

Research Article**FORMULATION AND EVALUATION OF DEXIBUPROFEN FAST DISINTEGRATING TABLETS WITH NATURAL SUPER DISINTEGRANTS**Dr. G. Nagaraju^{1*}, V. Sirisha², Kavati Ramakrishna³, Dr. Hareesh Dara¹¹ Department of Pharmaceutical Chemistry, Dhanvanthari Institute of Pharmaceutical Sciences, Sujathanagar, Kothagudem.¹ Department of Pharmaceutics, Sree college of pharma, nayakulagudem, Kothagudem, Telangana.² Department of Pharmaceutics, Dhanvanthari Institute of Pharmaceutical Sciences, Sujathanagar, Kothagudem.³ Department of Pharmaceutics, Pulipati Prasad college of pharmacy, Pulipati Prasad college of pharmaceutical sciences, khammam.

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ABSTRACT

In this present research work, an attempt was made to develop solid dispersions for the enhancement of solubility, dissolution and bioavailability of Dexibuprofen and also to find the effect of natural super disintegrants in the development of quickly disintegrating tablets. Solid dispersions were prepared by solvent evaporation method using PEG 20,000 as carrier in different ratios. The optimized solid dispersions were prepared in the form of quick disintegrating tablets using different natural super disintegrants in different concentrations. The prepared tablets were evaluated and subjected to in vitro dissolution studies to select the best formulation. Among all the formulations Gum karaya containing formulations KF11 and KF12 shown to better release rate of Dexibuprofen from the dosage form. Finally the optimized formulations were subjected to pharmacokinetic studies in rabbits. The solid dispersion reached peak concentration (C_{max}) 11445.46 ng/ml at t_{max} of 2 h while it was observed to be 9140.84 ng/ml at t_{max} of 3 h in case of control tablet, indicating that enhancement of absorption in solid dispersion pattern of Dexibuprofen than pure form. The AUC of control and KF11 tablets of Dexibuprofen were 31495.16 and 43126.52 ng-h/ml correspondingly. These results indicated that the KF11 tablet showed enhancement of AUC when compared to control tablet of Dexibuprofen.

Keywords: Dexibuprofen, super disintegrants, Gum karaya, Solid dispersion

INTRODUCTION

The Center for Drug Evaluation and Research (CDER), USFDA defined Fast dissolving/disintegrating tablets (FDDTs) are "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". Recently European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" defined as uncovered tablet for buccal cavity, where it disperses before ingestion". Fast disintegrating tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. When faster the drug into solution, quicker the absorption and onset of clinical

effect [1].

MATERIALS AND METHODS

Dexibuprofen drug was gifted by Aurobindo Pharmaceuticals, Hyderabad, Telangana, India. Plantago ovate seeds, Fenugreek seed mucilage, Gum karaya, PEG20000, Avicel PH 102, Mannitol, Talc, Magnesium stearate, Sodium saccharine and orange flavor from local manufacturers.

Solubility investigation of Dexibuprofen

As the pH of the spit run from 6 to 7.4, the dissolvability of medication was contemplated in solvents of pH 6.8 phosphate cushions and refined water. A 100 mg of medication was taken and solubilized in 100 ml of solvents independently and the dissolvability was watched. Then an appropriate medium was chosen relying on the dissolvability results [2].

Construction of standard chart of Dexibuprofen***Corresponding author:****Dr. G. Nagaraju**

Department of Pharmaceutical Chemistry, Dhanvanthari Institute of Pharmaceutical Sciences, Sujathanagar, Kothagudem.

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Adjustment bend of Dexibuprofen was plotted in 6.8 pH phosphate support which was chosen from dissolvability study Dexibuprofen was evaluated spectrophotometrically at λ max of 260 nm [3].

Preparation of Solid Dispersions

The solid dispersion is arranged by utilizing PEG20000 as transporter in the ratios of 1:1, 1:2, 1:3, 1:4 1:5 and 1:6 using acetone as solvent-by-solvent evaporation method. Drug and bearer were weighed and triturated in mortar and pestle for 5min [4]. This physical mix was then separated in acetone with reliable blending. This dissolvable was dispersed on warming mantle kept up at $45^{\circ}\text{C} \pm 2^{\circ}\text{C}$ this model were dried in a desiccators for 24hrs over anhydrous Calcium Chloride. Dried mass was rejected, squashed pummeled and went through sifter 60. Formulae of solid dispersions of Dexibuprofen was shown in table 1

Table 1: Formulae of Solid Dispersions of Dexibuprofen

Solid Dispersion	Dexibuprofen	PEG20,000	Ratio
KS1	50	50	1:1
KS2	50	100	1:2
KS3	50	150	1:3
KS4	50	200	1:4
KS5	50	250	1:5
KS6	50	300	1:6

In-vitro drug release study: In-vitro separating assessments promising solid scatterings were performed by USP XXIII Type-II deterioration mechanical get together (Electrolab, Model TDT-06N) Using paddle stirrer at 50 rpm, 900-milliliter pH 6.8

phosphate pad is used dispersion medium at $37 \pm 0.5^{\circ}\text{C}$. Aliquots that break down medium (5 ml) are undoubtedly withdrawn at times (2, 4, 6, 8, 10, 15 & 30 min), proportional volume is immediately removed with new medium. Samples were separated by 0.22-layer layer channel plate examined for drug content by measuring the absorbance at 260 nm [5].

Pre-Compression studies: The following pre compression studies were conducted for Dexibuprofen and excipient mixture which includes bulk density, tapped density, angle of repose, Hausner ratio, Compressibility index. The results were expressed as mean \pm S.D in table 3.

Preparation of quick disintegrating tablets: Dexibuprofen, basic super disintegrants like Plantago ovate seeds, Fenugreek seed mucilage, Gum karaya, microcrystalline cellulose, mannitol were correctly measured and experienced 40-work mix for 15 minutes on screen and glass mortar to get uniform sized particles. The get mixture was filled with magnesium stearate and talc powder mixing continued for another 5 minutes. The sodium saccharin and orange flavor is added to the pie mix. The resulting mixture (See table 2) is compressed into tablets vertically using 12 mm round level up to the punch of the rotary tablet machine.

Evaluation of quick disintegrating tablets of Dexibuprofen: The prepared quick disintegrating tablets of Dexibuprofen were evaluated for uniformity of weight using 20 tablets [6], hardness (Monsanto tester) using 5 tablets, thickness (vernier calipers) using 5 tablets, friability (Rochefriabilator) using 10 tablets, drug content using 10 tablets, in vitro dissolution studies using 3 tablets. The results were expressed as mean \pm S.D in table 4.

Table 2: Formulae of quick disintegrating tablets of Dexibuprofen with super disintegrants

S.No.	Ingredients (mg)	FF1	FF2	FF3	FF4	FF5	FF6	FF7	FF8
1	Dexibuprofen KS6 (Solid dispersion equivalent to 50 mg of Pure drug)	350	350	350	350	350	350	350	350
2	MCC PH 102	q.s	q.s	q.s	q.s.	q.s	q.s	q.s	q.s
3	Mannitol	25	25	25	25	25	25	25	25
4	Plantago Ovata	4.5	9	13.5	18	-	-	-	-
5	Fenugreek Seed Mucilage	-	-	-	-	4.5	9	13.5	18
6	Gum Karaya	-	-	-	-	-	-	-	-
7	Sodium Saccharine	9	9	9	9	9	9	9	9
8	Orange flavor	9	9	9	9	9	9	9	9
9	Talc	3	3	3	3	3	3	3	3
10	Magnesium stearate	9	9	9	9	9	9	9	9
	Total Tablet Weight	450	450	450	450	450	450	450	450

In vitro drug release study

The in-vitro dissolution study of tablets of flurbiprofen by using USP XXIII Type-II dissolution contraction (Electrolab, Model TDT-06N) using paddle stirrer at 50 rpm at $37 \pm 0.5^\circ\text{C}$ pH 6.8 phosphate buffer as medium. One tablet was used in each test. Aliquots of separating medium (5 ml) were undoubtedly withdrawn between periods (2, 4, 6, 8, 10, 15 & 30 min) and were quickly separated by an equal volume of new medium[7]. Models were separated by 0.22 film channel plate and checked for content by surveying absorbance at 260nm.

In-vivo pharmacokinetic studies of Dexibuprofen

Medication content in the plasma tests was evaluated utilizing the created HPLC technique. A standard chart was plotted to decide the medication by dissecting plasma tests containing various measures of medication. In the present examination blend of phosphate support (pH 3.5): acetonitrile (35:65) arrangement was utilized as the versatile stage.

Chromatographic conditions

The Chromatographic techniques were done on Shimadzu HPLC furnished with C18 segment and UV indicator. Portable stage was separated through 0.45 μm film channel and pushed through the segment Symmetry C18 (X Terra, 4.6 x 150 mm) 5 μm , at a stream pace of 1ml/min and run time was 10 min. Stock arrangement (1mg/ml) of medication was readied utilizing the versatile stage. The section was equilibrated for 30 min and the dissected at 260nm utilizing an UV identifier[10].

Pharmacokinetic assessment in hares

The institutional creature moral advisory group (IAEC) of Chaitanya College of Pharmacy Education and Research, Hanamkonda, Warangal agreed the proposed protocol of bioavailability study of quickly disintegrating tablets of Ketofrofen. The approval was recorded and protocol approval number was 02/IAEC/CCPER/CPCSEA/2017.

Subjects and Study Design

Twelve male pale skinned person hares a weight of 1.9 ± 0.2 kg was used for this assessment. In the present assessment, the hybrid report was followed, in which twelve male purified individual rabbits were assigned to two proportional social events[8] (Pack I and Get-Together II). At the time of the study, Pack I (n = 6) chose Power Tablet (50 mg isolate), however, Group II (n = 6) had the KF11 quickly self-destructive tablet (segment 50 mg). Those who fast for life have free access to water from twelve hours of evaluation. Unpretentious amount water is added to surface tablet before handling. The mouth was closed for 2 minutes to stop biting or gulping tablet. Two millilitres of water facilitated coming about to dosing. In the second time evaluation, following 35 days waste of time period, pack I got KF11 rapidly disintegrating tablet and social event II gained power tablet. Blood tests were assembled at 0.125, 0.25,

0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, and 24 h in the wake of dosing from irrelevant vein.

HPLC analysis of Ketofrofen plasma samples

The accumulated blood tests were centrifuged at 4000 rpm for 15 min serum wash drawn moved to 5ml small scale rotator tubes. The acetonitrile for 1ml above serum was fused and centrifuged for 10min at 3000rpm supernatant fluid in segregated set away at -40°C for the assessment test for unaltered medicine. A set up HPLC technique was used to quantify medicate serum fixation [9].The quantitative attestation medication in plasma was performed by utilizing HPLC technique into embedding supernatant fluid into HPLC zone (circle volume 20 μl and stream rate 1 ml / min). The evaluation was performed at temperature run time set to 10min.

Pharmacokinetic parameters

Pharmacokinetic parameters were solved using the Drug Scatter Plasma Stabilization Time information. Pharmacokinetic parameters were reviewed from plasma data for each subject using PK Solver (Change 2.0, Baylor College of Medicine, Houston, TX). From plasma focus vs. plot, Pinnacle Plasma Fixation (Cmax) has the opportunity to connect at apex plasma levels (tmax). The results are shown in table 5.

RESULTS AND DISCUSSION

Solubility studies of Dexibuprofen: As Dexibuprofen is a class II drug. It was poorly solubilized in pH 6.0 and 6.8 pH buffer with increase in pH range solubility was increased it was easily solubilized in dichloromethane, acetone and methanol.

Construction of standard graph of Dexibuprofen: Standard graph of Dexibuprofen was plotted as per the procedure in experimental method. The standard graph showed good linearity with $R^2 = 0.996$ which indicates that it obeys "Beer - Lamberts" law.

Preformulation study: The results for characterization of blended powder are shown in table 3. The bulk density of blend varied between 0.301-0.338g/cm³. The tapped density was found in the range of 0.331-0.398g/cm³. Hausner's ratio was less than 1.25 indicating good flow characteristics, compressibility index less than 25% were considered as free flowing ones i.e. 9.8-14.8, the angle of repose below 35 degrees ranges indicates good flow properties i.e. 21.22-28.33. [5]

Table 3: Precompression results of formulations KF1-KF12

Formulae	Angle of Repose (θ)	Bulk Density (gm/cm ³)	Tapped Density (gm/cm ³)	HR ratio	Carr's Index
KF1	22.67 \pm 1.15	0.324 \pm 0.008	0.356 \pm 0.012	1.109	12.4
KF2	23.3 \pm 1.52	0.316 \pm 0.031	0.369 \pm 0.031	1.111	9.8
KF3	22.1 \pm 1.00	0.317 \pm 0.010	0.362	1.143	13.7

KF4	25.67±1.52	0.312 ± 0.01	±0.026 0.365 ±0.010	1.157	13.1
KF5	26.67 ±1.15	0.319±0.0018	0.361 ±0.176	1.113	10.3
KF6	27.33 ±2.08	0.313±0.014	0.379 ± 0.014	1.141	11.1
KF7	22.33 ±1.52	0.338±0.005	0.344 ±0.011	1.143	12.1
KF8	27.1 ±1.73	0.319±0.006	0.331 ± ±0.022	1.239	13.8
KF9	28.33 ±1.52	0.315±0.007	0.365 ±0.012	1.249	14.8
KF10	22.33 ±2.08	0.326±0.006	0.387 ± 0.020	1.163	13.2
KF11	21.22 ±2.51	0.301±0.016	0.368 ±0.012	1.219	10.4
KF12	23.67±2.51	0.315±0.006	0.398 ±0.003	1.224	12.9

Dissolution Studies of Solid Dispersions

The solid dispersions were prepared with carrier PEG 20,000 in ration 1:1, 1:2, 1:3, 1:4 1:5 and 1:6 using acetone as solvent-by-solvent evaporation method. When dissolution studies were conducted to solid dispersions and pure drug solid dispersion with 1:6 showed better. The %CDR of drug was increased with in attention of carrier concentration. The results were shown in figure 1.

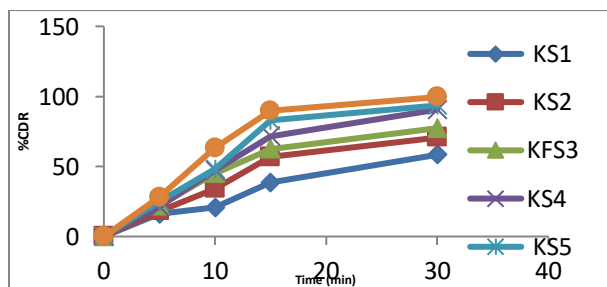


Figure 1: Dissolution profiles (%CDR) of solid dispersions of Dexibuprofen

Evaluation of quick disintegrating tablets of Dexibuprofen

Thickness was in the range of 2.98 to 3.08mm, % weight variation was within the pharmacopeial limits of $\pm 7.5\%$, the hardness is in the range of 3.04-321kg/cm², friability was

observed less than1%, the wetting time was rapid in all the formulations the range of 18-33sec, in vitro disintegration time is in the range of 21.33-27.66, drug content was found within the range of 98.22-99.94 indicating uniform distribution of drug in all the formulated tablets as per pharmacopeial specifications.

Plantago Ovata as super disintegrant shown poor %CDR values when compared with other natural super disintegrants. Among Plantago ovata tablets, formulation KF4 4% showed maximum release of drug with 90% for 30 min. Increased concentration of Plantago ovata may increase release drug with the wicking mechanism. Gum karaya showed maximum medication discharge when contrasted and different plans. Among these tablets, detailing KF11 3% indicated most extreme arrival medication with 99% for 30 min. further increment in centralization of the Gum karaya hindered medication discharge in ensuing expanded focus KF12 4% with the release of 96%. Fenugreek seed mucilage tablets, formulation KF8 4% showed maximum release of drug with 93% for 30 min. at concentration 3% drug release was found to be 87% and at concentration 2% drug release was 74% only. These studies suggested that increased concentration of Fenugreek seed mucilage may increase release drug with wicking mechanism burst release mechanism. The results are shown in figure 2.

Figure 2: Dissolution data of Dexibuprofen quickly disintegrating tablets containing Plantago ovate, Fenugreek seed mucilage, Gum karaya.

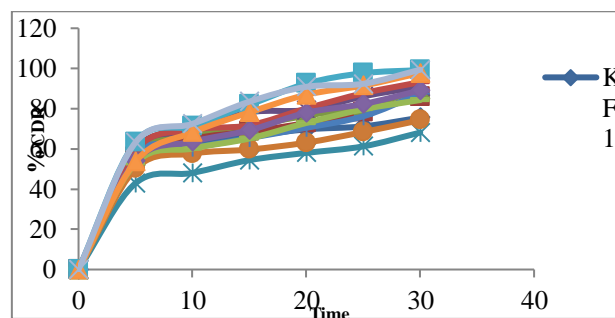


Table 4: Post compression parameters of quick disintegrating tablets of Dexibuprofen

Table 4: Post compression parameters of quick disintegrating tablets of Dexibuprofen

Formulae	Weight Variation (mg)	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)	Drug Content	Wetting time(sec)	Water absorption ratio	In-vitro Disintegration (sec)
KF1	450.1±1.619	3.03±0.209	3.11±0.205	0.52±0.020	99.57±0.157	29.00±2.00	31.00±2.00	26.67 ±1.52
KF2	449.3±2.336	3.06±0.314	3.15±0.044	0.51±0.025	99.64±0.332	25.67±1.52	32.00 ±4.00	27.66 ±1.52
KF3	449.1±2.458	3.08±0.265	3.14±0.265	0.48±0.041	99.21±0.340	23.33±2.64	34.00 ±2.00	25.33 ±2.00
KF4	449.3±2.131	2.98±0.288	3.16±0.265	0.49±0.025	98.03±0.468	33.00±4.04	41.00 ±4.00	24.25 ±2.00
KF5	448.7±2.846	3.04±0.189	3.11±0.245	0.49±0.025	99.29±0.605	32.00±1.00	51.30±2.56	23.35 ±2.523
KF6	451.6±2.549	3.00±0.200	3.13±0.313	0.51±0.030	99.92±0.824	30.00±3.00	38.30 ±3.51	23.33 ±1.52
KF7	450.1±2.213	3.01±0.177	3.14±0.252	0.49±0.015	99.94±0.703	28.00±2.00	41.00 ±2.00	22.54 ±1.00
KF8	449.9±1.494	3.04±0.190	3.07±0.223	0.36±0.026	99.13±0.460	28.67±3.50	34.00 ±2.51	21.33 ±2.00
KF9	449.2±1.897	3.03±0.214	3.04±0.229	0.41±0.020	98.54±0.860	29.33±1.52	42.00 ±3.78	23.35 ±2.00
KF10	450.5±1.032	2.99±0.154	3.10±0.246	0.47±0.020	98.22±0.393	26.00±3.00	43.67 ±2.00	23.15 ±2.08
KF11	450.8±1.686	3.02±0.188	3.12±0.226	0.52±0.017	99.87±0.363	18.00±2.00	30.33 ±4.16	21.65 ±1.52
KF12	449.3±1.414	3.00±0.188	3.21±0.249	0.48±0.015	98.95±0.836	22.00±2.00	31.00 ±3.60	22.14 ±2.00

In-vivo pharmacokinetic Studies

The HPLC technique was created all out run time was set to 10 min and chromatograms of Dexibuprofen appeared at 3.907 min. The chromatograms of blank plasma, pure Dexibuprofen in plasma and Dexibuprofen in mobile phase were shown in figure 3, 4 and 5. The peak area of Dexibuprofen in mobile phase and plasma was almost similar that indicating that there was no interference of any peak with drug peak.

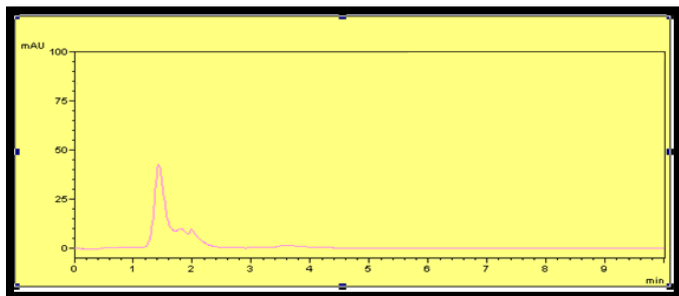


Fig 3: Chromatogram of blank plasma

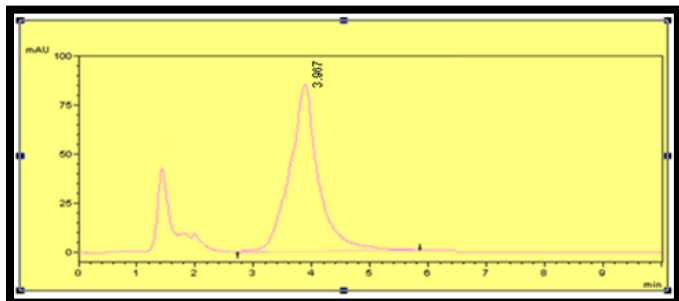


Fig 4: Chromatogram of pure Dexibuprofen in plasma

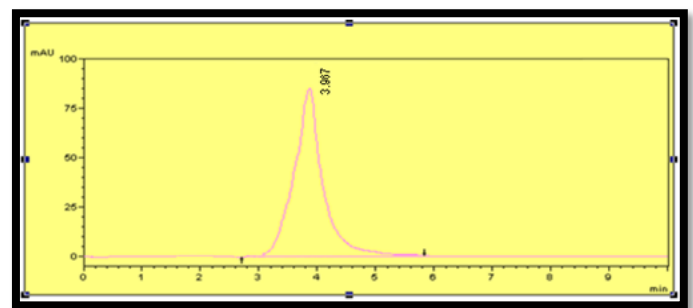


Fig 5: Chromatogram of Dexibuprofen in mobile phase

Pharmacokinetic evaluation in rabbits

In this plan, pharmacokinetic assessment was done on quickly deteriorating tablets KF11 in contrast with control tablet of Dexibuprofen. The in-vitro information examination among control and quick dissolving tablets were given in figure 6.

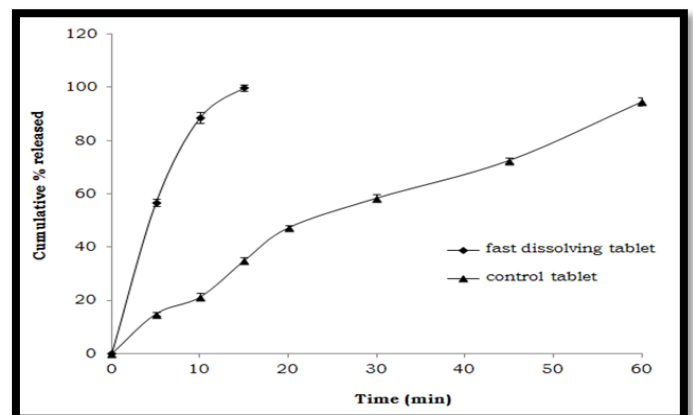


Figure 6: In-vitro Dexibuprofen release from control and optimized formulation (n=3)

Table 5: Pharmacokinetic parameters of Dexibuprofen control and KF11 rapidly disintegrating tablets (Mean±S.D, n=12)

Parameters	Control tablet	KF11 RDTs	t-test at 0.05 LS
ka (1/h)	0.402±0.01	0.486±0.01	Significant
ke (1/h)	0.135±0.01	0.134±0.01	Not Significant
t1/2 (h)	5.13±1.25	5.18±1.52	Not Significant
T max (h)	3.00±0.01	2.00±0.01	Significant
C max (ng/ml)	9140.84±614.36	11445.46±149.23	Significant
AUC 0-∞(ng-h/ml)	31495.16±619.92	43126.52±688.89	Significant
AUMC 0-∞(ng-h ² /ml)	175957.60±3046.49	258895.00±3103.94	Significant
MRT (h)	5.58±0.03	6.00±0.03	Significant

From the pharmacokinetic assessment, Dexibuprofen showed up very quickly inside 10 min. in plasma. Increased worth of Ka was observed in KF11 when compared to control tablet that shows the enhanced absorption rate. The t1/2 was found as 5.13 and 5.18 hr for control and KF11 tablets respectively. The solid dispersion arrived at top focus of (Cmax) 11445.46 ng/ml at tmax of 2 h while it apparently was 9140.84 ng/ml at tmax of 3 h for control tablet, demonstrating that improvement ingestion in strong scattering example of Dexibuprofen than unadulterated structure.

The AUC of control and KF11 tablets of Dexibuprofen were 31495.16 and 43126.52 ng-h/ml correspondingly. These outcomes demonstrated that the KF11 tablet indicated upgrade of AUC when contrasted with control tablet of Dexibuprofen. The MRT of control and KF11 quickly crumbling tablets were 5.58 h and 6.00 h individually.

The factual investigation of pharmacokinetic parameters of control and KF11 quickly breaking down tablets was performed by matched t-test. From the outcomes there was noteworthy contrast in the ka among control and KF11 quickly breaking down tablets, demonstrating that the pace of assimilation is more in the event of KF11. There was a huge contrast of AUC0-∞ saw among control and KF11 tablets, which demonstrate the improvement of degree of ingestion of Dexibuprofen.

CONCLUSION:

Quick disintegrating tablets of Dexibuprofen could be prepared from solid dispersion with plantago ovata, fenugreek seed adhesive and gum karaya by using direct compression technique. The evaluation parameters of all quick disintegrating tablets had shown satisfactory results. Gum karaya can be utilized as better regular superdisintegrant in the advancement of quickly crumbling tablets of Dexibuprofen. The results propose

accomplishment of helpful focus in site decline medication symptoms and the improvement of patient consistence. It can be concluded that the designed and developed quick disintegrating tablets can defeat the drawback of poor and whimsical oral bioavailability of Dexibuprofen related with current showcased oral definition.

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CONFLICT OF INTEREST: The authors declare that they have no conflict of interests.

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