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FORMULATION AND EVALUATION OF THE LORNOXICAM SUSTAINED RELEASE TABLETS BY USING NATURAL POLYMERS

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Abstract:
The main aim of the study formulation and evaluation of the lornoxicam sustained release tablets by using natural polymers. Definition and assessment of the continued delivery tablets of the Lornoxicam. For improvement of the tablets diverse excipients are utilized. The utilized avrious excipients are the karayagum, sodium alginate , pvpk30, Mg.sterate, Talc, MCC utilized as the diluents, Mg.sterate utilized as the ointments. Powder is utilized as Glidant. The plan is created by the utilizing direct pressure method.The detailing is set up by utilizing distinctive excipients .The excipients are hpmc and xanthin gum in different arrangements for medication to deliver in 10hrs. The pre pressure boundaries are done, for example, the mass thickness ,tap thickness, compressability file, Hauners proportion, Angle of rest. The all boundaries are gone under inside range great stream. The post pressure boundaries are done, for example, the saddle, thickness, weight variety, friability, breaking down. The assessment boundaries of theoptimised plan F8 tablets esteems.The weight variety of network tablets, 4 00mg. The hardness of the network tablets, 3.1(Kg/cm2).Thickness of the network tablets, 2.50mm. Breaking down of the framework tablets,25 mins. Friability of the network tablets, 0.256 % . In-vitro tranquilize disintegration investigations of the oral dispersible tablets, 98.65% . The all boundaries go under adequate standards inside scope of limts. The In-vitro medicate discharge examines are finished by USP-II mechanical assembly paddle strategy. The improved definition F9gives the drag out delivery upto 10hrs the medication discharge

Keywords: *Formulation, Evaluation, Lornoxicam, Sustained Release Tablets, Natural Polymers*

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INTRODUCTION:

Natural polymers are polymers that break down in a normal and biocompatible way and lose their individuality when they come into contact with biological components.1 These polymers are chosen over semi-synthetic and synthetic excipients. Bacterial growth, lot to lot variation, unpredictable ratio of hydration, and lower thickness during preservation are all issues that need to be addressed. Incorrect mechanical characteristics and low strew.2 Chemical adjustments were performed to improve the stability and process ability of newly discovered gums. If the newly created gums are biodegradable and biocompatible, they can be employed; if not, a biodegradable component can be added to make them biodegradable.3 To alter of molecular interaction between polymers, a variety of techniques can be applied. There are two approaches to choose from: physical and chemical.4 Physical technique Dry heat, water-logged steam, microwave, UV, even gamma radiation can all be utilized to generate a molecular interaction between polymers.5 Polymers are treated with chemicals such aldehydes, epichlorohydrin, borax, or glutaraldehyde in the chemical approach. Temperature cross-linking is single of the greatest advantageous cross-linking operations as it eliminates the need for harsh organic chemicals in large-scale production, as well as the associated equipment and methods.6 Because of the increased dose flexibility for design, the oral route of delivery for sustained release systems had gained considerable attention. The type of delivery system, the ailment being handled, the patient, the duration of medication, and the drug quality are all significant considerations in the design of oral sustained release delivery systems.7 The major goal of therapy is to keep the amount of drug in the blood at a steady level for a longer time. A major component of reaching this goal is the establishment of appropriate dose regimens. Sustained-release dosage forms are a type of drug administration that releases medication continuously over time to give long-term therapeutic benefit. Dosage is given in a single dose.8 Lornoxicam, a non – steroidal anti-inflammatory medication (NSAID) from the oxicam family, has been proven to have significant anti-inflammatory and analgesic properties. Lornoxicam is commonly used to treat symptomatic ache and infection in people with osteoarthritis and rheumatoid arthritis, as well as pain from gynecological, orthopedic, gastrointestinal and dental treatment.9-10 The main aim of the study formulation and evaluation of the lornoxicam sustained release tablets by using natural polymers.

MATERIALS:

Table 1: Materials used to be formulate

S.No.	MATERIALS	SOURCE
1.	Lornoxicam	RA chem Pharma
2.	Sodium alginate	Arun Pharma
3.	Karayagum	Shinetsu company
4.	MCC	Evonik company
5.	Talc	Evonik company
6.	Pvpk 30	Laxmi chem. Pvt.ltd
7.	Magnesium stearate	Clariant pharma

METHODOLOGY:

Formulation table of Lornoxicam sustained release tablets

Table 2: showing formulation table of Lornoxicam

Ingridients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Lornoxicam	50	50	50	50	50	50	50	50	50	50
Karaya gum	5	-	10	-	15	-	20	-	20	30
Sodium aliginate	-	5	-	10	-	15	-	20	20	-
Cross povidone	5	5	5	10	10	10	10	10	10	10
Mcc	336	336	331	326	321	321	316	316	296	306
Talc	2	2	2	2	2	2	2	2	2	2
Magnesium stearate	2	2	2	2	2	2	2	2	2	2
Total wt	400	400	400	400	400	400	400	400	400	400

Oral dispersable tablets formulated by using direct compression method

The dispence accurate quantity of drug of Lornoxicam by using different polymers in different quantity in nine formulation alternatively. The accurate quantity of polymers and drug under go for sieving. Ofter sieving the drug and excipients such as the karaya gum and sodimalginate and mcc under go for mixing. After mixing process adding of talc and magnesium stearate undergo direct compression by using multi compression mission.The talc used as glident and magnesium stearate used as lubricant.

RESULTS AND DISCUSSION:

Organoleptic charecters

Table 3: showing results of organoleptic characters

Properties	Results
Description	powder
Taste	Taste less
Odour	Odour less
Colour	White to almost white powder

Solubility studies

Table 3: Solubility of the Lornoxicamin various solvents

Solvent	**Solubility properties of drug**
ethanol	Freely Soluble
DMSO	Slightly Soluble
Water	Sparingly Soluble
Methanol	soluble

Calibration curve of the Lornoxicam in dmso

Table 4: showing calibration values of Lornoxicam

Concentration (µg/ml)	**Absorbance in dmso**
0	0
1	0.178
2	0.386
3	0.568
4	0.74
5	0.92

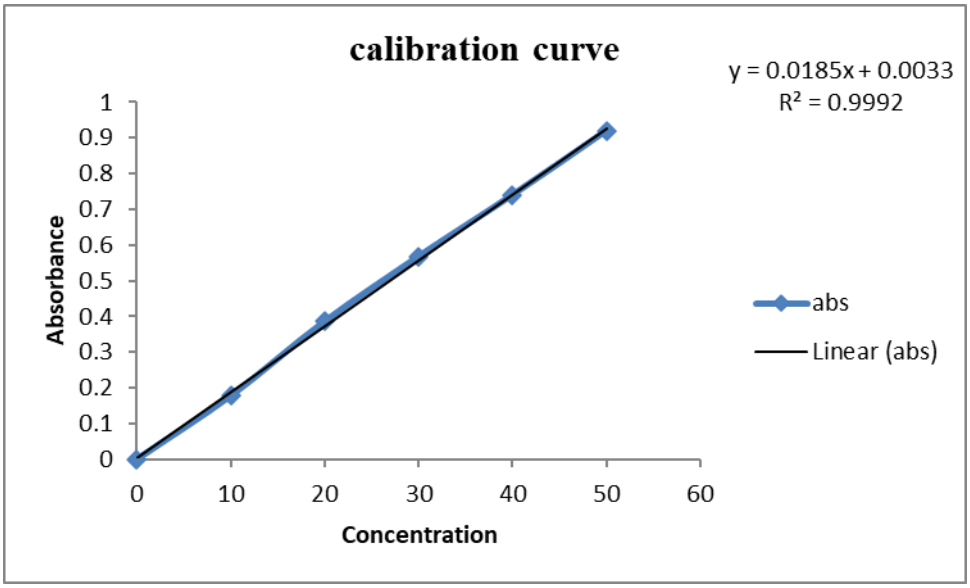

Fig. No 1: showing picture of the calibration plot in dmso

Calibration curve of the Lornoxicam in methanol

Table 5: showing calibration values in methanol

Concentration (µg/ml)	Absorbance in methanol
0	0
1	0.15
2	0.29
3	0.47
4	0.62
5	0.78

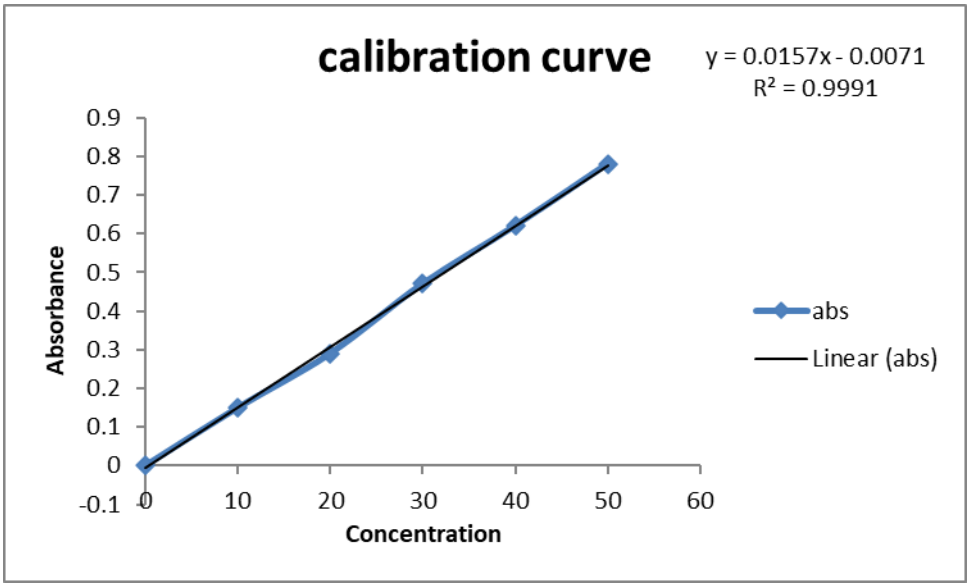

Fig.No 2: showing calibration plot in methanol

FTIR Studies

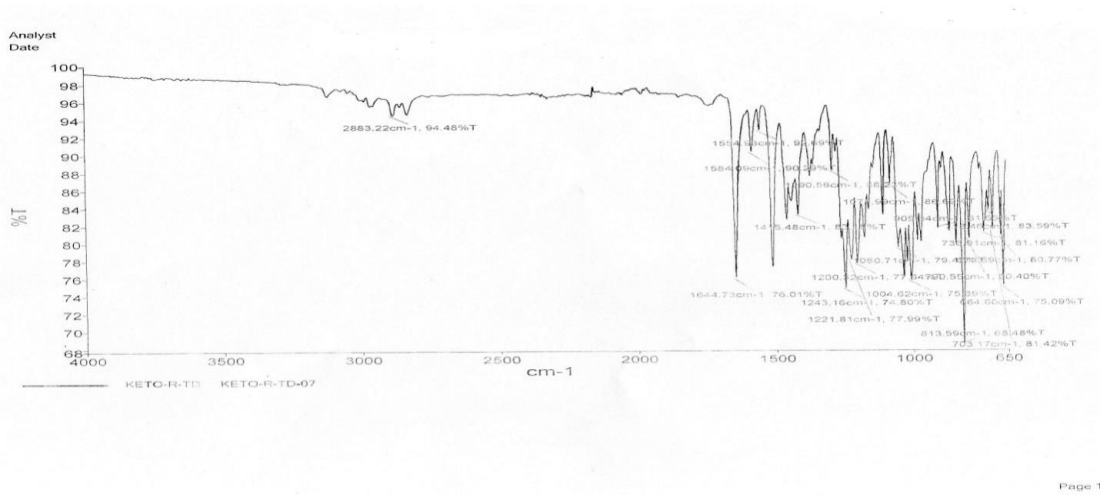

Fig.No 3: It shows the pure spectra o the Lornoxicam

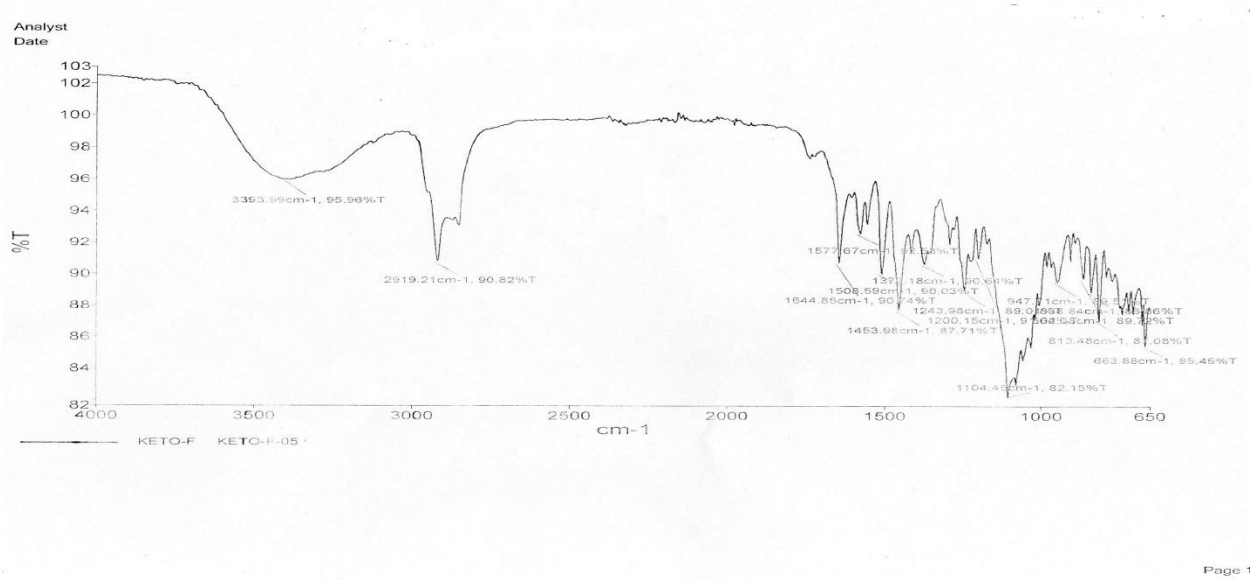

Fig.No 4: The fig shows the FTIR spectra of the drug and polymer blend

Table 6: Showing values of pure drug of Lornoxicam

Functional groups	**Puredrug Lornoxicam**
C-H Bending	1713.96 cm^{-1}
C=C STRETCH	2314.91 cm^{-1}
C=O Stretching	1240.03 cm^{-1}
C-H STRETCH	3002.43 cm^{-1}
O-H Stretching	3014.04 cm^{-1}
N-H STRETCH	3740.51 cm^{-1}

Table 7: Showing spectra values of drug and polymer blend

Functional groups	**drug+polymer**
C-H Bending	1703.56 cm^{-1}
C=C STRETCH	2243.91 cm^{-1}
C=O Stretching	1267.03 cm^{-1}
C-H STRETCH	2870.43 cm^{-1}
O-H Stretching	3010.04 cm^{-1}
N-H STRETCH	3117.51 cm^{-1}

Pre-compression parameters:

Table 8: showing values of the pre compression parameters

Formulation	Angle of repose (θ)	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio
F1	25.38±0.13	0.40±0.02	0.50.02	20±0.13	1.25±0.01
F2	22.52±0.28	0.44 ±0.02	0.56±0.04	20±0.04 1.	1.27±0.01
F3	27.19±0.19	0.44±0.00	0.54±0.01	18.61±0.11	1.22±0.02
F4	28.51±0.16	0.45±0.01	0.55±0.01	18.33±0.15	1.22±0.01
F5	23.60.21	0.41±0.01	0.50±0.00	18±0.05	1.21±0.02

Discussion: The all the F1-F5 formulations pre compression parameters such as the angle of repose,bulkdensity,tapdensity,husnersratio,compressability index all comes under the within range of limites. All the formulations fallow the good flow.

Post compression parameters for F1-F5 Formulations

Table 9: showing post compression parameters of F1-F5

Formulation	Weight variation	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug content (%)	Disintigration (mins)
F1	399±1.02	2.50±0.01	3.2±0.06	0.232	87.24±0.22	35
F2	398±0.08	2.6±0.00	3.8±0.06	0.246	89.57±0.42	38
F3	398.002	2.5±0.01	3.71±0.00	0.386	90.43±0.13	30
F4	399±0.003	2.00±0.01	3.65±0.06	0.326	92.83±0.42	28
F5	399±0.08	2.10±0.01	3.65±0.10	0.446	92.86±0.32	28

Formulation	Weight variation	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug content (%)	Disintigration (mins)
F6	399±1.02	2.40±0.01	3.4±0.06	0.232	93.24±0.22	25
F7	398±0.08	2.2±0.00	3.1±0.06	0.256	94.57±0.42	26
F8	401.002	2.3±0.01	3.2±0.00	0.226	96.43±0.13	25
F9	400±0.003	2.00±0.01	3.0±0.06	0.226	99.83±0.42	24
F10	400±0.08	2.50±0.01	3.1±0.10	0.256	96.86±0.32	25

In –vitro drug release studies for all formulations

Table 10: showing in—vitro drug release studies

Time in hrs	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
1	10.23	12.65	15.89	18.56	20.56	22.32	22.52	21.65	22.15	23.21
3	18.35	25.65	28.36	30.56	35.62	40.53	41.53	42.62	45.15	48.65
4	75.35	50.36	55.68	56.12	57.65	57.65	56.72	58.56	59.12	58.52
6	89.35	60.78	64.65	68.42	70.56	70.55	71.62	72.62	78.32	79.22
8	100.33	80.41	70.42	74.74	79.56	80.18	81.43	82.65	92.63	89.23
10	105.65	85.96	80.75	82.23	85.65	89.83	89.53	89.65	98.65	96.23

All comparative graph

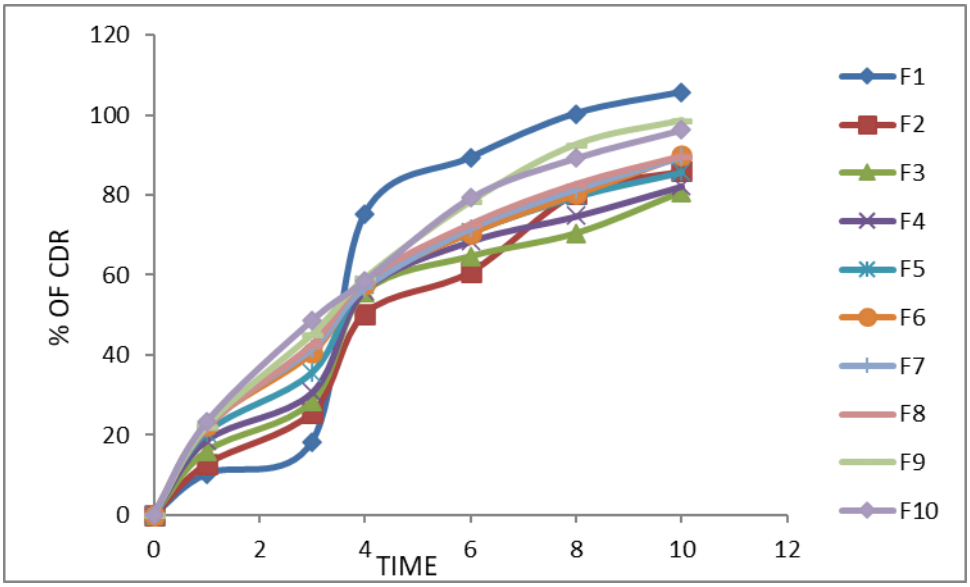

Fig.No 5: showing picture of in vitro drug release studies comparative graph

Table 11: Comparative graphs for f1-f5

Time in hrs	F1	F2	F3	F4	F5
0	0	0	0	0	0
1	10.23	12.65	15.89	18.56	20.56
3	18.35	25.65	28.36	30.56	35.62
4	75.35	50.36	55.68	56.12	57.65
6	89.35	60.78	64.65	68.42	70.56
8	100.33	80.41	70.42	74.74	79.56
10	105.65	85.96	80.75	82.23	85.65

Table 12: COMPARATIVE GRAPHS FOR F6-F10

Time in hrs	F6	F7	F8	F9	F10
0	0	0	0	0	0
1	22.32	22.52	21.65	22.15	23.21
3	40.53	41.53	42.62	45.15	48.65
4	57.65	56.72	58.56	59.12	58.52
6	70.55	71.62	72.62	78.32	79.22
8	80.18	81.43	82.65	92.63	89.23
10	89.83	89.53	89.65	98.65	96.23

Table 13: Kinetic profile data

Time	%cdr	Log T	√T	Log%cdr	ARA	Log%ARA
0	0	1	0	0	100	2
1	22.15	0	1	1.34537373	77.85	1.89125862
3	45.15	0.47712125	1.73205081	1.65465775	54.85	1.73917663
4	59.12	0.60205999	2	1.77173443	40.88	1.61151089
6	78.32	0.77815125	2.44948974	1.89387268	21.68	1.33605928
8	92.63	0.90308999	2.82842712	1.96675166	7.37	0.86746749
10	98.65	1	3.16227766	1.99409709	1.35	0.13033377

ZERO ORDERB REACTION

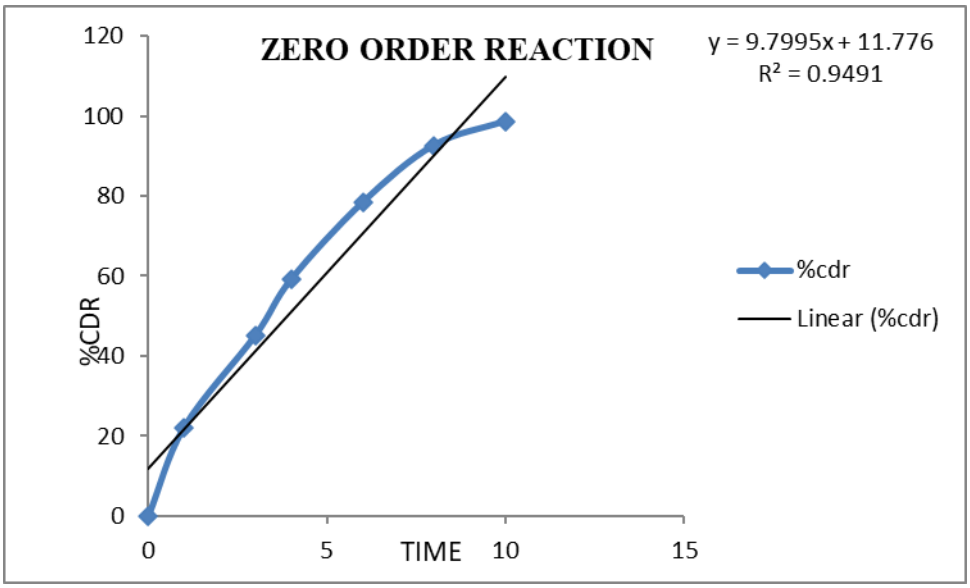

Fig.no 6: Zero order reaction

FIRST ORDER REACTION

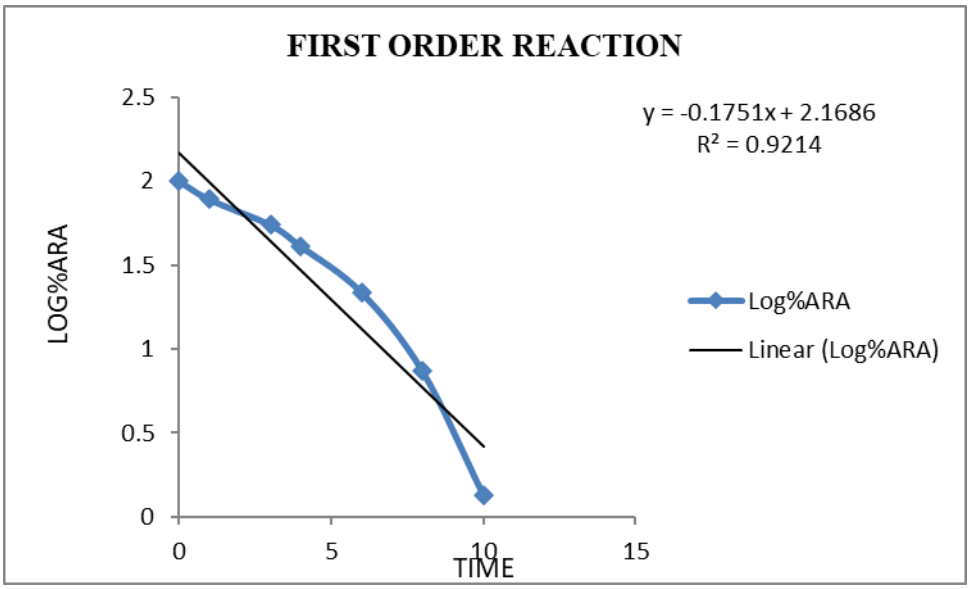

Fig.no 7: First order reaction

HIGUCHI EQUATION

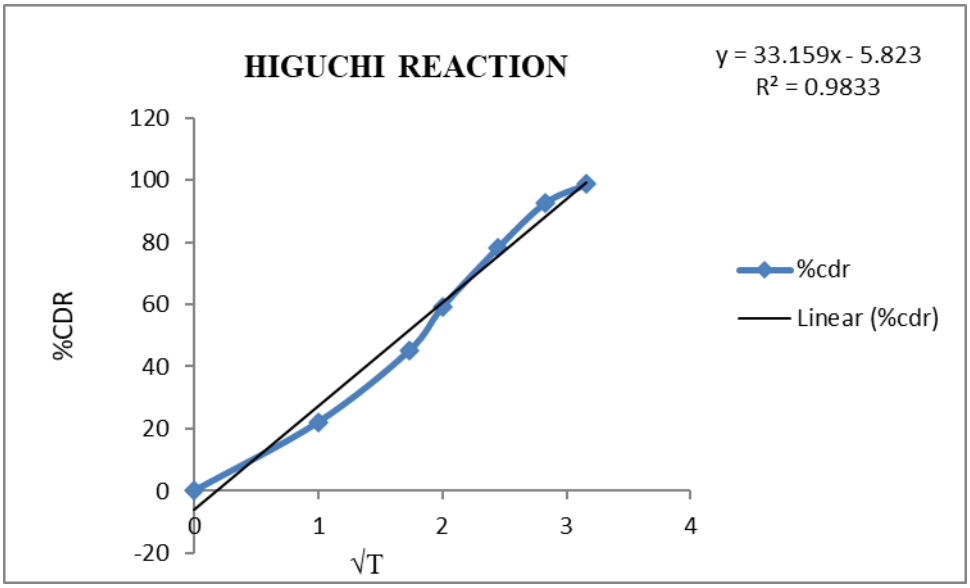

Fig.no 8: Higuchi equation

KROSS MAYER PEPPAS

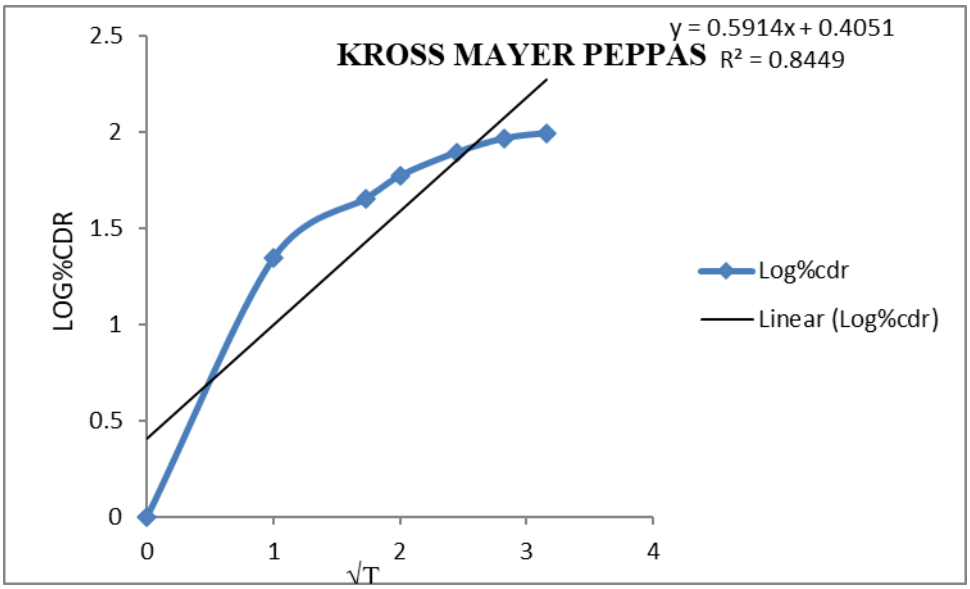

Fig.no 9: Kross mayer peppas

Stability samples are stored at

- Accelerated: 40±2^{0}C/75±5% RH
- Intermediate: 30±2^{0}C/65±5% RH
- Long term: 25±2^{0}C/60±5% RH

Testing Intervals

- Accelerated: Initial, 3 months.

Table 14: Results of stability studies of optimized formulation F-8

Formulation Code	Parameters	Initial	1st month	2nd month	3rd month	Limits as per Specifications
F-8	25^{0}C/60%RH % Release	98.65	99.7	97.56	99.53	Not less than 85 %

DISCUSSION:

It was concluded that stability studies of the optimized F8was carried out using the samples at temperatures 40^{0}C ± 2^{0}C/ 75% ± 5%RH for a period 3 month the Lornoxicam oral dispersible tablets are observed and there is no significant change in the release characteristics and physicochemical properties.

SUMMARY AND CONCLUSION:

Definition and assessment of the continued delivery tablets of the Lornoxicam. For improvement of the tablets diverse excipients are utilized. The utilized avrious excipients are the karayagum, sodium alginate , pvpk30, Mg.sterate, Talc, MCC utilized as the diluents, Mg.sterate utilized as the ointments. Powder is utilized as Glidant.

For definition plan the writing survey is completed. The medications determination and the polymer choice depends on the assortment of audit literature. Thepolymers picking likewise completed by the survey writing.

Before going to improvement, the pre detailing considers are done, for example, the shading, smell, taste, solvency examines. The medication and the excipient compatability contemplates are finished by utilizing the FTIR examines.

The plan is created by the utilizing direct pressure method.The detailing is set up by utilizing distinctive excipients .The excipients are hpmc and xanthin gum in different arrangements for medication to deliver in 10hrs. The pre pressure boundaries are done, for example, the mass thickness ,tap thickness,

compressability file, Hauners proportion, Angle of rest. The all boundaries are gone under inside range great stream. The post pressure boundaries are done, for example, the saddle, thickness, weight variety, friability, breaking down.

The assessment boundaries of theoptimised plan F8 tablets esteems:

The weight variety of network tablets, 4 00mg. The hardness of the network tablets, 3.1(Kg/cm2).Thickness of the network tablets, 2.50mm. Breaking down of the framework tablets,25 mins. Friability of the network tablets, 0.256 % . In-vitro tranquilize disintegration investigations of the oral dispersible tablets, 98.65% . The all boundaries go under adequate standards inside scope of limts. The In-vitro medicate discharge examines are finished by USP-II mechanical assembly paddle strategy. The improved definition F9gives the drag out delivery upto 10hrs the medication discharge

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