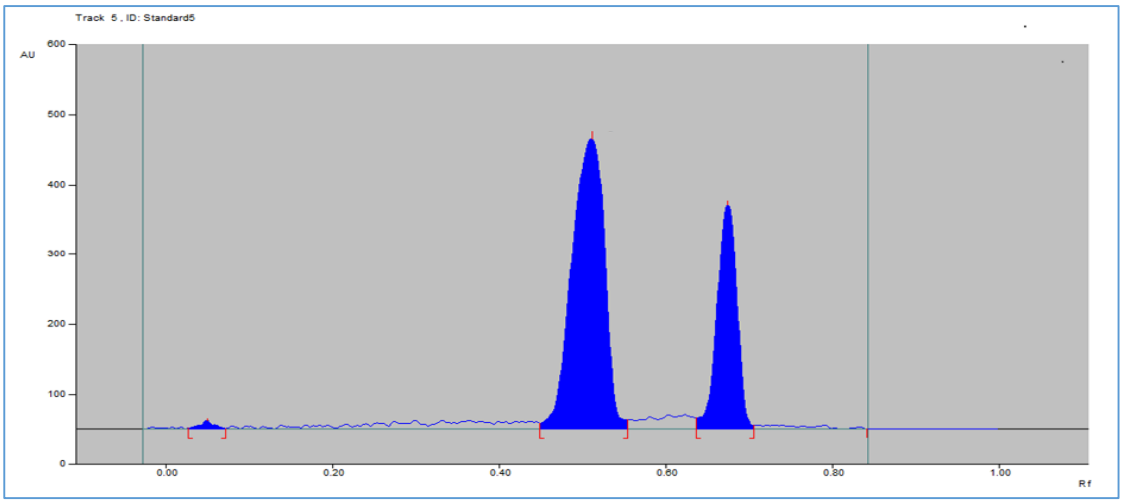


Fig no 19: HPTLC densitogram of Tolperisone HCl and Diclofenac sodium by sun light degradation (24 hrs.)

Table no 17: Stability data of drug

Sr. No	Stress Type	% recovery of Tolperisone HCl	Deceased area of Diclofenac sodium	% degradation of Tolperisone HCl	% degradation Of Diclofenac Sodium
1	Acid	94.06	5345	5.94	-
2	Base	89.89	5240	10.11	-
3	Oxidation	95.65	5389	4.35	-
4	Thermal	97.07	5410	1.93	-
5	Sunlight	100	-	-	-

Tolperisone HCl was more degrade than Diclofenac Sodium in different stress condition. Diclofenac Sodium degrade significantly in alkaline condition. Tolperisone HCl degrade significantly in acidic, basic, oxidized and thermal condition.

CONCLUSION:

Review of literature reveals that no stability indicating HPTLC method reported for simultaneous estimation of Tolperisone HCl and Dcilofenac sodium in combined solid dosage form. So, the HPTLC method has been developed for simultaneous estimation of Tolperisone HCl and Dcilofenac sodium in combined tablet dosage

form.Simple,accurate, precise and reproducible method for simultaneous estimation of ToperisoneHCl and Dcilofenac sodium in Tablet dosage form has been developed by HPTLC. The proposed method gives good resolution of Tolperisone HCl, Diclofenac Sodium and degradant product in degradation study. So, proposed method can be applied for routine quality control test.

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