Journal of Current Pharma Research
(An Official Publication of Human Journals)
An International Peer Reviewed Journal For Pharmacy, Medical & Biological Science
DOI: 10.25166 CODEN: JCPRD6 NLM ID: 101744065
ISSN: Print: 2230-7834 Online: 2230-7842
SJIF Impact Factor: 6.913

Human Journals
Research Article
May 2023 Vol.:17, Issue:4

Development and Evaluation of Fast Dissolving Tablets

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Submitted: 05 May 2023
Accepted: 20 May 2023
Published: 25 May 2023

Keywords: Fast disintegrating tablets, Natural super disintegrants, *In- vitro* release.

ABSTRACT

Fast dissolving tablets are useful in patients such as pediatrics, geriatric, bedridden or developmentally disabled who face difficulty in swallowing conventional tablets or capsules and liquid orals or syrups leading to ineffective therapy. Tramadol HCl is a centrally-acting synthetic opioid analgesic. The mechanism of action of Tramadol HCl is not completely understood, but it may bind to mu-opioid receptors and inhibit the reuptake of norepinephrine (NE) and serotonin. The present study was aimed at developing & evaluating fast dissolving tablets of Tramadol HCl using natural superdisintegrants like Plantago Oveta & Hibiscus rosa. Fast dissolving tablets were prepared by direct compression method. Drug polymer compatibility was characterized by FTIR. Pre and post compression parameters were carried out. Tablets were evaluated for their physico chemical properties, *in-vitro* release and stability studies. Drug was compatible with superdisintegrants. Preformulation studies were found as per literature limits. Precompressional studies revealed good micromeritic properties of powder blend for direct compression. The hardness (2.86 to 3.0 kg/cm^2), friability (0.58 to 0.86), drug content (96.3 to 98.7 %) and disintegration time (15 - 86 sec) of fast dissolving tablets were found uniform and reproducible. Dissolution of tablets was directly proportional to the concentration of super disintegrants and 10 % concentration was found optimum. A selected tablet (F9) was found superior than all the other formulation with respect to disintegration and dissolution.

INTRODUCTION:

Traditional tablets and capsules administered with an 8-oz. glass of water may be inconvenient or impractical forsome patients. Recent developments in technology have presented viable dosage alternatives for patients may have difficulty in swallowing tablets or liquids. However, some patients have difficulty in swallowing (Dysphagia) or chewing solid dosage forms which are common problem of all age groups, particularly pediatrics and geriatrics, because of physiological changes associated with these groups. Other categories that experience problems using conventional oral dosage forms include are mentally ill, uncooperative and nauseated patients, those with motion sickness, sudden episodes of allergic attack or coughing. Sometimes, it may be difficult to swallowthe conventional products due to unavailability of water[1,2]. These problems cause the need for delivering drugs to patients efficiently and with few side effects have prompted pharmaceutical companies to engage in the development of new drug delivery systems. Fast dissolving tablets are perfect fit for all these kinds of patients.

Fast Dissolving Tablets (FDTs) [3-13]

FDT is a solid dosage form that disintegrates and dissolves in the mouth withoutwater within 60 s or less. It provides an advantage particularly for paediatrics and geriatric patient's who have difficulty in swallowing conventional tablets and capsules. These are the tablets which will rapidly disintegrate in the mouth without need ofwater, so these are very useful in the condition where water is not available and in case of motion sickness, sudden episodes of coughing during common cold, allergic condition and bronchitis. Recent market studies indicated that more than half of the patient's population prefers FDTs to other dosage forms. This is because of several advantages such asease of administration, ease of swallowing, pleasant taste and the availability of several flavours. It also offers several clinical and business advantages. The European Pharmacopoeia however defines a similar term, Orodisperse, as a tablet that can be placed in the mouth where it disperses rapidly before swallowing. These tablets are distinguished from conventional Sublingual tablets, Lozenges and Buccal tablets, which require more than a minute to dissolve in the mouth. Fast dissolving tablets (FDT) are also known as 'rapid disintegrating', 'mouth dissolving', 'rapid-dissolve', 'quick disintegrating', 'orally disintegrating', 'rapid melt', 'fast melts', 'orodispersible', 'melt-in-mouth', 'quick dissolving', 'porous tablets', 'EFVDAS' or

'Effervescent Drug Absorption System'. The basic approach in development of orally disintegrating tablets (ODT) is the use of disintegrants. Disintegrants are substances that are added to drug formulation that facilitate the breakup or disintegration of tablet content into smaller particles that dissolve more rapidly in aqueous environment. The various disintegrants includes synthetic derivatives such as sodium carboxy methyl cellulose, cross povidone, sodium starch glycollate, cross carmellose sodium, and natural derivatives such as alginates, cellulose, agar, locust bean, pectin, tragacanth, chitosan and gum karaya. Isapghula consists of dried seeds of the plant *plantago ovata* and it contains mucilage which is present in the epidermis of the seeds. Natural origin is preferred over semi-synthetic and synthetic substances because natural poymers are obtained easily from the natural origin and they are cost effective, non-toxic, biodegradable, eco-friendly, devoid of any side effect, renewable and also provide nutritional supplement. It is proved from the studies that natural polymers are safer and more effective than the synthetic polymers.

PREFORMULATION STUDIES:

- Selection of excipients and its combinations suitable for the fast-dissolving drugdelivery system.

- Drug-excipients compatibility study.

- Preparation of standard calibration curve of Tramadol Hydrochloride in methanol and phosphate buffer pH 6.8.

➢ ***Design of FDT formulations of Tramadol Hydrochloride by direct compression method:***

- Isolation of mucilage.

➢ ***Evaluation of pre-compression parameters of the formulations.***

Bulk density, Tapped density, Angle of repose, Carr's index, Hausner's ratio

- ***Evaluation of post-compression parameters of the formulations.***

a) Weight variation, Hardness, Friability, Content uniformity, *In vitro* dispersion time, Wetting time, *In vitro* dissolution study.

- ***Stability studies of promising formulations***

Materials Used: Table No. 1

Materials	**Source**
Tramadol Hydrochloride	Microlab Pvt, Banglore
Plantago ovate	From local market
Hibiscus rosa	From local market
Aspartame	Loba chemicals, Mumbai, Maharashtra.
Microcrystalline cellulose	Yarrow chem. Products, Mumbai
Na. saccharin	Rolex chem. Industries, Mumbai,
Talc	Loba chemicals, Mumbai, Maharashtra.
Aerosol	Yarrow chem. Products, Mumbai,
Flavours	Loba chemicals, Mumbai, Maharashtra.
Potassium dihydrogen phosphate	Yarrow chem. Products, Mumbai,
Sodium hydroxide	Loba chemicals, Mumbai, Maharashtra.

Equipment used: Table No. 2

Equipment	Model/ Source
UV-spectrophotometer	1800, Shimadzu Corporation, Japan
Digital balance	BL-220H, Shimadzu Corporation, Japan
Digital pH meter	Micropro lab mate
Dissolution apparatus	TDT-08 L, Electrolab
Hot air oven	KOA-1-Kemi
Hardness tester	Digital Hardness Tester (EH01) Electrolab.
Friability test apparatus	EF2- Electrolab
Tablet punching machine	Clit, Ahmedabad CPM08-10

Table No. 3. Composition of FDT of Tramadol HCl using superdisintegrats like Plantago ovate mucilage and Hibiscus rosa mucilage

SI. no	Formulation Code	Ingredients (mg).									
		Tramadol HCl	Plantago ovate mucilage	Hybiscus rosa mucilage	MCC	Aspartame	Na. saccharin	Aerosol	Flavour	Talc	Total weight
1	**F0**	50	---	---	108	10	12	4	12	4	200
2	**F1**	50	10	---	98	10	12	4	12	4	200
3	**F2**	50	15	---	93	10	12	4	12	4	200
4	**F3**	50	20	---	88	10	12	4	12	4	200
5	**F4**	50	---	10	98	10	12	4	12	4	200
6	**F5**	50	---	15	93	10	12	4	12	4	200
7	**F6**	50	---	20	88	10	12	4	12	4	200
8	**F7**	50	5	5	98	10	12	4	12	4	200
9	**F8**	50	7.5	7.5	93	10	12	4	12	4	200
10	**F9**	50	10	10	88	10	12	4	12	4	200

EVALUATION OF FAST DISSOLVING TABLETS OF TRAMADOL HCl:

✓ ***In-vitro* Drug Release Profiles:**

Tablet were place in USP XXIII dissolution test apparatus in the bucket containing 900 ml of Phosphate buffer pH 6.8. The speed of paddle of was set to 50 rpm and at 37±0.5 ^{o}C temp. 5 ml of solution was withdrawn at fixed time interval and measuredat 273 nm.

Apparatus used	:	USP XXIII dissolution test apparatus. Dissolution		
medium	:	Phosphate buffer pH 6.8.		
Dissolution medium	:	900 ml. Temperature	:	37±0.5 ^{o}C. Speed of
basket paddle	:	50 rpm.		
Samples withdraw	:	5 ml. Absorbance measured	:	273 nm.

✓ ***Stability studies:***

Selected formulations were subjected to stability studies as per I.C.H. Guidelines. Following conditions were used for stability studies.

✶ 30 C/65 % RH analyzed at a time interval of 30 days till a period of 60 days.

✶ 40 C/75 % RH analyzed at a time interval of 30 days till a period of 60 days.

PREFORMULATION STUDIES OF TRAMADOL HYDROCHOLRIDE:

Table No. 4. Preformulation studies of Tramadol hydrochloride.

Properties	**Reported**	**Results**
Description	Crystalline powder[44]	Crystalline powder
Taste	Very bitter[44]	Very bitter
Odor	Odorless[44]	Odorless
Color	White[44]	White
Solubility	Freely soluble in water[44] Soluble in phosphatebuffer pH 6.8	Freely soluble in water Soluble in phosphatebuffer pH 6.8

✓ **UV absorption maxima of Tramadol HCl in phosphate buffer pH 6.8**

The Standard Stock Solution was prepared and scanned as per the method described in methodology section.

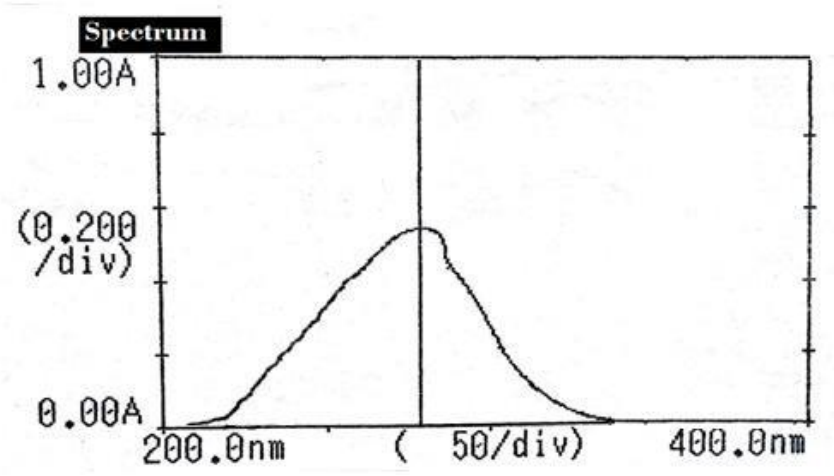

Figure No. 1: UV- spectrum of Tramadol hydrochloride.

✓ **Calibration curve of Tramadol HCl in phosphate buffer pH 6.8:**

The calibration curve and the data obtained by the procedure described in methodology section are given in Table No.5 and Figure No. 1.

Table No.5. Calibration curve data for Tramadol HCl in phosphate buffer pH 6.8

Concentration (µg/ml)	**Absorbance***
0	0
30	0.138
60	0.309
90	0.454
120	0.627
150	0.756
180	0.910

*Average of three trials.

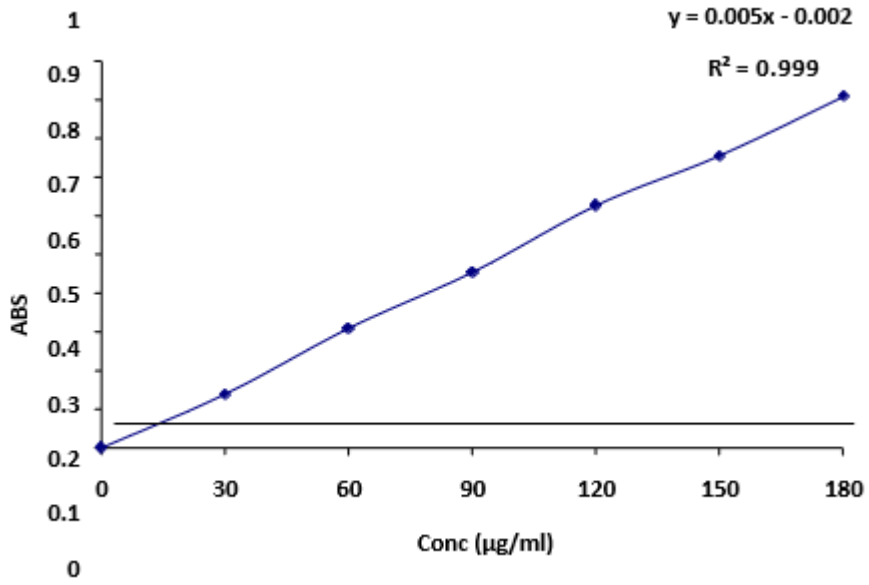

Figure No: 2. Calibration curve data for Tramadol HCl in phosphate buffer pH 6.8

Table No. 06. Comparison of FT-IR spectra of pure drug and excipient

	O-H Stretching (cm^{-1})	C-H (Aromatic) (cm^{-1})	C-H Stretching (cm^{-1})	O-CH Ether (cm^{-1})	N-C-H (ether) (cm^{-1})	C=C (Aromatic) (cm^{-1})	C-O-C (Ether) (cm^{-1})
Tramadol	3570	3130	2950	2850	2780	1615	1260
Tramadol + PG	3498	3298	2945	2681	2448	1649	1299
Tramadol + HR	3530	3199	2954	2748	2557	1620	1280
Tramadol + PG + HR	3525	3145	2948	2789	2655	1612	1265

VALUATION OF FAST DISSOLVING TABLETS OF TRAMADOL HCl:

Preformulation studies: Table No. 07. Preformulation studies of powder blends

Formulation Codes.	Angle of Repose (ø)	Bulk Density(gm/cc)	Tapped Density(gm/cc)	Carr's Index (%)	Hausner's Ratio
F0	29.46±0.748	0.3933±0.012	0.4330±0.007	14.50±0.408	1.22±0.026
F1	29.56±0.520	0.3933±0.006	0.4476±0.010	11.36±0.558	1.14±0.028
F2	29.24±0.526	0.3856±0.007	0.4416±0.010	12.94±0.983	1.14±0.040
F3	28.64±0.800	0.3840±0.005	0.4346±0.009	13.50±0.725	1.11±0.048
F4	29.76±0.489	0.3838±0.010	0.4473±0.011	11.51±0.744	1.17±0.035
F5	29.24±0.702	0.3813±0.006	0.4379±0.010	11.41±0.683	1.14±0.057
F6	28.99±0.612	0.3806±0.013	0.4303±0.011	11.23±0.452	1.14±0.057
F7	29.76±0.643	0.3940±0.013	0.4336±0.014	12.43±1.144	1.13±0.028
F8	28.95±0.694	0.3900±0.017	0.4316±0.010	11.44±0.410	1.13±0.028
F9	28.82±0.484	0.3887±0.006	0.4254±0.013	11.36±0.727	1.12±0.049

Post-compression parameters:

Table No. 08 Post-compression parameter of FDTs of Tramadol HCl

Formulation Codes	Thickness* (mm)	Hardness* (kg/cm^2)	%Friability*	% Weight Deviation**
F0	4.06±0.057	2.86±0.047	0.86±0.124	199.6±1.56
F1	3.96±0.047	2.93±0.124	0.73±0.124	199.5±1.62
F2	3.96±0.057	2.96±0.124	0.76±0.205	199.4±1.62
F3	3.86±0.057	2.90±0.124	0.69±0.163	199.6±1.90
F4	4.03±0.057	2.93±0.081	0.77±0.131	199.6±1.42
F5	4.03±0.057	2.73±0.127	0.74±0.122	200±1.26
F6	4.03±0.047	2.80±0.047	0.62±0.088	199±1.42
F7	4.06±0.057	3.00±0.086	0.80±0.081	199.4±1.28
F8	4.03±0.0.47	2.96±0.098	0.63±0.124	199.4±1.30
F9	4.10±0.0.47	2.90±0.079	0.58±0.124	199.9±1.50

All Values are expressed as mean ± SD, n=3.

Table No. 09 Post-compression parameter of FDTs of Tramadol HCl

Formulation codes	Wetting Time*(sec)	Drug Content* (%)	Disintegration Time*(sec)
F0	280.5±1.65	96.5±0.0125	240.5±9.17
F1	68.66±1.25	98.7±0.0147	48.66±1.24
F2	64.33±2.32	97.3±0.0159	43.66±1.69
F3	22.64±2.45	97.4±0.0369	16.66±1.21
F4	120.4±2.24	98.3±0.0365	86.33±1.24
F5	72.33±0.94	98.6±0.0254	54.33±1.60
F6	48.00±3.01	96.5±0.0145	34.00±0.81
F7	75.3±4.23	97.8±0.0145	60.00±0.81
F8	47.5±3.54	97.6±0.0258	34.66±2.05
F9	20.66±1.48	96.3±0.0241	15.66±0.47

All values are expressed as mean ± SD, n=3*, 6

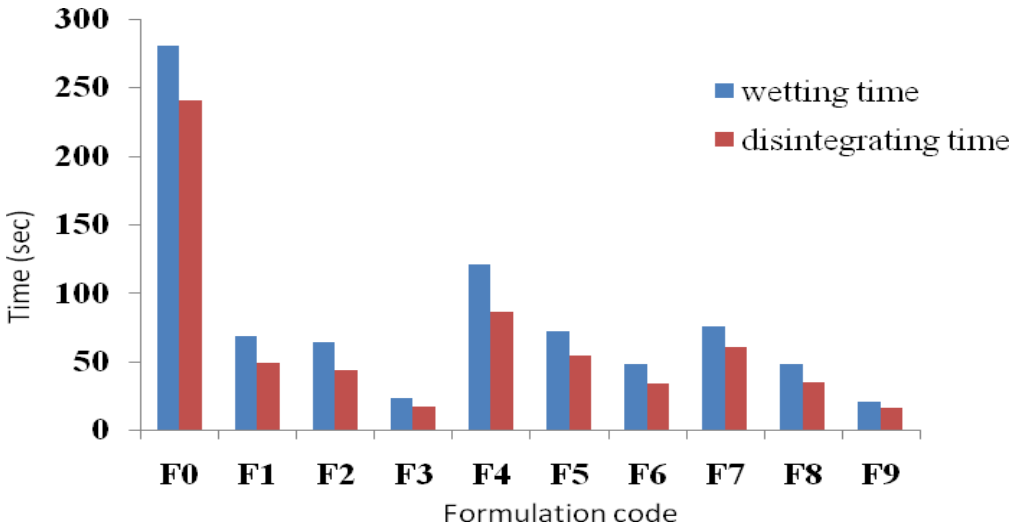

Fig. No 3 Effect of concentration of superdisintegrants on disintegration time and wetting time of fast disintegrating tablets

N-VITRO DISSOLUTION STUDIES: **Table No. 10. *In-vitro* release data of Formulation F0**

Time (min)	%CDR F0
0.5	0
1	1.9
1.5	3
2	4.2
2.5	7.3
3	9.8
3.5	12.4
4	14.16
4.5	14.88
5	15.1

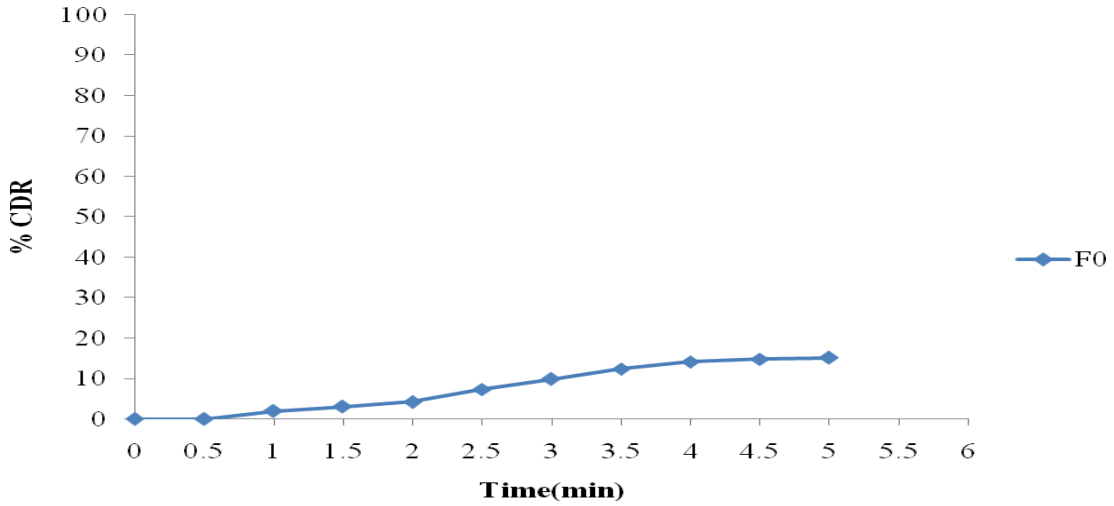

Figure No. 4. *In-vitro* release profile of Formulation F0

Table No. 11. In-vitro release data of Formulation F1, F2 and F3 (Containing PG mucilage 5%, 7.5% and 10% respectively).

Time (min)	%CDR		
	F1	F2	F3
0	0	0	0
0.5	7.24	10.8	40
1	9.2	15.9	50.1
1.5	10.4	21.8	61.9
2	11.5	27.6	69.1
2.5	14.5	29.9	78.4
3	15.7	33.4	85.7
3.5	18.5	37.1	89.7
4	19.6	41.2	92.4
4.5	20.7	44.6	94.9
5	24	44.6	97.5

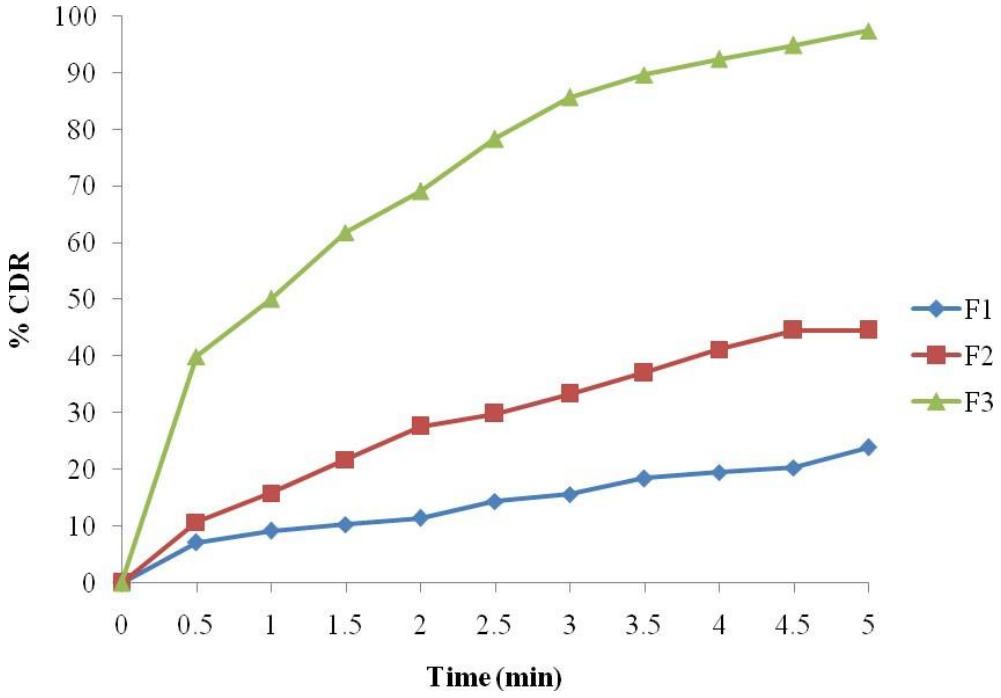

Figure No.5. *In-vitro* release profile of Formulation F1, F2 and F3

Table No. 12. In-vitro release data of Formulation F4, F5 and F6 (Containing HR mucilage 5%, 7.5% and 10% respectively)

Time (min)	%CDR		
	F4	F5	F6
0	0	0	0
0.5	0	7.2	10.8
1	3.6	11.6	17
1.5	7.2	14.5	24.5
2	10.9	19.6	28.4
2.5	12.3	22.5	34.7
3	14.5	29.8	37.5
3.5	18.9	34.1	44.8
4	21.8	36.3	49.4
4.5	23.2	41.2	55.7
5	24.7	45.6	61.8

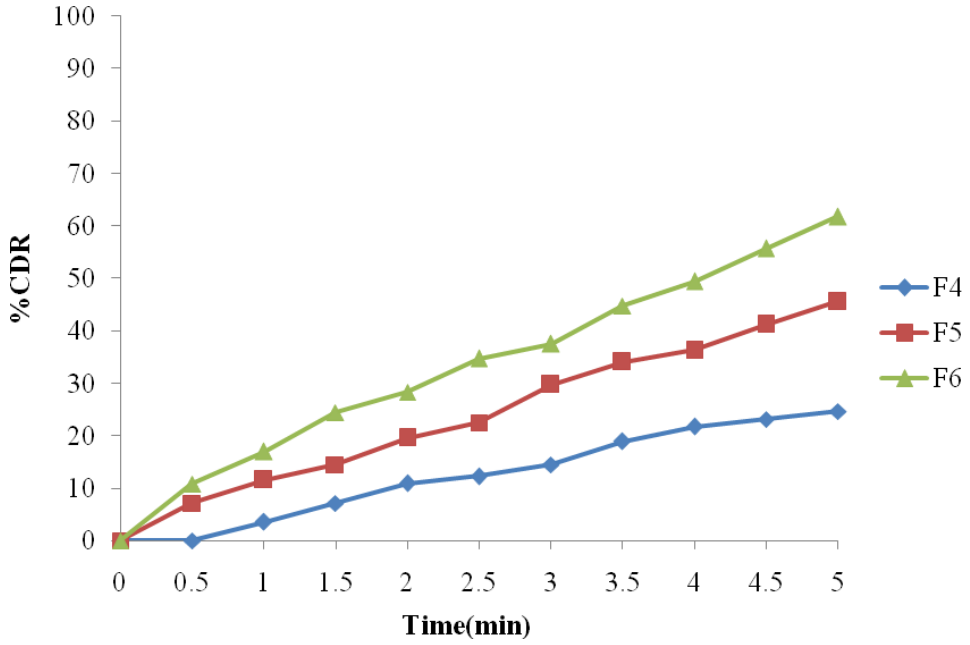

Figure No.6. *In-vitro* release profile of Formulation F4, F5 and F6

Table No. 13. In-vitro release data of Formulation F7, F8 and F9 (Containing combination of PG & HR mucilage 5%, 7.5% and 10% respectively)

Time (min)	%CDR		
	F7	F8	F9
0	0	0	0
0.5	15.2	20.9	38.5
1	24.7	28.7	50.2
1.5	32.7	41.8	59.5
2	41.1	45.11	68.2
2.5	55.1	54.5	76.4
3	68.4	65.4	85.7
3.5	77.3	79.5	90.5
4	85.5	8902	94.2
4.5	90	92.7	97.2
5	94.4	96.0	99.6

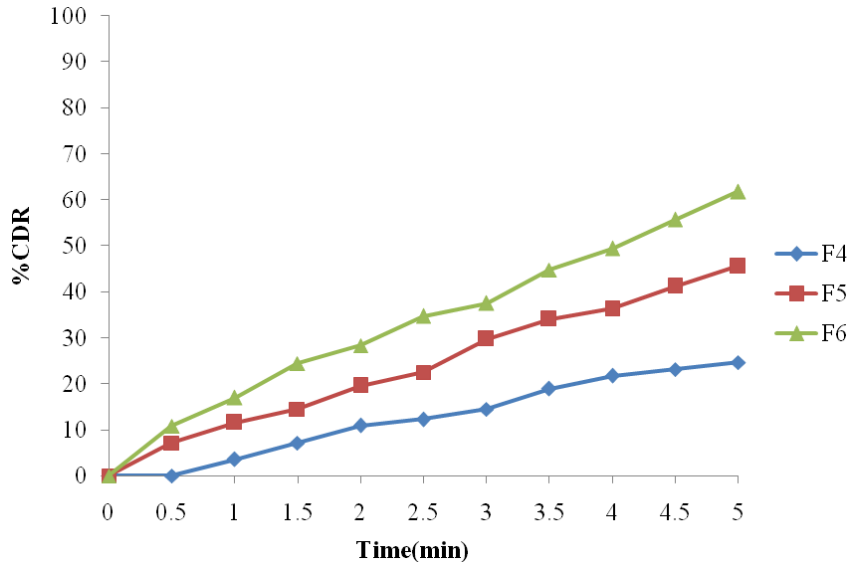

Figure No.7. *In-vitro* release profile of Formulation F7, F8 and F9

STABILITY STUDIES:

Table No. 14. Physico-chemical characterization of best formulation F3 and F9 during stability studies.

Time (Days)	Hardness (kg/cm^2)		Friability (%)		Disintegration time (sec)		Wetting Time (sec)		Drug Content (%)			
	F3	F9	F3	F9	F3	F9	F3	F9	F3	F9		
0	_		2.90	2.96	0.58	0.63	16	14	22	24	97.4	99.6
30	**At 30 ± 2 °C/ 65 ± 5 %RH**		2.8	2.88	0.552	0.618	14	14	23	23	98.4	101.2
	At 40 ± 2 °C/ 75 ± 5 %RH		2.72	2.75	0.573	0.629	15	15	23	23	98.7	99.8
60	**At 30 ± 2 °C/ 65 ± 5 %RH**		2.69	2.69	0.549	0.615	14	14	25	22	98.21	99.86
	At 40 ± 2 °C/ 75 ± 5 %RH		2.8	2.74	0.570	0.623	15	13	25	21	98.32	99.45

Table No. 15. *In-vitro* release of Tramadol HCl fast dissolving tablets from Formulation F3 containing PG (10%) after stability studies:

Time (min)	Cumulative Drug Release (%)				
	At 0 day	After 30 Day		After 60 day	
	-	A*	B**	A*	B**
1	45	44.3	48.14	42.52	42.82
3	78.9	70.5	72.26	69.94	69.04
5	97.5	97.3	95.06	96.72	93.34

A*: 30±2°C and 65±5% RH and B**: 40±2°C and 75±5% RH.

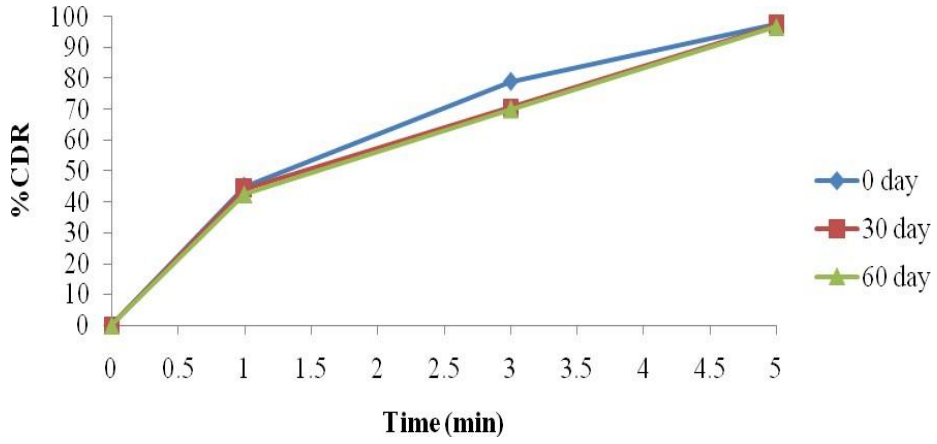

Figure No.8. In-vitro dissolution profile of F3 (A) after stability studies

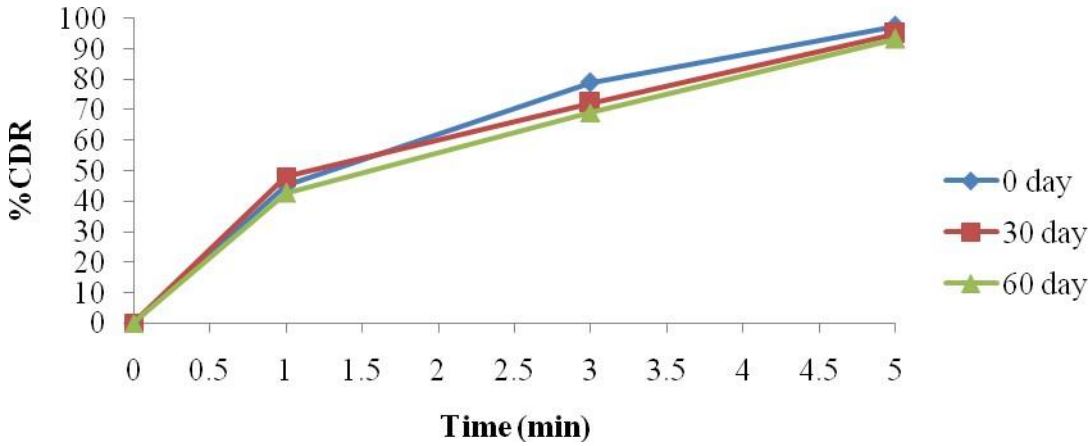

Figure No. 9. *In-vitro* dissolution profile of F3 (B) after stability studies

Table No. 16. In-vitro release of Tramadol HCl fast dissolving tablets fromformulation F9 containing Combination of (5% PG + 5% HR) after stability studies

Time (min)	Cumulative Drug Release (%)				
	At 0 day	After 30 Day		After 60 day	
	-	A*	B**	A*	B**
1	32.5	31.7	29.4	37.9	25.1
3	63.3	61.2	60.7	62.3	59.0
5	99.6	98.5	97.8	98.	97.1

A*: 30±2°C and 65±5% RH and B**: 40±2°C and 75±5% RH.

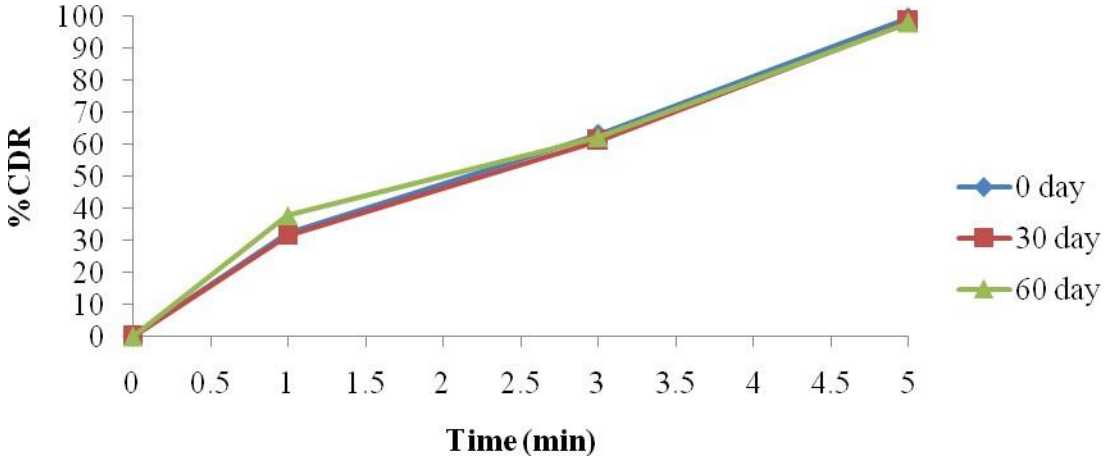

Figure No. 10. In-vitro dissolution profile of F9 (A) after stability studies

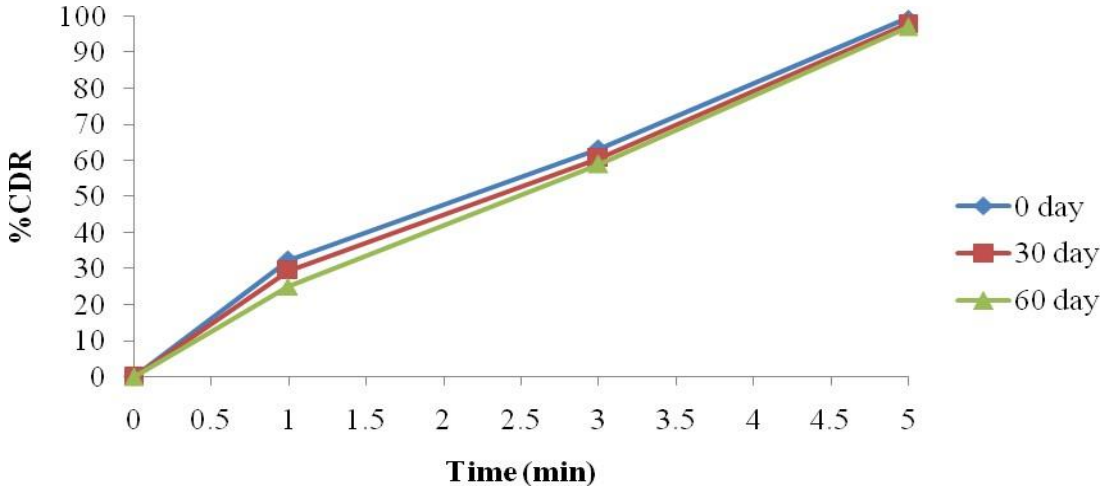

Figure No. 11. *In-vitro* dissolution profile of F9 (B) after stability studies

The following conclusions can be drawn from the results obtained:

A preformulation study of Tramadol HCl complies with the reported literature limits. The IR spectra revealed that, there was no interaction between disintegrants and drug. All the disintegrants and excipients used were compatible with drug.

From the present study, it can be concluded that fast dissolving tablets of Tramadol HCl can be prepared by direct compression technique using natural superdisintegrats. Evaluation parameters like hardness and friability indicates that the tablets were mechanically stable in all the formulations. Percentage weight variation and disintegration time and drug content were found to be within the pharmacopoeial limits in all the formulations. Wetting time signified that Plantago ovate mucilage powder and Hibiscus Rosa mucilage powder in concentration of 10% per tablet act as good disintegrants. *n-vitro* release rate studies showed that the drug release were maximum from formulation F3 (containing 10% of PG mucilage powder) and F9 (containing combination of 5% PG + 5% HR mucilage powder). Overall formulation F3 (containing 10% of PG mucilage powder) and F10 (containing combination of 5% PG + 5% HR mucilage powder) based on disintegration time, wetting time and drug release were found to be an excellent fast dissolving tablets. All the formulations were found to be stable over the storage period and at different condition tested. The most popular solid dosage forms are being tablets and capsules; one important drawback of these dosage form for some patient, is the difficulty to swallow. For these reasons tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Fast dissolving tablets are those when put on tongue, disintegrates instantaneously releasing the drug, which dissolves or disperse in saliva.

The concept of formulating fast dissolving tablets of Tramadol HCl offer suitable and practical approach in serving the desired objective of faster disintegration and dissolution characteristic with increase bioavailability and to know the effect of natural superdisintegrants.

Tramadol HCl is a centrally-acting synthetic opioid analgesic. The mechanism of action of Tramadol HCl is not completely understood, but it may bind to mu-opioid receptors and inhibit the reuptake of norepinephrine (NE) and serotonin. The ability of Tramadol HCl to inhibit the neuronal uptake of monoamines in the same concentration range at which it binds to mu-opioid receptors differentiates it from typical opioids. Tramadol HCl consists of (+) and

(-) enantiomers that appear to interact synergistically to produce antinociception. The (+) enantiomer is fivefold more potent in 5- hydroxytryptamine (5-HT) uptake and has a greater affinity for mu receptor binding than for NE uptake. The (-)enantiomer is five- to tenfold more potent in NE uptake inhibition and has less affinity for mu receptor binding than for 5-HT uptake Electrophysiological studies show that Tramadol HCl, like morphine, depresses motor and sensory responses of the spinal nociceptive system by a spinal and a supraspinal action. Some opioid activity is derived from low-affinity binding of the parent compound and higher-affinity binding of the mono- O-desmethyl Tramadol HCl (M1) metabolite to the opioid receptors. The analgesic potency of M1 is about six times greater than that of Tramadol HCl in animal models and 200 times more potent in mu-opioid receptor binding. Fast dissolving tablets of Tramadol HCl were prepared using various natural superdisintegrants such as Plantago ovata mucilage powder and Hibiscus rosa mucilage powder in different concentrations.

Prepared tablets were subjected to different evaluation parameters such as hardness, thickness, friability, weight variation, and drug content uniformity, *in-vitro* disintegration time, wetting time, *in-vitro* dissolution studies and stability studies. Results revealed that preformulation of drug and powder blends complies with the reported literature limits. The FT-IR spectra of drug and excipients showed that there is no interaction between them. And the tablets of all formulation have acceptable physical parameters. The tablets prepared by direct compression method showed weight variation in the range of 199.4 1.28mg to 200 1.26mg which is below ±7.5%, hardness 2.73±0.127kg/cm^2 to 3.00±0.086kg/cm^2, thickness of 3.96±0.045mm to 4.10±0.100mm, percentage friability was found not more than 0.86±0.124%, *in-vitro* disintegration time of 15.66±0.47sec to 86.33±1.24 sec, drug content uniformity was found in between 96.3±0.0241% to 98.7±0.0147%, wetting time was found in between 20.66±1.48sec to 120.4±2.45sec. Formulation F3 (containing 10% of PG mucilage) and F9 (containing combination of 5%PG + 5% HR mucilage) Showed 97.5% and 99.6% drug release within 5 min.

Stability study shows no significant changes in the post-compression parameters and drug release. This indicates that the tablets are fairly stable at storage condition.

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