

FORMULATION AND EVALUATION OF KETOPROFEN TABLETS BY USING NATURAL SUPERDISINTEGRANTS

*Dr. Ritesh S. Bathe, Bhagyashri R. Latare, Akash P. Punwatkar, Akchal P. Kawade and Akansha C. Dahat

Department of Pharmaceutics, Siddhivinayak College of Pharmacy, Warora, Chandrapur, Maharashtra.



*Corresponding Author: Dr. Ritesh S. Bathe

Department of Pharmaceutics, Siddhivinayak College of Pharmacy, Warora, Chandrapur, Maharashtra.

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ABSTRACT

The end of the present exploration is to formulate Conventional Ketoprofen tablets. Ketoprofen is a non-steroidal anti-inflammatory (NSAID) medicine with analgesic, anti-inflammatory, and antipyretic goods. It's extensively used in the treatment of inflammation and pain associated with rheumatic diseases similar as rheumatoid arthritis, osteoarthritis, and in soft towel injury. Conventional Ketoprofen tablets were prepared by using wet granulation system using natural superdisintegrants like Potato bounce, sludge bounce and Taro (Arabi) bounce. The set tablets were characterized for their hardness, frangibility, weight variation, decomposition time and in vitro dissolution studies. The capability of the tablet to release the medicine briskly depends on the attention and type of superdisintegrants. In this study the conventional tablets containing Potato bounce, sludge bounce and Taro (Arabi) bounce used as the superdisintegrants in the rate of 111. Where the F3 shows better released of medicine. About 75.81 of the medicine was released from the tablets in 3 hour. Thus, grounded on the evaluation parameters, in vitro medicine release profile of F₃ expression containing Taro (Arabi) bounce is optimized as the stylish expression with high decomposition rate. Keywords Conventional Tablets, Rheumatoid arthritis, Osteoarthritis, Superdisintegrants, Ketoprofen, Corn bounce, Taro bounce, in vitro evaluation.

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INTRODUCTION

The oral route of administration have wide acceptance up to 50- 60 of total lozenge forms and also considered as the most extensively employed route of administration due to its wide range of advantages like stability, ease of administration, accurate lozenge, tone drug and case compliance. Hence oral solid lozenge forms are substantially preferred. Among all the lozenge forms, the tablet lozenge form is the most popular, because of ease of transportability and lower manufacturing cost. The disadvantage of oral lozenge forms similar as Dysphasia or difficulty in swallowing can be overcome by developing fleetly disintegrating and dissolving tablet lozenge forms which dissolve in slaver and doesn't bear water for swallowing. The briskly the medicine into result, hastily the immersion and onset of clinical goods. Some medicines are absorbed from the mouth, pharynx, esophagus, as the slaver passes down into the stomach. Solid cures may be administered orally as maquillages, capsules, cachets, capsules or tablets. These lozenge forms contain a volume of medicine which is given as a single unit and they're known inclusively as solid unit lozenge forms, indeed in the case of sustained action medications which, technically,

contain the fellow of several normal boluses of medicine. The strict expression conditions of ultramodern specifics, the numerous advantages of tablet and capsule drug, coupled with expanding health services and the commitment demanded for large scale profitable manufacture, have led to a steady decline in the prescribing of maquillages and capsules. Tablets and capsules, on the other hand, presently regard for well over two third of the total number and cost of drugs produced each over the world.

SUPERDISINTEGRANTS

Disintegrating agents are substances routinely included in the tablet phrasings to prop in the break- up of the compacted mass into the primary patches to grease the dissolution or release of the active constituents when it's put into a fluid terrain. They plump humidity penetration and dissipation of the tablet matrix. The major function of disintegrants is to oppose the effectiveness of the tablet binder and physical forces that act under contraction to structure the tablet. lately new accoutrements nominated as "superdisintegrants" have been developed to ameliorate the decomposition processes. Superdisintegrants are another interpretation

of super absorbing accoutrements with knitter- made swelling parcels. These accoutrements aren't planned to absorb significant quantities of water or waterless fluids, but planned to swell veritably presto. They're physically dispersed within the matrix of the lozenge form and will expand when the lozenge form is exposed to the wet terrain. These newer substances are more effective at lower attention with lesser disintegrating effectiveness and mechanical strength. Superdisintegrants are generally used at a low position in the solid lozenge form, generally 1- 10 by weight relative to the total weight of the lozenge unit. Their patches are generally small and pervious, which allow for rapid-fire tablet decomposition in the mouth without a reprehensible mouth sense from either large patches or gelatinizing. The patches are also compressible which improves tablet hardness and its frangibility. Effective superdisintegrants give bettered compressibility, comity and have no negative impact on the mechanical strength of phrasings containing high- cure medicines.1 Added to a tablet expression to grease its breaking or decomposition when it connections water in the GIT.

Example: Starch – 5 - 20 % of tablet weight. Bounce secondary - Primogel and Explotab.

STARCH

Bounce is a carbohydrate conforming of a large number of glucose units joined together by glycosidic bonds. This polysaccharide is produced by all green shops as an energy store. It's the most common carbohydrate in the mortal diet and is contained in large quantities in similar staple foods as potatoes, wheat, sludge (sludge), rice, and cassava. It's either used as uprooted from the factory and is called "native bounce", or it undergoes one or further variations to reach specific parcels and is called "modified bounce". Pure bounce is white, tasteless and odourless greasepaint that's undoable in cold water or alcohol. It consists of two types of motes the direct and spiral amylose and the fanned amylopectin. Depending on the factory, bounce generally contains 20 to 25 amylose and 75 to 80 amylopectin. It's egregious that bounce has moved from its traditional part as food to being a necessary drug. The wide use of bounce in the drug is grounded on its glue, thickening, gelatinizing, swelling and film- forming parcels as well as its ready vacuity, low cost and controlled quality. From the foregoing, to suppose that bounce is still ordinary inert excipients is to be unconscious of the influence this important biopolymer plays in remedial outgrowth of bioactive halves. bounce has proven to be the deviser's " friend " in that, it can be employed in the medication of colorful medicine delivery systems with the eventuality to achieve the deviser's desire for target or defended delivery of bioactive agents. sludge bounce, redundant white sludge bounce, wheat bounce and potato bounce are long- known and dependable excipients used as undoable diluents that act as padding in the expression of tablets and capsules, and as maquillages for sachets,

all while retaining a decomposition function. Generally bounce is insulated from potatoes, wheat, sludge (sludge), rice, and cassava etc. But Starch birth from Taro (*Colocasia esculenta*) tuber has not been reported considerably so, The purpose of this study is to prize the bounce from Taro (*Colocasia esculenta*) and assessing it, and further using taro bounce as disintegrating agent in tablet expression with over all evaluation. In short from this exploration exertion it can be said that taro bounce can be introduced to the ultramodern period of exploration, and hence it can be proved better and effective than other natural beans substantially as disintegrants and can be further modified with colorful inquiries made over it.

GENERAL PROPERTIES OF TABLET DOSAGE FORMS

- 1) A tablet should have elegant product identity while free of blights like chips, cracks, abrasion and impurity.
- 2) Should have sufficient strength to repel mechanical shock during its product packaging, shipping and allocating.
- 3) Should have the chemical and physical stability to maintain its physical attributes over time.
- 4) The tablet must be suitable to release the medicinal agents in a predictable and reproducible manner.

IDEAL CHARACTERISTICS OF CONVENTIONAL TABLETS ARE

- 1) Mask or overcome the inferior taste of a medicine.
- 2) Have affable mouth feel.
- 3) Convenience of administration and accurate dosing as compared to liquids.
- 4) They should fluently disintegrate and dissolve.
- 5) Rapid dissolution and immersion of the medicine, which may produce rapid-fire onset of action.
- 6) Exhibition low perceptivity to an environmental condition similar as moisture and temperature.
- 7) Allow the manufacture of tablets using conventional processing and packaging outfit at low cost.
- 8) They should have low perceptivity to environmental conditions like humidity, temperature etc.
- 9) They should have high medicine lading.
- 10) Ease of administration to cases that refuse to swallow a tablet, similar as pediatric and senior cases and psychiatric cases.

ADVANTAGES OF THE TABLET DOSAGE FORM ARE

- 1) They're unit lozenge forms and offer the topmost capabilities of all oral lozenge forms for the topmost cure perfection and the least content variability.
- 2) Cost is the smallest of all oral lozenge forms.
- 3) Lighter and compact.
- 4) Easiest and cheapest to package and strip.
- 5) Easy to swallow with least tendency for hang- ups.
- 6) Sustained release product is possible by enteric coating.

DISADVANTAGES OF THE TABLET DOSAGE FORM ARE

- 1) Delicate to swallow in case of children and unconscious cases.
- 2) Some medicines repel contraction into thick compacts, owing to unformed nature, low viscosity character.^[2]

AIM: Formulation and evaluation of Ketoprofen tablets by using various natural superdisintegrants.

OBJECTIVE

1. To develop a pharmaceutically efficient, stable and quality improved formulation of conventional Ketoprofen tablet by using various natural superdisintegrants to obtain faster rate of drug release.
2. Extraction and evaluation of starch from various natural sources i. e. Potato, Corn and Taro (Arabi).
3. To obtain desired optimum formulation of Ketoprofen 250 mg tablets (F₁, F₂, and F₃) by using various natural superdisintegrants.
4. To determine which disintegrants has the fastest disintegration time by doing various tests.
5. To Study the effect of Ketoprofen as conventional release tablet dosage form with faster disintegration rate.
6. Comparative study of various natural superdisintegrants with their action on drug disintegration rate.

PLAN OF WORK

1. a work.
 - a. Collection of Information about essential substances.
 - b. Collection of Tuber (Potato, Arabi) and grains of Maize.
 - c. Extraction of starch from tubers and grains.
 - d. Preliminary testing of starch.
 - e. Formulation of tablet by using extracted starch as superdisintegrating agent by wet granulation method.
 - f. Overall Evaluation of formulated tablets and its properties. (Hardness, weight variation, % friability, Disintegration time, Dissolution and so on...).
 - g. Result.
2. Data compilation.
3. Report writing.
4. Presentation of data.

PLANT PROFILE

1. POTATO

Synonyms: Yam, Aaloo, Batate, Murphy, Spud, Tater.

Biological Source: Tubers of *Solanum tuberosum*.

Family: *Solanaceae*.

Chemical Constituents: It contains 25% dry matter, including 10-23% starch 1.4-3.0% high quality protein vitamins C, B₁, B₂, B₆, PP, K.

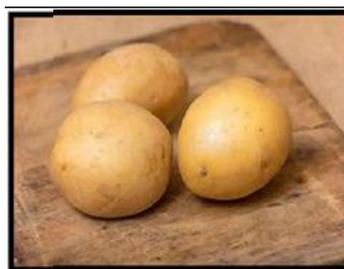


Fig. 01: Potatoes tubers.

Therapeutic Uses

- Treat health of eyes
- Protect liver from injury
- Prevent cancer
- Promote digestion
- Used as antioxidants

Indication: It limited appetite so people can lose weight.

Side Effects: Excess use may cause weight gain.^[9]

2. MAIZE

Synonyms: Chief cereal crop, Mealie, Sweet.

Family: *Poaceae*.

Chemical Constituents

It contains Ash corn, Indian corn, Maqua. (0.7-1.3%), Fats (3.21-7.71%), Protein (7.71-14.60%), Crude fibre (0.80-2.32%), Carbohydrates (69.659-74.549%).

Biological Source: Dried or wet kernels of a wild grass i. e. *Balsas's teosinte*.



Fig. 02: Maize kernels.

Therapeutic Uses

- Treat liver disorder
- Treat hypertension
- Treat depression

Indication: Used in bakery industry, as well as thickening sauces, gravies.

Side Effects: Increase blood sugar levels.^[10]

3. TARO (ARABI)

Synonyms: Taro, Kalo, Eddy root, Wild taro, Arvi, Talas.

Chemical Constituents: Taro starch contained 96.9 – 98.2% carbohydrates, 0.7–1.9% protein, 0.1–0.3% fat, 0.1–0.9% fiber, 0.1–0.4% ash, and 182.0–200.1 mg/100g.

Biological Source: Dried or wet *Colocasia esculenta* tubers of calcium oxalate.

Indication: Individuals suffering from type-2.

Family: *Araceae* diabetes should regularly vegetable consume this.

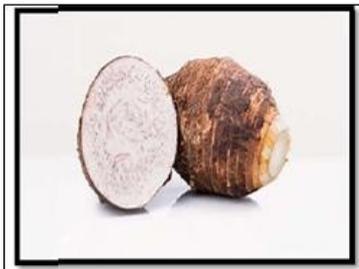


Fig. 03: Taro tuber.

Therapeutic Uses

- Controls blood sugar
- Improves digestive health
- Improves blood circulation.

Side Effects: Can cause burning sensation, irritation.^[11]

DRUG PROFILE

Ketoprofen is a non-steroidal anti-inflammatory

medicine. (NSAIDS).

Chemical Name: 2-(3- benzoylphenyl) - propionic acid.

Molecular Formula: C₁₆H₁₄O₃.

Molecular Weight: 254.29.

It has a pKa of 5.94 in methanol water (31) and an n-octanol water partition measure of 0.97(buffer pH7.4). Ketoprofen is a white or out-white, odorless, non-hygroscopic, fine to grainy greasepaint, melting at about 95 °C.

It's freely answerable in ethanol, chloroform, acetone, and ethers and answerable in benzene and strong alkali, but virtually undoable in water at 20 °C.

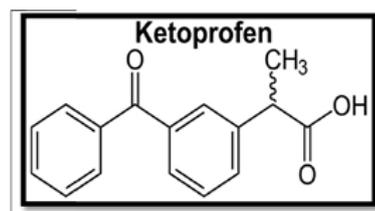


Fig. 04: Structural Formula of Ketoprofen.

MATERIALS

Tuber of Potatoes and Arabi were purchase from local market. And Corn grains were gifted by Mrs. Varsha Patil, Warora. While other required equipment and chemical was obtained from as given following

Table 01: Equipment used in Formulation of Ketoprofen Table.

Electronic weighing balance	Schimadzu, Philippias
Monsanto hardness tester	Inco India
Roche friabilator	DBK, India
Disintegration apparatus	DBK, India
Dissolution apparatus	Lab India, India

Table 02: List of chemical used with their suppliers.

Sr. No.	Materials	Suppliers
1.	Ketoprofen	Zim laboratory, Nagpur
2.	Potato starch	Procure Local Market
3.	Corn starch	Procure Local Market
4.	Taro starch	Procure Local Market
5.	Lactose	R. K. Chemicals India (agpur)
6.	Magnesium Stearate	Research Lab Fine Chemical Ind stries, Mumbai
7.	Talc	Hi media Laboratories Pvt. Ltd

PREPARATION OF NATURAL SUPERDISINTEGRANTS

❖ **POTATO STARCH**



Fig. 05: Isolation of Potato starch.

- Take three medium size potatoes.
- Peel a raw potato and cut into small pieces
- Grind them in a motor sufficient water, and pestle with and record the original weight.
- Then 1 of NaCl result used in the water to proper birth of bounce from the potatoes.
- Also filter the homogenate through a.
- Wash 3 – 4 times and decant the muslin cloth to remove the patches.

- Allow the filtrate to settle. Bounce fleetly settles at the bottom. Decant the bounce free supernatant precisely.

❖ **CORN STARCH**

Supernatant. Collect the compact mass of bounce and allow it to dry.

- Record the final weight of insulated bounce.^[13]



Fig. 06: Isolation of Corn Starch.

- Take a fresh 2-3 corn. (We can use sweet corn or white corn).
- Take out the corn kernels. And remove corn
- Add corn grains into a bowl.
- Add water and clean 1-2 times. Add water
- After extracting starch the residue can be used for compost making.
- Sieve it again using a fine strainer cotton cloth or cheese cloth.

Note: The finer the pores of the strainer, the soak for 1-2 hours.

- If corn is too hard and dry soak for 6 to 12 finer and smoother your corn starch or becomes. hours until them soft.
- After 2 hour corn become soft.
- Remove it from water. Add soaked corn into a Grinding jar.
- Cover and allow it to rest for 1 to 2 hours so that

the starch separates from the water.

- After 2 hours, now the sediments are well.
- Grind the corn in batches; by more starch comes out.
- Add equal amount of water to doing this grind the settled. Pour out the water completely.
- Thick starch settles at the bottom of the bowl. corn and grind until very smooth.
- Remove the yellow liquid, Spread.
- Grind all the corn in same way.
- Add water little by little till all corn starch completely extracted. Keep adding water as required. sediment as a thin layer o a broad plate.
- Sun dry the wet starch for a whole day.
- After 4 hours in Sun drying, once dries it start to develop cracks.
- Collect the corn starch.^[14]

❖ **TARO STARCH (Arabi)**



Fig. 07: Isolation of Taro Starch (Arabi).

Taro tubers was collected and gutted duly washed. After washing external covering sub caste was hulled. The tuber was than sliced and kept for drying at room temperature. After drying, the dried sliced tuber

pieces were

- Performing result was kept overnight.
- On coming day the solid and liquid sub caste gets separated, solid material gets deposited at the bottom of

the glass teacup while the liquid floats at upper face. Crushed in mixer grinder to form the The liquid sub caste is decanted and greasepaint. This greasepaint is further used for birth of bounce. Remaining deposition is washed with excess of water.

ISOLATION BY SIMPLE PROCESS

- After washing the water the bounce greasepaint is decanted and is attained by

PRELIMINARY TESTING OF STARCH MICROSCOPIC VIEW

To see the starch granules under the compound microscope

- Taro greasepaint (50 gm) was dispersed in 100 ml of water taken and filtration through whattman’s sludge paper, greasepaint is kept for drying.
- The admixture was homogenized for about 30 mines, by using homogenizer.
- The attained greasepaint bounce greasepaint. after drying is.



Fig. 08: Prepared Starch Powders of Corn, Potato and Taro.

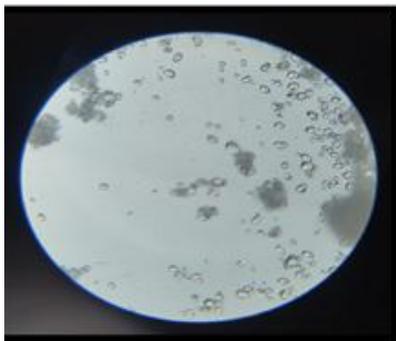


Fig. 09: Globules of Potato Starch.

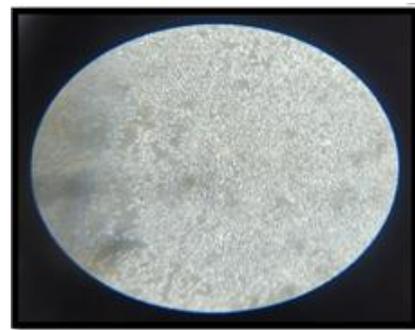


Fig. 11: Globules of Taro Starch.

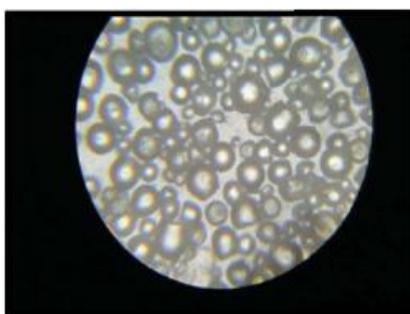


Fig. 10: Globules of Corn Starch.



Fig. 12: Identification tests for Starch.

IDENTIFICATION TEST

Table 03: Identification test for prepared Starch.

Sr. No.	Test	Observation	Conclusion		
			Potato Starch	Corn Starch	Taro Starch
1.	Iodine test	Colour change to blue or black	+	+	+
2.	Mix Water + starch powder and give heat.	Formation of jelly	+	+	+

(Ref. Fig No.11).

METHODOLOGY
FORMULATION OF KETOPROFEN TABLET
USING EXTRACTED STARCH AS NATURAL
SUPERDISINTEGRATING AGENT

Formulation of Ketoprofen tablets is formulated by using extracted Potato Starch, Corn Starch and Taro Starch as Superdisintegrating agents with other excipients. Later on tablet was prepared by Wet granulation methods.

FORMULA

Table 04: Formula for formulation of Ketoprofen Tablet 250 mg IP.

Sr. No.	Ingredients	Category	Con. %	Quantity taken for one tablet (mg)
1.	Ketoprofen	API	10 %	25 mg
2.	Lactose	Diluents	81 %	202.5 mg
3.	Potato / Corn / Taro Starch	Superdisintegrants	07 %	17.5 mg
4.	Talc	Glidant	0.2 %	0.5 mg
5.	Magnesium Stearate	Lubricant	1.8 %	4.5 mg

Each tablet contains 25 mg Ketoprofen.

PRE-COMPRESSION STUDIES

These studies are conducted before compressing the compact mass of a tablet to assess the parcels of the powder mix. The five way involved in these studies are bulk density, tapped density, angle of repose, Carr's index, and Hausner's rate.

Bulk Density

Bulk Density refers to the mass of the greasepaint mix divided by its bulk volume. To measure bulk density, the powder mix is poured into a measuring cylinder, and the original weight is recorded. The volume enthralled by the powder mix is determined using the following formula;

Tapped Density

Tapped density is the rate of the total mass of the powder mix to its tapped volume. Originally, the powder mix is poured into a measuring cylinder. The cylinder is also tapped gently about 500 times on a hard face, and the tapped volume of the greasepaint is noted. However, tapping is repeated 1000 times, and the tapped volume is recorded, If the difference between two volumes is further than 2. Tapping is continued in a bulk density outfit until the difference between posterior volumes is lower than 2. Tapped density is expressed in g/ ml and calculated as follows;

Bulk density = (Mass of Powder) / (Bulk volume of Powder)

Tapped density = (Mass of greasepaint) / (Tapped volume of greasepaint)

Angle of Repose (θ)

The angle of repose is determined using the channel system. The Powder mix is poured through a channel, which can be raised vertically until a specified cone height (h) is attained. The compass of the mound (r) is measured, and the angle of repose (θ) is calculated using the formula

$$\text{Carr's Index} = (Dt - Db) / Dt \times 100$$

Hausner's rate

The Hausner's Ratio (HR) is a circular measure of the ease of greasepaint inflow. It's calculated by dividing the tapped density by the bulk density

$$\theta = \tan^{-1} (h/r)$$

Carr's Index:

Carr's index is used to determine the compressibility and inflow of the powder. It's calculated using the tapped density (Dt) and bulk viscosity (Db) of the powder;

Hausner's ratio = Tapped Density / Bulk Density

These pre-compression studies help in understanding the inflow. Pre-Compression parameter of the mix of the maquillages used for the expression of the tablet by using colorful natural Superdisintegrants was noted in Table 05.^[3]

Table 05: Pre-compression Parameter.

Parameters	Formulations		
	F ₁	F ₂	F ₃
Bulk density (g/cm ³)	0.49	0.42	0.48
Tapped density (g/cm ³)	0.51	0.57	0.58
Angle of repose (°)	25.21	28.39	24.01
Carr's index (%)	22.00	22.8	22.5
Hausner's ratio	0.97	1.35	1.29

PREPARATION OF KETOPROFEN TABLETS BY WET GRANULATION METHOD

- Directly weight amounts of each component were

mixed in mortar.

- An applicable volume of the binder with boiled water (Binder Paste Formulation) was added as

- binding agent and mixed for 20 min in mortar.
- The damped mass was sieve with sieve no. 22 and Dried at 50° C in a hot air roaster.
- The dried grainy mass was passed through sieve no. 40 to gain invariant size grains.

- The batch of the grains and specified quantum of the Talc were also mixed with calculated equal volume of Magnesium Stearate.
- Also compressed under constant pressure into single punch tablet punching machine.^[2]



Fig. 13: Preparation of Granules by Wet Granulation Method.

SINGLE-PUNCH TABLET MACHINE

Tablets are made by compressing a expression tablets in a small period. The compounding containing a medicine or medicines with excipients on a stamping machine called druggist uses a variation of It's called a single- punch these machines. tablet press and presses. Tablet presses are designed with

- 1) Hopper for holding and granulation feeding. pieces of casted tubular essence. The nethermost essence piece has a small depression in one end of the tube; the top essence piece has one end that's phased into a.
- 2) Dies that define the size and shape of the tablet.
- 3) Punches for compressing the granulation within the dies.
- 4) Cam tracks for guiding the movement of the punches.

5) A feeding medium for moving granulation small rod that will just fit into the small depression in the other piece. The rod doesn't go all the way to the bottom of the depression, but leaves a small gap. The punch is fitted into a press so that when the handle is depressed and released, the rod goes into and also comes out of the nethermost piece to make a tablet. A hopper following introduction of the dies the greasepaint material is placed into the.

Tablet punching machines are generally used in the pharmaceutical assiduity. They're high- speed machines that produce thousands of nethermost piece, and the handle is depressed and released. The maquillages are compressed and enthrall the size of the gap designed in the punch.^[2]



Fig. 14: Prepared Ketoprofen Tablets (F₁, F₂, F₃).

EVALUATION PARAMETERS^[2]

The conventional Ketoprofen tablets were evaluated for hardness, friability, weight variation, disintegration and *in vitro* release study.

hardness tester. The tablet was fitted lengthwise between plunger and force applied. Note down the pressure at which the tablet was crushed. It's measured in Kg/ cm². 6 tablets were used for this study.

HARDNESS

The tablet hardness was determined by the Monsanto

Table 06: Hardness test.

Sr. No.	Formulations	Hardness Kg/cm ²			£ Average
1.	F ₁	4.1	4.4	4.2	4.2
2.	F ₂	4.2	4.5	4.5	4.5
3.	F ₃	4.1	4.2	4.2	4.2

- Hardness was found to be acceptable as per pharmacopeial unit.

% FRIABILITY

It is calculated by Roche friability apparatus. Six tablets were subjected to the device which provided a combined effect of shock and abrasion from height of six inches with each rotation, at 25 rpm speed and operated for 100 revolutions. Tablets were dusted and reweighed. Compressed tablets that lose less than 0.5-1.0% of their

weight were generally considered acceptable. It is expressed in percentage (%) and calculated by the following formula:

$$\text{Friability (\%)} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Table 07: % Friability test.

Sr. No.	Description	Weight of tablets (gm)		
		F ₁	F ₂	F ₃
1.	Wt. of 10 tablets before (W ₁)	2.50	2.49	2.50
2.	Wt. of 10 tablets after (W ₂)	2.48	2.47	2.47
3.	Wt. Difference (W ₁ -W ₂)	0.03	0.02	0.03
% Friability		0.801%	0.830%	0.807%

- Friability was found to be acceptable as per pharmacopeial unit.

weight was calculated. The individual weight of each tablet was measured to determine its variation. Weight variation was determined by comparison of individual tablet weight with average weight.

WEIGHT VARIATION

The weight of 20 tablets was measured and average

Table 08: Weight Variation (%) test.

Sr. No.	Weight of tablets W ₁ (gm)			Standard Deviation (+ 5 %)			Result / Remark
	F ₁	F ₂	F ₃	F ₁	F ₂	F ₃	
1.	0.246	0.232	0.234	Lower Limit (LL) = 0.231	Lower Limit (LL) = 0.229	Lower Limit (LL) = 0.231	All tablets were found to be within a range. (S. D. + 5 %), only two was failed. Hence, Weight Variation test was found to be acceptable as per pharmacopeial unit.
2.	0.235	0.241	0.233				
3.	0.251	0.247	0.252				
4.	0.243	0.258	0.241				
5.	0.232	0.235	0.245				
6.	0.241	0.234	0.244				
7.	0.247	0.233	0.259				
8.	0.258	0.252	0.232				
9.	0.235	0.241	0.231				
10.	0.234	0.245	0.236				
11.	0.233	0.244	0.246				
12.	0.252	0.259	0.235				
13.	0.241	0.232	0.251				
14.	0.245	0.231	0.243				
15.	0.244	0.236	0.232				
16.	0.259	0.250	0.241				
17.	0.232	0.246	0.247				
18.	0.231	0.235	0.258				
19.	0.236	0.251	0.235				
20.	0.250	0.243	0.234				
Total	4.845	4.845	4.829	Upper Limit (UL) = 0.254	Upper Limit (UL) = 0.254	Upper Limit (UL) = 0.253	
£ Average Wt. of tablets	0.242	0.243	0.241				

- % Weight Variation (+ 5) was found to be acceptable as per pharmacopeial unit.

containing decomposition medium maintained at 37°C. Start the outfit (to move the hand basket assembly containing the tablets), and record the time needed for all of the six tablets to break into patches and to pass to the decomposition medium.

DISINTEGRATION TIME TEST:

Place one tablet in each of the six tubes of the hand basket (tablets are named aimlessly). The teacup

Table 09: Disintegration time test.

Sr. No.	Formulations	Disintegration Time
1.	F ₁	15 minutes 42 seconds
2.	F ₂	19 minutes 58 seconds
3.	F ₃	10 minutes 24 seconds

- Friability was found to be acceptable as per pharmacopeial unit.

IN VITRO RELEASE STUDY

In vitro release studies were carried out using USP type (paddle type) outfit (electro dissolution tester). Dissolution medium was 900 mL acidic (0.1 N HCL) buffer (pH0.1) with paddle gyration at 75 rpm and temperature was maintained at 37 ± 1°C and the

study was carried out for 12 hrs. Aliquots of 10 mL were withdrawn after each hour and an original quantum of fresh buffer maintained at the same temperature was replaced to maintain sink condition. The samples were anatomized for Ketoprofen content at 254 nm by UV – spectrophotometer and calculated the medicine release using estimation curve of Ketoprofen.

Table 10: Calibration curve of Ketoprofen.

Sr. No.	Concentration (µg/ml)	Absorbance (nm)
1.	0	0
2.	5	0.212
3.	10	0.468
4.	15	0.695
5.	20	0.825
6.	25	1.023

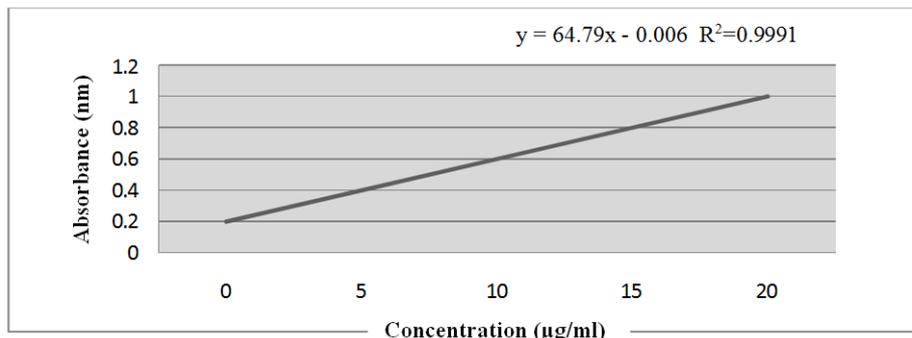


Fig. 15: Calibration curve for Ketoprofen in 0.1 N Hcl (pH 1.2).

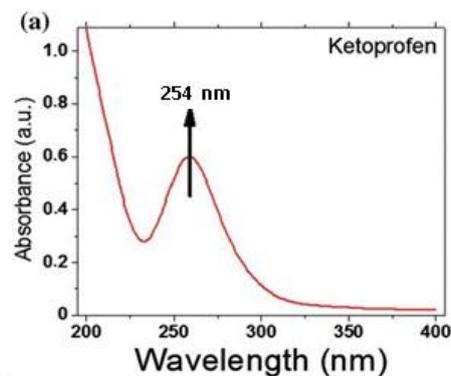


Fig 16: AUC of Ketoprofen (λ_{max}).

Table 11: Concentration V/s Absorbance.

Sr. No.	Concentration (µg/ml)			Absorbance (λ)		
	F ₁	F ₂	F ₃	F ₁	F ₂	F ₃
1.	0	0	0	0	0	0
2.	0.5	0.5	0.5	75	80	77
3.	1.0	1.0	1.0	158	165	160

4.	1.5	1.5	1.5	257	262	258
5.	2.0	2.0	2.0	282	288	284
6.	2.5	2.5	2.5	297	295	296
7.	Unknown			253 nm	255 nm	254 nm

- Unknown concentration was found to be 1.4 µg/ml.

CUMMULATIVE DRUG RELEASE (%)

For F₁ % CDR

Table 12: % CDR at F₁.

Time (min)	Abs. (nm)	Conc ⁿ . (µg/ml)	DF 10x	µg/5ml	C _r 5x	µg/900 ml	C _r 900x	mg/ml	CDR	%CDR
0	0	0	0	0	0	0	0	0	0	0
15	0.021	9.25	92.5	46.25	46.25	8325	83250	83.25	0.333	33.3
30	0.249	11.02	110.2	55.1	96.35	9918	93168	93.168	0.372	37.26
60	0.328	12.38	123.8	61.9	158.25	11142	10431	104.31	0.417	41.72
90	0.498	14.35	143.5	71.75	230	12915	11722	117.22	0.46	46.89
120	0.581	16.61	166.1	83.05	313.05	14949	13217	132.17	0.528	52.86
150	0.592	17.24	172.4	86.2	399.25	15516	14769	147.69	0.590	59.07
180	0.599	18.38	183.8	91.9	491.15	16542	16423	164.23	0.656	65.69

- Dissolution was found to be **65.69 % in 180 minutes** in case of Formulation F₁ Containing potato starch.

For F₂ % CDR

Table 13: % CDR at F₂.

Time (min)	Abs. (nm)	Conc ⁿ . (µg/ml)	DF 10x	µg/5ml	C _r 5x	µg/900 ml	C _r 900x	mg/ml	CDR	%CDR
0	0	0	0	0	0	0	0	0	0	0
15	0.289	9.87	98.7	49.35	49.35	8883	88830	88.83	0.355	35.53
30	0.376	11.78	117.8	58.9	58.9	10602	99432	99.432	0.397	39.77
60	0.485	13.88	138.8	69.4	128.3	12492	11192	111.92	0.447	44.76
90	0.521	15.66	156.6	78.3	206.6	14094	12601	126.01	0.504	50.407
120	0.581	16.78	167.8	83.9	290.5	15102	14112	141.12	0.564	56.44
150	0.593	17.91	179.1	89.55	380.05	16119	15723	157.23	0.628	62.89
180	0.601	19.92	199.2	99.6	479.65	17928	17516	175.16	0.700	70.06

- Dissolution was found to be **70.06 % in 180 minutes** in case of Formulation F₂ Containing Corn starch.

For F₃ % CDR

Table 14: % CDR at F₃.

Time (min)	Abs. (nm)	Conc ⁿ . (µg/ml)	DF 10x	µg/5ml	C _r 5x	µg/900 ml	C _r 900x	Mg/ml	CDR	%CDR
0	0	0	0	0	0	0	0	0	0	0
15	0.292	10.49	104.9	52.45	52.45	9441	94410	94.41	0.377	37.764
30	0.934	13.89	138.9	69.45	69.45	12501	10691	106.91	0.427	42.764
60	0.482	15.98	159.8	79.9	149.35	14382	12129	121.29	0.485	48.517
90	0.556	16.88	168.8	84.4	233.75	15192	13648	136.48	0.545	54.594
120	0.598	17.79	177.9	88.95	322.7	16011	15249	152.49	0.609	60.998
150	0.61	18.93	189.3	94.65	417.35	17037	16953	169.53	0.678	67.813
180	0.66	19.97	199.7	99.85	517.2	17973	18750	187.50	0.750	75.002

- Dissolution was found to be **75.01 % in 180 minutes** in case of Formulation F₃ Containing Taro starch.

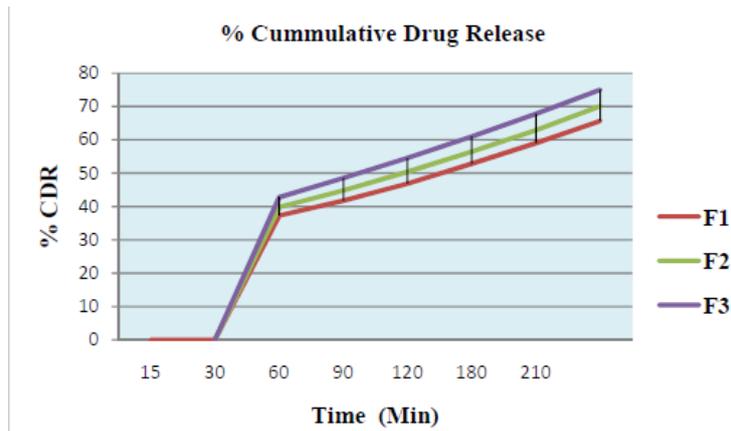


Fig. 17: Graph Between Time V/s %CDR.

RESULT AND DISCUSSION

Table 15: Organoleptic Evaluation.

Evaluation Parameters	Formulations		
	F ₁	F ₂	F ₃
Appearance	Solid, Flat		
Colour	White		
Odour	Odourless		
Shape	Round		

Table 16: QC Test for Ketoprofen conventional tablets.

Evaluation Parameters	Formulations		
	F ₁	F ₂	F ₃
Hardness (Kg/cm ²)	4.2	4.5	4.2
% Friability	0.801%	0.830%	0.807%
% Weight Variation	All tablets were found to be within a range. (S. D. + 5 %), only two was failed.		
% CDR in 3 Hrs	65.69%	70.06%	75.01%
Disintegration time	15 min 42 sec	19 min 58 sec	10 min 24 sec

Evaluations of all the formulations containing different natural superdisintegrants were found to be in an acceptable range.

The hardness of all formulations was found to be in the range of 4 Kg/cm² to 5.42 Kg/cm² and friability was found to be in the range of 0.50% to 0.82%. The weight variation was observed as 1.00 to 1.99%. Disintegration time of conventional tablets was found to be less than 20 min. About 75.01% of the drug was released from the tablets in 3 hours.

SUMMARY

To survey of the various literatures for selection of research domain and studied to get appropriate information about selected domain. Main aim of this study to formulation and evaluation of Conventional tablets of Ketoprofen, Tablets was prepared by using natural superdisintegrants i. e. Potato Starch, Corn Starch and Taro starch. The required starches were isolated from various natural sources like Potato, Corn kernels and Taro tubers. After preliminary testing of isolated starch. The Starch used for preparation of tablet as superdisintegrants by wet granulation method. Prepared tablets of Ketoprofen 250 mg (F₁, F₂, F₃) was

evaluated for Hardness test, % Friability, % weight Variation, Disintegration time test and in vitro drug release studies to decide higher disintegration rate. In Conclusion, Taro starch containing Tablets was optimized as the best formulation with higher Disintegration rate among Potato starch and Corn starch.

DISCUSSION, FUTURE PERSPECTIVES

The present study reveals that results attained showed some differences on the parcels of the bounce attained from Taro and other traditional bounce sources like potato and sludge. Taro has been reported to have 70 – 80 bounce with small grains, Because of the small sizes of its bounce grains, taro is largely digestible. On the base of current evaluation of parcels of bounce it has been set up that taro bounce can be employed as a better disintegrant as compared to the other traditional beans, Beans are used since a long time as excipients in pharmaceutical medications. Substantially sludge bounce, potato bounce and wheat bounce are used and monographic in several pharmacopoeias. The classical functionalities of native beans in the history are paddings and disintegrants in tablets and padding’s in dermatological maquillages. Also modified beans have been used as padding- binders in tablet technology. After

this current exploration exertion Taro bounce can be introduced in the pharmaceutical field and further exploration can be done over this bounce to make it stressed in the arena of pharmaceutical exploration. In addition to food use, taro has set up some artificial operations. The veritably small size of taro bounce grains makes them ideal in ornamental phrasings like face greasepaint and in dusting medications which use aerosol allocating systems. In malignancy of the below uses, the large-scale isolation and application of this bounce isn't rehearsed anywhere. So after this exploration exertion the taro bounce can be brought to the minds of experimenters and it can gain attention in the field of pharmaceutical exploration.

CONCLUSION

The conventional tablets of Ketoprofen (F₁, F₂, F₃) containing Potato starch, Corn starch and Taro (Arabi) starch (Which were used as a natural superdisintegrants) in the ratio of 1:1:1 was prepared and evaluated. Where the F₃ shows better released of drug. About 75.81% of the drug was released from the tablets in 3 hour. Therefore, based on the evaluation parameters and in vitro drug release profile, F₃ formulation containing Taro (Arabi) starch is optimized as the best formulation with high disintegration rate.

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