FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS BY USING MUSA PARADISIACA

1) K DurgaPrasad, 2) Miss A.Sujana. 3) R.vengamma 4) I.kalyani.

1) Assistant professor, Narayana Pharmacy College, Chinthareddypalem Nellore.(E- Mail- durgaprasad kondeti@gmail.com & Phone No 7306775758)

2) Bpharmacy Student, Narayana Pharmacy College (E-mail: adigopulasujana@gmail.com & Phone No 9346411763.)

3) Bpharmacy Student, Narayana Pharmacy College (E-mail : vengammajnv@gmail.com & phone No 9381577356)

4) Bpharmacy Student, Narayana Pharmacy College (E-mail: kalyaniprakashini1@gmail.com Phone No 9182815974)

Correspondence author: K Durga Prasad

E-mail: durgaprasad kondeti@gmail.com & Phone No 7306775758

ABSTRACT:

Diclofenac Sodium is a nonsteroidal anti-inflammatory drug (NSAID) widely used as an anti-inflammatory, analgesic and antipyretic agent. However oral bioavailability is poor with only 50% of the dose reaching systemic circulation due to extensive first pass metabolism. The elimination half-life is 2 to 4 hrs. Diclofenac sodium is available as in the form of tablet for the treatment of the signs and symptoms of osteoarthritis or rheumatoid arthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications. The dose of the drug ranges from 50, 75, and 100 mg/day. This dosage form needs an immediate release for fast relief of pain. Hence an attempt has been made for preparation of fast dissolving tablets of, diclofenac sodium with an aim of reducing the drug releasing time and providing faster onset of action to relieve PAIN. This would be advantageous as conventional solid dosage forms are often associated with a faster disintegrating time. The fast dissolving tablets containing banana powder provide quick disintegration of tablets thereby releases the drug immediately

FAST DISSOLVING TABLETS: FDDTs disintegrate and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets.

ADVANTAGES OF FDT

- Improved patient compliance
- Rapid onset of action and may offer an improved bioavailability. Patient can easily administer this type of dosage form
- Useful for pediatric, geriatric and psychiatric patients
- Suitable during traveling where water is may not be available Gives accurate dosing as compared to liquids
- Good chemical stability.

PLANT PROFILE:

- BOTANICAL NAME: Musa paradisiaca
- COMMON NAMES : Balbis banana, Mealy banana, Plantain
- EDIBLE PLANT PART: Fruit

- DISTRIBUTION : Asia, temperate and tropical regions
- PROPAGATION : Seed and Suckers
- CHEMICAL CONSTIUENTS: Starch, Phenolic acids, Sterols
- USES : Edible, Anti microbial act, Ulcer healing activity

PREPARATION OF BANANA POWDER:

Green bananas are purchased from local market and are thourghly washed under running tap water. Then the bananas made peel out by using sterile knife and cut into small disc. The rolls are dried under hot air oven by maintain temperature at 60 C for 4 hours. After drying the discs are powder in mixture.

Musa paradisiaca.

Cutting and drying

Grinding.

Musa paradisiaca powder

COMPOSITION OF FORMULATIONS

The fast disintegration tablets are planned to have Diclofenac sodium 50mg drug loading by using banana powder as a super disintegrating agent. The purpose of incorporating banana powder is to favor quick release of drugs. The burst release of drug at the initial stage promotes quick on set of action. The best formulation was developed based on the release rate of the drug.

FORMULATION CODE:

S.NO	INGREDIENTS	F1	F2	F3	F4	F5	F6
1	Drug	50mg	50mg	50mg	50mg	50mg	50mg
2	Musa paradisiaca	25mg	50mg	75mg	100mg	125mg	150mg

3	Lactose	25mg	25mg	25mg	25mg	25mg	25mg
4	Talc	2%	2%	2%	2%	2%	2%
5	Mg . sterate	2%	2%	2%	2%	2%	2%

S.NO	INGREDIENTS	F7	F8	F9	F10
1	Drug	50mg	50mg	50mg	50mg
2	SSG	75mg	100mg		
3	MCC			75mg	10mg
4	Lactose	25mg	25mg	25mg	25mg
5	Talc	2%	2%	2%	2%
6	Mg. sterate	2%	2%	2%	2%

PHYSICAL EVLUVATION OF POWDER BLEND

ANGLE OF REPOSE:

In order to determine the flow property, the angle of repose was determined. It is the maximum angle that can be obtained between the free standing surface of powder heap and horizontal plain.

Ø= tan (h/r)

Where;

h= height

R=radius

Ø = angle of repose

ANGLE OF REPOSE	TYPE OF FLOW OF PODWER
<25	Excellent
25-30	Good
30-40	Passable
>40	Very good

Bulk density and tapped density

About 5 gm of powder (W) from each formula was introduced into a 25ml measuring cylinder. The initial volume was noted and then the measuring cylinder was loaded in bulk density apparatus and tapped for 500 times on a flat surface at 2sec interval. The final volume after tapping was noted for calculations. The bulk density and tapped density was calculated by using formulas.

Bulk density =W/V

Tapped density =W/Vf

Where, W=weight of the powder

V=initial volume

Vf =final volume

COMPRESSIBILITY INDEX (Carr's indices)

Compressibility index is an important measure that can be obtained from the bulk and tapped densities. In theory the less compressible a material the more flowable it is. A material having a value of less than 20to 30 % is defined as the free flowing material.

Carr's index	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor

33-38	Very poor
>40	Very very poor

HAUSER'S RATIO:

It indicates the flow properties of the powder and it measured by the ratio of tapped density to the bulk density. Hauser's ratio is calculated by using the formula:

Hauser's ratio = tapped density /bulk density

TYPES OF QULATIY CONTROL TEST:

1. **OFFICIAL TEST :**
- Weight variation test
- Drug content
- Disintegration time test
- Dissolution test

2. **UN OFFICIAL TEST :**
- Thickness
- Hardness
- Friability

OFFICIAL TEST:

WEIGHT VARIATION TEST: Weight variation test is done by weighing 20 tablets individually and calculating the average weights and comparing the individual tablet weighs to the average. The value of weight variation test is expressed in percentage the following formula is used;

Weighed variation = (IW – AW)/AW X 100%

Where;

IW=Individual weight

AW= Average weight

Range of weight	**Variation allowed**
<130	± 10%
130-324	±7.5%
>324	±5%

INVITRO DISINTEGRATION STUDIES: The invitro disintegration study of diclofenac tablets was performed by USP disintegration apparatus. Fill the beaker with 900 ml of pure distilled water and place the tablet in six sets of basket and if prescribed add a disc. Temperature of immersion fluid should be range between 37+_2 c. observe tablet for disintegration after completion note down all the values. Lift up the beaker after completion of all the process.

Categories of tablet	**Disintegration time**
Uncoated tablets	15
Coated tablets	60
Enteric coated tablets	60
Film coated tablets	30
Effervescent tablet	5
Soluble tablets	3
Dispensable tablets	3

UNOFFICIAL TEST:

HARDNESS: This test is also known as "crushing strength test". Tablet hardness has been defined as the force required for breaking a tablet in diametric compression test.

Equipment used in this test:

- Monsanto hardness tester
- Pfizer hardness tester
- Strong cobb hardness tester
- Erweka hardness tester

Pfizer hardness tester: The Pfizer tester compresses tablet between a holding anvil and a piston connected to force reading gauze when its plier- like handle and gripped the point where the tablets get breakdown. It is noticed by reading gauze.

FRIABILITY TEST: "FRIABILITY is the phenomenon where the surface of the tablet is damaged or shown a site of damage due to mechanical shock." The major purpose is to evaluate the ability of the tablets to with stand the breakage during transporting and handling. **Roche friabilator** is most commonly used for determining % friability of the tablet.

%friability can be calculated by using following formula

% friability =W1-W2/W1X100

Where, W1= weight of tablet before testing

W2= weight of tablet after testing

RESULT: Fast dissolving Diclofenac tablets were prepared and evaluated.

PHYSICAL EVALUVATION OF POWDER BLEND:

ANGLE OF REPOSE: The angle of repose for all 10 formulations was found to be excellent when compared to standard values

S.No	Formulation code	Angle of repose
1	F1	22°.43'
2	F2	22°.58'
3	F3	23°.52'
4	F4	23°.52'
5	F5	22°.58'
6	F6	22°.43'
7	F7	23°.52'
8	F8	22°.58'
9	F9	23°.52'
10	F10	23°.52'

BULK DENSITY& TAPPED DENSITY:

S.No	Formulation code	BULK DENSITY(g/ml)	TAPPEDD DENSITY(g/ml)
1	F1	0.5524	0.6478
2	F2	0.5541	0.6484
3	F3	0.5537	0.6458

4	F4	0.5514	0.6487
5	F5	0.5578	0.6452
6	F6	0.5564	0.6458
7	F7	0.5489	0.6423
8	F8	0.5595	0.6489
9	F9	0.5490	0.6578
10	F10	0.5571	0.6548

COMPRESSIBILITY INDEX (Carr's indices):

The Carr's index was found to be within the limit of 5-15, when it is compared with standard values so, the powder blend has excellent flow property.

S.No	Formulation code	Carr's index (%)
1	F1	9.55
2	F2	9.84
3	F3	9.81
4	F4	9.86
5	F5	9.88
6	F6	9.81
7	F7	9.84
8	F8	9.88
9	F9	9.84
10	F10	9.85

Hausner ratio:

The Hausner ratio was found to be excellent when compared to standard values.

S.No	Formulation code	Hausner ratio
1	F1	1.107
2	F2	1.108
3	F3	1.108
4	F4	1.111
5	F5	1.118
6	F6	1.102
7	F7	1.107
8	F8	1.112
9	F9	1.101
10	F10	1.105

"All the pre compression parameters were found to be within the limit so; the powder blend shows good flow property".

OFFICIAL TEST:

WEIGHT WARIATION TEST:

Not more than 2 tablets are outside the percentage limit and no tablet and no tablet differ by more than 2 times the percent limit. So, it passes the weight variation test as per USP.

S.NO	FORMULATIONS	WEIGHT VARIATION TEST
1	F1	Pass
2	F2	Pass
3	F3	Pass
4	F4	Pass
5	F5	Pass
6	F6	Pass
7	F7	Pass
8	F8	Pass
9	F9	Pass
10	F10	Pass

DISINTEGRATION TEST:

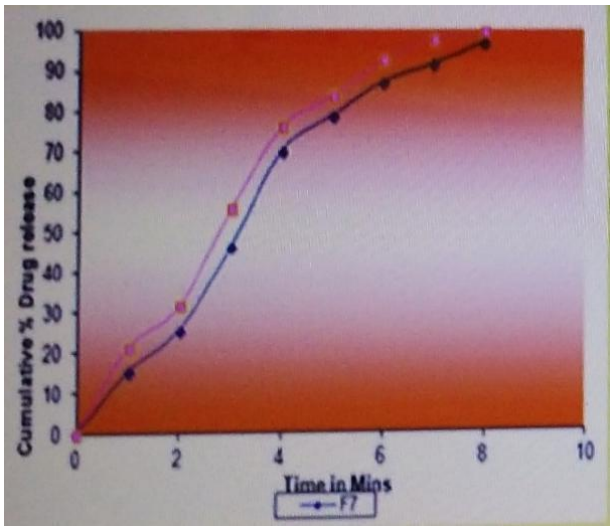
S.NO	FORMULATION	DISINTEGRATION TEST (MIN)
1	F1	08
2	F2	08
3	F3	07
4	F4	06
5	F5	08
6	F6	08
7	F7	06
8	F8	06
9	F9	06
10	F10	05

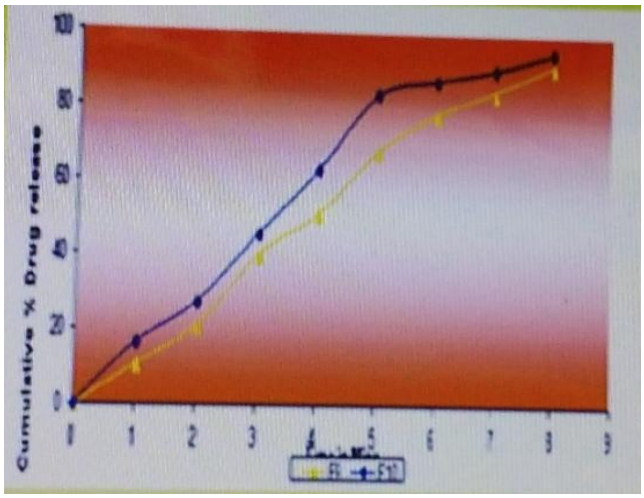
INVITRO DISINTEGRATION STUDIES:

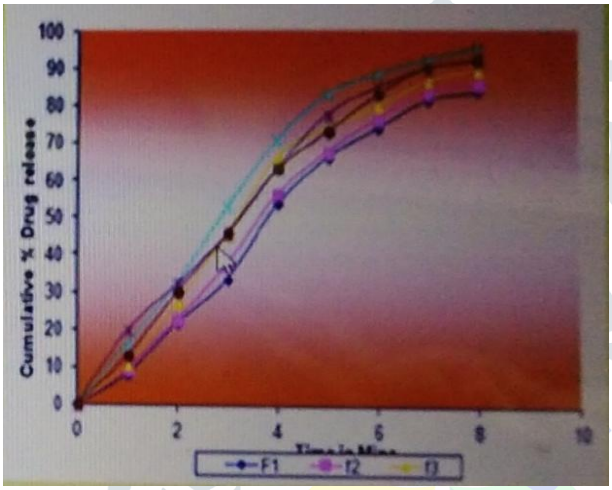
TIME	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
1	8.2	9.63	10.58	15.9	19.7	13	15.36	21.3	10.58	16.4
2	21.8	22.8	27.8	32.2	32.2	30.1	25.58	31.5	20.82	27.37
3	33.5	37.6	45.59	52.7	45.58	45.58	46.06	55.6	40.01	45.58
4	53.6	56.3	66.5	70.8	63.23	63.01	70.01	76	51.09	63.26
5	66.2	67.8	74	83.05	77.7	73.1	78.7	83.37	68.27	83.77
6	74	76.5	79.8	88.36	84.9	82.9	87.1	92.7	78.56	87.91
7	81.4	83.6	89.4	92.3	90.09	90.32	91.52	98	84.9	90.91
8	83.7	85.7	89.3	95.37	92.3	92	96.82	99.7	92	95.66

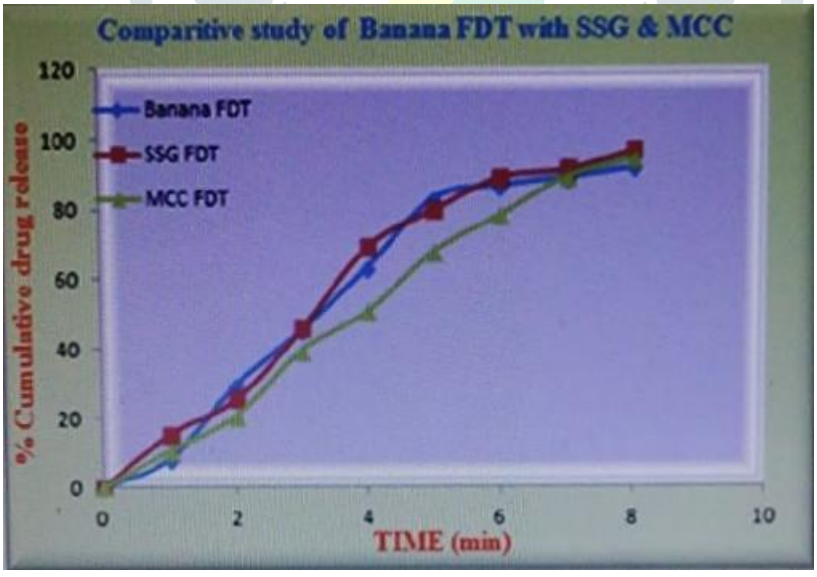
The fast dissolving formulation F4 contain Diclofenac sodium 50 mg and Musa paradisiaca powder 100 mg shows 95.37% of drug release at 8^{th} min and disintegrated at 6^{th} min was selected as best formulation.

Graphical representation:









UN OFFICIAL TEST:

HARDNESS:

S.NO	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	2.5	2.5	2.5	2.9	2.8	2.9	3	3	2.4	2.9

2	2.4	2.5	2.5	3	2.6	2.5	2.5	2.5	2.5	2.5
3	2.9	2.9	3	3	2.8	2.7	2.8	2.8	2.9	2.6
4	3	2.5	2.5	2.5	3	2.9	2.9	2.9	3	2.8
5	2.5	2.7	2.8	2.8	3	3	2.8	2.8	2.8	3

FRIABILITY:

S.NO	FORMULATIONS	FRIABILITY TEST
1	F1	Pass
2	F2	Pass
3	F3	Pass
4	F4	Pass
5	F5	Pass
6	F6	Pass
7	F7	Pass
8	F8	Pass
9	F9	Pass
10	F10	Pass

"The physical evaluation of the powder demonstrated that are of good strength and are suitable for high speed compression".

Conclusion:

Diclofenac Sodium is a nonsteroidal anti-inflammatory drug (NSAID) widely used as an anti-inflammatory, analgesic and antipyretic agent. However oral bioavailability is poor with only 50% of the dose reaching systemic circulation due to extensive first pass metabolism. Hence an attempt has been made for the preparation of fast dissolving tablets of diclofenac sodium with an aim of fast disintegration. The fast dissolving tablets is having Musa paradisiaca powder to provide quick disintegration and for immediate release of drug. Formulation studies using FTIR spectroscopy was done to reveal that there was no incompatibility between drug and Musa paradisiaca powder. The fast dissolving formulation F4 contain Diclofenac sodium 50 mg and Musa paradisiaca powder 100 mg shows 95.37% of drug release at 8^{th} min and disintegrated at 6^{th} min was selected as best formulation. The physical evaluation of the powder demonstrated that are of good strength and are suitable for high speed compression .Further the effect of direct compression vehicle was evaluated in the formulation of F7& F8 the dissolution rate of F4 was compared with the super disintegrating agent SSG by performing different formulation F9&F10.

REFERENCE:

1. Hiremath SP, Chidambar M. Formulation and evaluation of Orodispersible tablets of a model anti-hypertensive drug. Int J Pharm Pharm Sci 2017;11:34-8.

2. Chang RK, Guo X, Burnside BA. Fast dissolving tablet. Pharm Tech 2000;24:52-8.

3. Wadhavani AP. Indole 414 as novel superdisintigrants. Indian J Pharm Sci 1999;6:117-9.

4. Simmonds NW. Where our bananas come from. New Sci 2011;16:36-9.

5. WHO. Bulk density and tapped density of powders. Document 2012. No. QAS/11.450.

6. Mitul P, Jitendra P, Umesh M. Assessment of various pharmaceutical Excipient properties of natural Moringa oleifera gum. Int J Pharm Life Sci 2012;3:1833-47.

7. Microx. Micromeritics for Pharmaceutical System, Density and Porosity. Available from: http://www.micrx.com/Analytical-Services/ Density-and-Porosity.aspx.

8. United states Pharmacopoeia. US Pharmacopeial Convention 2005. p. 29-NF 24.

9. Indian Pharmacopoeia. Ministry of Health and Family Welfare. New Delhi: Government of India; 1996. p. 2.

10. WHO. The International Pharmacopoeia. Methods of Analysis: Methods for Materials of Plant Origin: Determination of Ash and Acid-insoluble Ash. Available from:http://www.apps.who.int/phint/en/p/docf/.

11. David B, Paul B. Remington: The Science and Practice of Pharmacy. Philadelphia, PA: Lippincott Williams & Wilkins; 2006.

12. Arti M, sangeetha G. In vitro-in vivo evaluation of fast-dissolving tablets containing solid dispersion of oxcarbazepine. Int J Pharm Pharm Sci 2016;8:124-31.

13. Lieberman HA, Lachman L., "Pharmaceutical dosage forms tablets" 3rd edition. New York: Marcel Dekker; page no.203.

14. Rangasamy Manivannan., "Oral disintegrating tablets: A future Compaction Publication" International Journal of Pharmaceutical Research and Development, 2009; page no.1: 1-10.