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Efficient Oral Dosage Forms For Nsaids: Formulation And Optimization Of Dispersible Tablets

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ABSTRACT

Recent lifestyle changes have necessitated the development of dosage forms suitable for various patient demographics, including pediatrics and geriatrics. This investigation delves into the potential of orally disintegrating tablets (ODTs) to address challenges encountered by patients with swallowing difficulties or non-compliance. ODTs, which rapidly disintegrate upon contact with saliva, present advantages in patient tolerance, compliance, and bioavailability over traditional oral dosage forms. Different manufacturing techniques, including lyophilization, molding, and compression, were assessed, with direct compression identified as the most viable method for producing structurally sound ODTs**.** Ibuprofen was selected as a model drug due to its widespread use and relatively low bioavailability in conventional dosage forms. Synthetic superdisintegrants were utilized to improve the bioavailability and stability of ibuprofen ODTs. The formulation development process entailed meticulous analysis, considering factors such as excipient selection, drug bioavailability, stability, and manufacturing efficiency. Emphasis was placed on continuous innovation in formulation research, extending to novel delivery methods like drone delivery. Furthermore, there is growing interest in leveraging the oral cavity for systemic drug delivery, particularly for patients with swallowing difficulties or those needing rapid drug effects. Sublingual drug delivery emerges as a promising alternative, particularly beneficial for individuals with dysphasia or other limitations. These advancements aim to enhance medication adherence and effectiveness across diverse patient populations.

Keywords: *Dispersible Tablets, Ibuprofen, Direct compression, Superdisintigration.*

1. INTRODUCTION

Recent decades have witnessed significant lifestyle changes, prompting a demand for dosage forms tailored to diverse patient demographics, including pediatrics and geriatrics. This evolving landscape has underscored the importance of developing dosage forms that address challenges such as swallowing difficulties and non-compliance. Orally disintegrating tablets (ODTs) have emerged as a promising solution, characterized by their rapid disintegration upon contact with saliva, which enhances patient tolerance, compliance, and bioavailability compared to traditional oral dosage forms. In past research, various manufacturing techniques, including lyophilization, molding, and compression, have been explored to produce structurally sound ODTs. **(Debjit et al. (2009).** Ibuprofen has often served as a model drug due to its widespread use and relatively low bioavailability in conventional dosage forms. Synthetic superdisintegrants have been employed to enhance the bioavailability and stability of ibuprofen ODTs, reflecting efforts to overcome formulation challenges and optimize therapeutic outcomes.

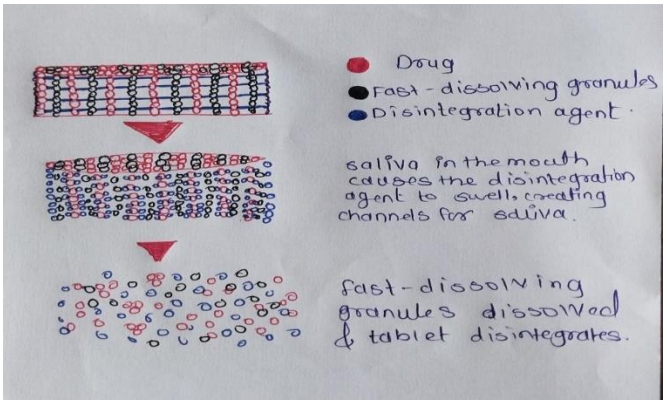
In the formulation of orally disintegrating tablets (ODTs) aimed at addressing challenges such as swallowing difficulties and non-compliance, the incorporation of superdisintegrants plays a pivotal role in ensuring rapid disintegration upon contact with saliva, thereby enhancing patient tolerance, compliance, and bioavailability. Superdisintegrants are essential components that facilitate the breakup of tablet matrices into smaller particles, accelerating the dissolution process and promoting drug release. This attribute is particularly crucial for patients with compromised swallowing abilities, as it enables easy administration and absorption of medication without the need for water, improving overall medication adherence.

Furthermore, superdisintegrants contribute to the stability and mechanical strength of ODTs, ensuring that the tablets maintain their structural integrity while disintegrating rapidly in the oral cavity. By optimizing drug delivery and enhancing patient convenience, the inclusion of superdisintegrants in ODT formulations underscores their significance in advancing pharmaceutical technology and improving healthcare outcomes for diverse patient populations.

The proposed investigation aims to contribute to this field by conducting a comprehensive analysis of formulation development factors, including excipient selection, drug bioavailability, stability, and manufacturing efficiency. By leveraging continuous innovation and exploring novel delivery methods such as drone delivery, this study seeks to advance the field of dosage form development. Moreover, there is growing interest in leveraging the oral cavity for systemic drug delivery, particularly for patients with swallowing difficulties or those requiring rapid drug effects. . **(Sastry et al. 2000)**. Sublingual drug delivery emerges as a promising alternative, offering benefits for individuals with dysphagia or other limitations. By enhancing medication adherence and effectiveness across diverse patient populations, these advancements hold considerable significance for improving healthcare outcomes.

Therefore, the purpose of this study is to investigate the formulation and delivery of ODTs, with a focus on optimizing drug bioavailability, enhancing patient compliance, and addressing the specific needs of various patient populations.

Mechanism of Action-(Seager 1998)



Aim and Objectives:

The aim of the present work was to design and evaluate orally disintegrating tablets containing particulate active ingredient using superdisintigrants and wherein its bitter taste is also masked

- Selection of the model Non-Steroidal Anti-Inflammatory Drug(NSAID)based on pharmacokinetic parameters suitable for formulating into an OTD**.** (Fu et al., 2004).
- Selection of appropriate excipients including superdisintegrats to develop the dosage form based unphysical-chemical properties and compatibilities of the active pharmaceutical ingredients(API) and excipients. (Sreenivas et al. 2005).
- Preparation of standard calibration curve for API. (Kei-ichi et al., 1997)

Formulation development of fast disintegrating tablet by direct compression method

2. MATERIALS AND METHOD

The equipment's and facilities of formulations and development department of Government college of pharmacy, Karad and physics department of shivaji university Kolhapur were used for development work. Following are the list of chemicals and instruments were used during product development.

List of ingredients and suppliers-

Sr.No	Name of Ingredients	Name of Suppliers
1	Ibuprofen	Aarti chemicals ,pvt.ltd
2	Crosscarmalose	Loba chemie, Mumbai India
3	Crospovidone	Loba chemie, Mumbai India

4	Mannitol	Loba chemie, Mumbai India
5	Sod. carboxyl methyl cellulose	Loba chemie, Mumbai India
6	Sucrose	Loba chemie, Mumbai India
7	Vanillin	Loba chemie, Mumbai India
8	Mg. stearate	Loba chemie, Mumbai India
9	Talc	Loba chemie, Mumbai India

3. EQUIPMENTS

List of equipment's with model-

Sr.No.	**Name Of Equipments**	**Manufacturer with model no.**
1	Single plan electronic balance	Shimadzu
2	Fourier transformed infrared spectrophotometer(FTIR)	Model ALPHA –E Bruker Germany
3	Hardness Tester	Monsanto
4	Friability Tester	Roche friability tester
5	Tablet Punching Machine	H.L scientific industries
6	UV visible spectrophotometer	Lab India 3000
7	USP II dissolution apparatus	Electro lab TDT-08L,Mumbai
8	Disintegration apparatus	Lab India

Methodology: The work will be carried out by following plan;

1.To do through Literature survey regarding sustained release matrix tablets. (Debjit et al. (2009) and Gupta et al. (2010), formulation technologies- while Sastry et al. (2000)

2. Selection and Procurement of –

a. Drug(Fu et al. 2004)
b. PolymersBangale et al. (2011) and Brown (2003).
c. Excipients Sreenivas et al. (2005) and Ashish et al. (2011)

3.Preformulation study to characterize drug and polymers by

a) FT-IR spectra (Yoshio et al., 2008).
b) UV-spectroscopy
c) Melting point
d) Solubility study (Sastry et al., 2000).

4. Formulation development study

a. Selection of tablet component from compatibility and solubility data.
b. Preparation of tablet (Seager, 1998)
c. Designing of batches. (Sudarshan and Dhaval 2012).

5. Characterizations of tablet

a) Tablet dimensions. (Gupta et al., 2010).
b) Hardness. (Chiman and Isha, 2013).
c) Weight variation test.
d) Friability.
e) In-vitro dissolution testing. (Bradoo et al., 2001)

D. Facilities Available:

a) Tablet compression machine. (Fu et al., 2004).
b) Hot melt extruder.
c) Analytical balance
d) Hardness tester.
e) Dissolution apparatus. (Gupta et al., 2010).
f) Friability apparatus.
g) Vernier calliper.
h) Sonicator.
i) UV- Spectrophotometer.
j) Fourier Transform Infra-Red Spectrophotometer. (FTIR). (Yoshio et **al., 2008).**

E. Requirements

2. a. Transmission Electron Microscopy (TEM). (Sudarshan and Dhaval, 2012).
3. b. Differential Scanning calorimetry (DSC).
4. c. Powder X-ray Diffraction (XRPD) (Fu et al., 2004).

Formulation of different batches- (Fu et al., 2004). (Gupta et al., 2010). Debjit et al. (2009). Yoshio et al. (2008) Sreenivas et al. (2005) Seager (1998) and Brown (2003) Sastry et al. (2000) Bradoo et al. (2001) and Prateek et al. (2012)

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ibuprofen	100	100	100	100	100	100	100	100	100
Crosscarmalose	15	15	15	30	30	30	45	45	45
Crospovidone	15	30	45	15	30	45	15	30	45
Mannitol	76	76	76	76	76	76	76	76	76
Sod.Carboxylmethyl cellulose	20	20	20	20	20	20	20	20	20
Sucrose	60	45	30	45	30	15	30	15	0
vanillin	4	4	4	4	4	4	4	4	4
Mg. Stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Total weight (300 mg)	300	300	300	300	300	300	300	300	300



4. RESULT AND DISCUSSION

Preformulation: - (Debjit B et al. 2009; Sastry et al. 2000; Fu Y et al. 2004)

Organoleptic properties of Ibuprofen were tested for organoleptic properties such as, appearance, color, and odor etc**.**

Table no.9.1 Organoleptic properties of drug

Sr.No.	Parameter	Reported	Observed	Conclusion/Comment
1.	Nature	Crystalline	Crystalline	Complies with the IP Specifications.
2.	Colour	Colourless	Colourless	
3.	Odour	Characteristic	Characteristic	

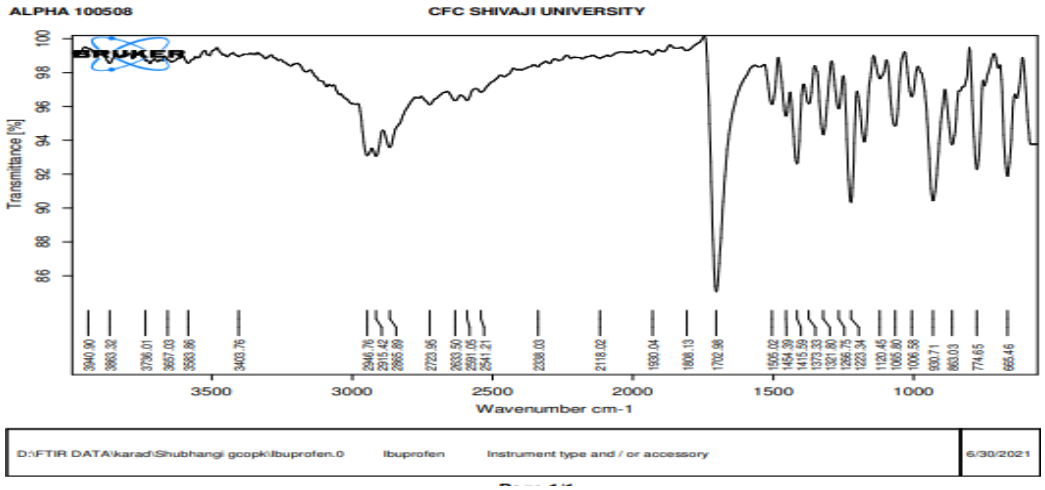
Melting point determination-(Seager H. 1998)

Melting point was studied with the help of capillary method by using digital melting apparatus. The point at which drug melts, was noted

Table no.9.2: Melting Point Determination

Sr.No	Parameter	Reported	Observed	Conclusion/Comment
1)	Melting point (◦c)	75-77◦c	75◦c	Complies with the IP specifications

FTIR Spectrum Interpretation- (Sreenivas SA et al. 2005), Bangale GS et al. (2011)



IR Spectra of Pure Drug

The FTIR Spectrum is used in a compatibility research to identify the interaction between the drug and the excipients

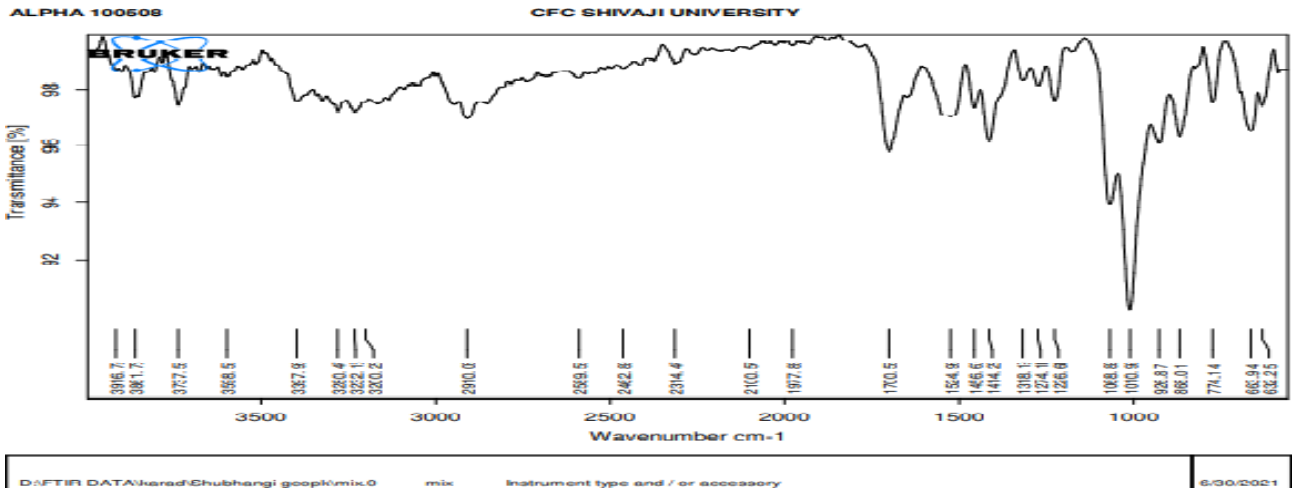


Fig No.9.2 IR Spectra of Pure Drug with Its

Excipients Table No.9.4.IR Spectra

Functional Groups	StandardRanges Wave Number	Observed Ranges Wave Number
	In cm^{-1}	In cm^{-1}
C=C	1620-1680	1645.87
COOH	1760-1690	1254.14
CH3,C-H	2960-2850	2960.96
Aromatic C-H	3000-3100	3046.01
CH3-CH	2960-2850	3046.01
C=O	1680-1760	1700.53
O-H	3600-3650	3614.94

Ranges of Ibuprofen and Its Excipients

Discussion

The model drug under study exhibits characteristics peaks at 3614.94 cm-1 (O-H free stretching), 1254.14 cm-1 (Carboxyl COOH Ester stretching),1700.53 cm-1 (Lactone C-O-Cstretching), 2960.96cm-1,3046.01 cm-1 (C-H stretching). These peaks were in agreement with literature which confirms that drug used was Ibuprofen.

The characteristic functional groups of Crosscarmalose, Crospovidone, and Ibuprofen as mentioned above were observed in the same position in the physical mixture IR spectrum. Which indicated that there is no incompatibility between drug and other excipients.

UV spectroscopy: **Fu Y et al. 2004)**

Determination of λ max of Ibuprofen in distilled water:

From stock solution, a suitable concentration of Ibuprofen (100µg/ml) was prepared by adding 10 mg of pure drug of Ibuprofen in solvent distilled water respectively and diluted to 100ml with same solvent and UV scan was taken in triplicate between the range 200- 400 nm. From the experimental work, the λ max of Ibuprofen in Distilled water was seen to be 259 nm. UV Spectrum showing λ max of Ibuprofen has shown in fig

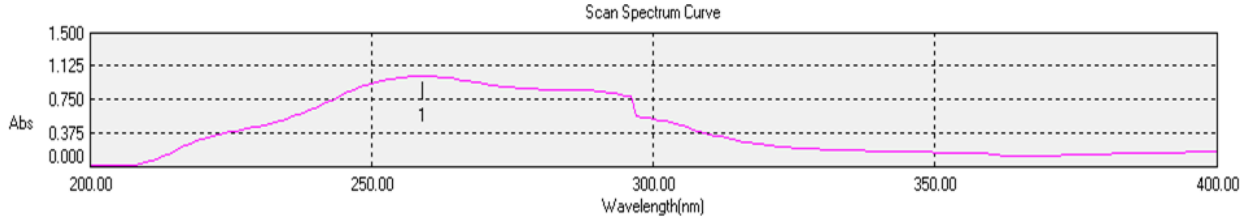


Fig no.9.3 Scanned spectrum curve of Ibuprofen in Distilled Water Table no.9.5. λmax Determination chart

Wavelength (nm)	Absorbance
259 λ	1.231

Determination of λ max of Ibuprofen in Phosphate buffer PH6.8 –

From the experimental work, the λ max of Ibuprofen in in Phosphate buffer PH6.8 was seen to be 259 nm. UV Spectrum showing λ max of Ibuprofen has shown in fig.

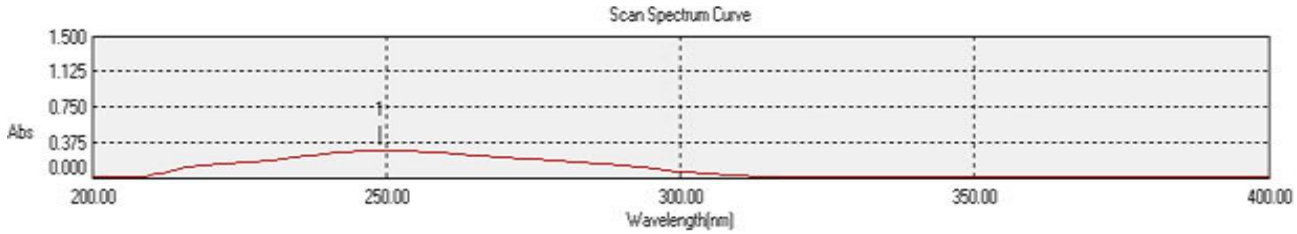


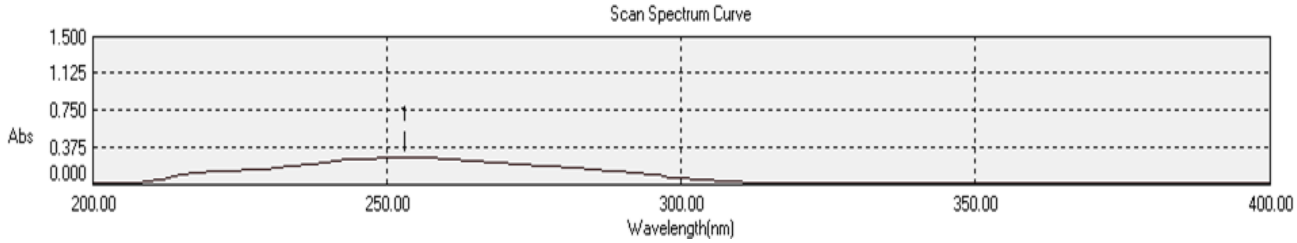
Fig no.9.4. Scanned spectrum curve of Ibuprofen in Phosphate Buffer PH 6.8 Table no.9.6. λmax

Determination chart

Wavelength(nm)	Absorbance
249	0.292

Determination of λ max of Ibuprofen in Methanol-

From the experimental work, the λ max of Ibuprofen in Methanol was seen to be 259 nm. UV Spectrum showing λ max of Ibuprofen has shown in fig.



Scanned spectrum curve of Ibuprofen in Methanol

λmax Determination chart

Wavelength(nm)	Absorbance
253	**0.276**

AUTHENTICATION OF SUPERDISINTEGRANTS: - (Sastry VS et al. 2000), Seager H (1998).

Organoleptic properties

The Superdisintegrats was studied for organoleptic properties such as appearance, colour and odour etc. The organoleptic properties of Crosscarmalose mentioned in below

Sr no	Parameter	Reported	Observed	Conclusion/Comment
1.	Nature	Fibrous powder	Fibrous powder	Complies with the specifications
2.	Colour	White	White	
3.	Odour	Odourless	Odourless	

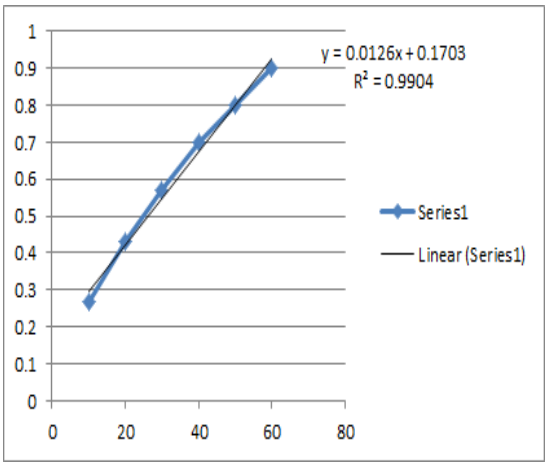
Table no 9.8. Study of Organoleptic properties of Crosscarmalose

The Superdisintegrats was studied for organoleptic properties such as appearance, color and odor etc. The organoleptic properties of Carbopol71GNFare mentioned in following table. **Study of Organoleptic properties of Crospovidone**

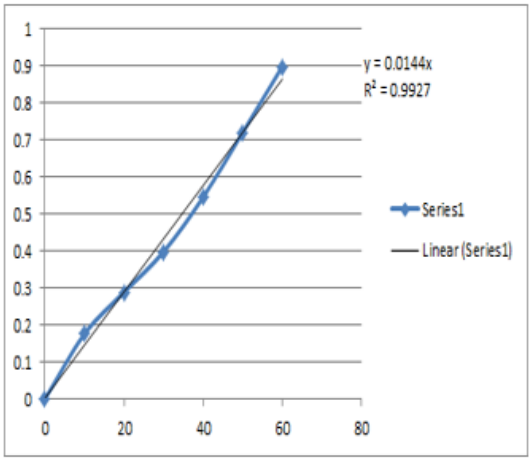
Sr.No	Parameter	Reported	Observed	Conclusion/Comment
1	Nature	Hygroscopic	Hygroscopic	Complies with the specifications
2	Colour	Light Yellow	Light Yellow	
3	Odour	Odourless	Odourless	

Calibration Curve Studies- (Brown D, 2003)

Calibration curve observations of Ibuprofen in Distilled water

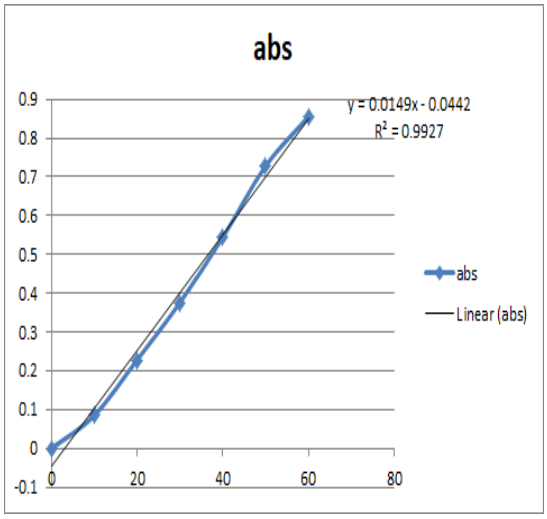


Calibration Curve Observations of Ibuprofen in Phosphate Buffer of P



Concentration	Absorbance			Mean Of Absorbance
	I	II	III	
0	0	0	0	**0**
10	0.174	0.176	0.177	**0.176± 0.001**
20	0.287	0.289	0.290	**0.289±0.001**
30	0.396	0.398	0.399	**0.398±0.001**
40	0.544	0.546	0.547	**0.546±0.001**
50	0.719	0.721	0.721	**0.721±0.001**
60	**0.897**	**0.899**	**0.900**	**0.899±0.001**

Calibration Curve Observations of Ibuprofen in Methanol



Concentration	Absorbance			Mean of Absorbance
	I	II	III	
0	0	0	0	**0**
10	0.083	0.085	0.086	**0.085±0.001**
20	0.226	0.228	0.227	**0.228±0.001**
30	0.374	0.376	0.375	**0.376±0.001**
40	0.542	0.544	0.543	**0.544±0.001**
50	0.726	0.728	0.727	**0.728±0.001**
60	**0.853**	**0.855**	**0.856**	**0.855±0.001**

Preformulation Studies of Oral Dispersible Tablets- (Chiman B et al. 2013)

Pre-compression study of Ibuprofen oral dispersible tablet

Batch	Bulk Density(gm/ml)	Tapped Density(gm/ml)	Angle of Repose	Carr's Compressibility Index(%)	Hausner's Ratio
F1	**0.55±0.01**	**0.58±0.01**	**26.34±0.45**	**12.5±0.5**	**1.24±0.021**
F2	**0.50±0.03**	**0.62±0.06**	**28.51±1.88**	**14.2±1.18**	**1.18±0.019**
F3	**0.51±0.01**	**0.47±0.02**	**26.89±0.55**	**12.5±0.5**	**1.17±0.031**
F4	**0.44±0.05**	**0.52±0.02**	**26.84±1.01**	**13.6±1.21**	**1.21±0.015**
F5	**0.42±0.09**	**0.50±0.02**	**25.22±2.62**	**14.28±1.03**	**1.23±0.014**
F6	**0.59±0.005**	**0.64±0.01**	**22.76±0.48**	**11.65±0.50**	**1.05±0.030**

F7	**0.48±0.002**	**0.62±0.07**	**27.21±0.57**	**14.22±0.48**	**1.19±0.038**
F8	**0.54±0.008**	**0.55±0.04**	**29.34±0.12**	**13.89±0.030**	**1.19±0.017**
F9	**0.43±0.004**	**0.52±0.09**	**27.92±0.78**	**15.43±0.019**	**1.21±0.031**

Concentration	Absorbance			Mean Of Absorbance
	I	II	III	
0	0	0	0	**0**
10	0.264	0.266	0.267	**0.266±0.001**
20	0.430	0.432	0.433	**0.432±0.001**
30	0.568	0.570	0.571	**0.570±0.001**
40	0.696	0.698	0.699	**0.698±0.001**
50	0.803	0.801	0.802	**0.801±0.001**
60	**0.899**	**0.901**	**0.902**	**0.901±0.001**

Post compression study Ibuprofen Oral dispersible tablet- Bradoo et al. (2001) and Prateek S et al. (2012).

Batch	Weight Variation (mg)	Hardness(kg/cm2)	Thickness(mm)	Diameter(mm)
F1	**348±0.46**	**3.14±0.05**	**3.40±0.08**	**5.9±0.09**
F2	**349±0.12**	**3.19±0.09**	**3.42±0.11**	**5.8±0.46**
F3	**351±0.75**	**3.0 ±0.14**	**3.41±0.23**	**6.0±0.01**
F4	**348±0.74**	**3.69±0.18**	**3.42±0.11**	**5.9±0.09**
F5	**350±0.19**	**3.40±0.11**	**3.43±0.19**	**5.8±0.74**
F6	**349±0.98**	**3.25±0.10**	**3.41±0.08**	**5.7±0.09**
F7	**351±1.04**	**3.52±0.08**	**3.42±0.19**	**5.8±0.74**
F8	**348±0.23**	**3.16±0.10**	**3.42±0.08**	**5.9±0.46**
F9	**347±0.92**	**3.10±0.10**	**3.41±0.11**	**5.7±0.09**

Post compression study of Ibuprofen oral dispersible tablet

Batch	Friability(%)	Disintegration Time (sec)	Drug Content(%)
F1	0.60±0.09	34±0.98	**98.07±0.12**
F2	0.65±0.11	31±1.23	**99.45±0.57**
F3	0.70±0.12	33±1.12	**98.00±0.98**

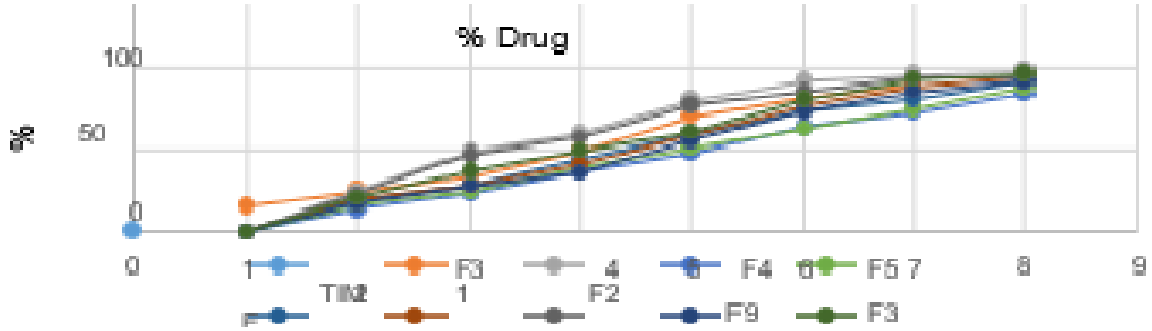
F4	0.65±0.92	41±1.98	**97.10±0.37**
F5	0.55±0.10	43±1.15	**98.12±1.12**
F6	0.65±0.10	48±95	**98.05±0.14**
F7	0.65±0.74	35±56	**99.26±0.28**
F8	0.50±0.46	39±12	**98.14±0.98**
F9	**0.60±0.19**	**44±95**	**99.21±0.45**

Wetting time study and Maximal Water uptake study for Ibuprofen tablet (Gupta A et al. 2010), (Ashish P et al. 2011).

Batch	Wetting Time(sec)	Maximal Water Uptake
F1	**59±0.12**	**96.56±1.45**
F2	**39 ±11**	**63.00±1.41**
F3	**42±1.63**	**75.11±1.48**
F4	**61±1.28**	**74.023±1.42**
F5	**58±1.16**	**65.03±1.15**
F6	**53±1.44**	**73.84±1.45**
F7	**44±1.08**	**90.24±1.85**
F8	**46±0.12**	**81.33±1.24**
F9	**59±1.15**	**77.85±1.19**

In- Vitro Drug Release

Comparative % drug release of all formula



Sr. No	Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2	1	1639± 0.45	25.14 ±0.64	21.38 ±0.81	14.11 ±0.52	16.79 ±0.51	19.10 ±0.40	20.12 ±0.56	23.24 ±0.65	17.72 ±1.0
3	2	25.48 ±0.43	49.29 ±0.36	30.33 ±0.33	23.45 ±0.57	25.03 ±0.64	28.39 ±0.59	28.19 ±0.51	47.16 ±0.45	28.07 ±1.05
4	3	34.28 ±0.51	69.57 ±0.59	49.72 ±0.63	36.73 ±0.57	39.65 ±0.49	44.37 ±0.95	41.34 ±0.91	57.63 ±0.58	36.39 ±0.79
5	4	49.47 ±0.81	80.64 ±0.52	60.99 ±0.61	47.77 ±0.79	51.35 ±0.84	59.43 ±0.27	59.05 ±0.38	76.90 ±0.65	56.19 ±0.87
6	5	70.32 ±0.65	92.23 ±0.57	81.09 ±0.71	64.17 ±0.33	63.47 ±0.61	74.01 ±0.56	77.29 ±0.67	85.50 ±0.45	56.19 ±0.80
7	6	81.95 ±0.71	96.13 ±0.50	93.10 ±0.49	72.35 ±0.52	73.48 ±0.66	81.02 ±0.72	89.04 ±0.56	93.60 ±0.48	73.69 ±0.55
8	7	90.29 ±0.29	98.50 ±0.33	96.36 ±0.76	84.32 ±0.60	88.95 ±0.34	92.39 ±0.47	94.38 ±0.63	93.60 ±0.49	85.29 ±0.47

Determination of kinetic parameters-

Dissolutions data fits to different kinetic equations-

Time (min)	% CDR
1	25.14
2	49.29
3	60.57
4	80.64
5	92.23
6	96.13
7	98.5

Zero order kinetic graph of optimized batch

Time (min)	% CDR
1	1.4003
2	1.6927
3	1.7822
4	1.9065
5	1.9065
6	1.9648
7	1.9828

First order kinetic

First order kinetic

5. CONCLUSION

The study investigated the formulation of fast dissolving tablets of Ibuprofen using direct compression method. The tablets exhibited favorable characteristics such as absence of capping and chipping, and met the acceptable standards for post-compression parameters including hardness, friability, thickness, and drug content. Compatibility studies via IR spectroscopy confirmed the suitability of excipients used. Notably, formulations F2 and F3 demonstrated promising disintegration times and wetting times, facilitating rapid dissolution in the oral cavity, with in-vitro drug release percentages reaching 98.50% and 96.60% respectively within 7 minutes. Such fast dissolving tablets could significantly enhance patient compliance, particularly among pediatric and geriatric populations, and individuals preferring easily administered dosage forms. Crospovidone was found to enhance oral dispersion rate and improve drug release, suggesting feasibility for large-scale production of satisfactory oral dispersible tablets of Ibuprofen, ultimately increasing its bioavailability.

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