RESEARCH PAPER

Exploring the Pharmaceutical Potential of Brown Rice Flour as a Natural Filler, Disintegrant, and Lubricant in Tablet Dosage Forms

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ABSTRACT

Background

Due to their biocompatibility, biodegradability, economic feasibility, and eco-friendliness, natural excipients are gaining importance in pharmaceutical formulations. Brown Rice Flour (BRF) exhibits unique characteristics, which can make it an efficient excipient candidate.

Objective

This study was conducted to assess the suitability of Brown Rice Flour as a multifunctional natural excipient in the formulation of immediate-release diclofenac sodium tablets.

Materials and Methods

Brown Rice Flour was assessed for its physicochemical properties and microbial content, as well as compatibility with diclofenac sodium. The immediate release diclofenac sodium tablets were manufactured through wet granulation method. Various experimental batches were prepared by using BRF as filler, disintegrant, and lubricant. Parameters before and after compression were evaluated, then optimized and validated.

Results

Brown Rice Flour possessed good flow properties and adequate drug-excipient compatibility. The formulations possessing BRF had adequate dissolution profile.

Conclusion

Brown Rice Flour is efficiently used as a multifunctional natural excipient in immediate release tablet formulations.

Keywords: Brown Rice Flour, Natural Excipient, Diclofenac Sodium, Immediate Release Tablet, Pharmaceutical Formulation, Natural Disintegrant, Natural Filler, Natural Lubricant.

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1. INTRODUCTION:

1.1 Pharmaceutical Excipients

Excipients are defined as inert materials that are added to pharmaceutical dosage forms in conjunction with APIs to enable easier manufacturing, stability, effective drug delivery, and patient acceptability.[1] Even though excipients lack any direct pharmacological action, their importance cannot be overstated since they affect several attributes including quality, safety, effectiveness, and efficacy of drugs. The manufacture of most pharmaceutical dosage forms is not possible by

solely relying on the active drug due to limitations associated with flow characteristics, compressibility, stability, and consistency of doses.[2] Hence, the need to use excipients to make up for these shortcomings and achieve a successful product.

Since the early days of pharmaceutical formulation, naturally derived excipients like starches, honey, gums, and vegetable extracts have been utilized as vehicles for medicines.[3] As technology in the field developed, several artificial and semi-artificial excipients emerged with improved efficiency. Nowadays, the growing awareness of environmental conservation and the desire by patients to consume natural products have spurred renewed interest in natural excipients.

1.2 Significance of Excipients in Medicines Formulation

Excipients are essential in the manufacturing of medicines and also help to improve the stability, delivery mode, effectiveness, and processability of medicines. Proper selection of excipients in formulations is important due to their impact on parameters such as hardness of the tablet, disintegration, solubility, and the efficacy of the drugs.[4]

Functions of Pharmaceutical Excipients

1. Increasing Bulk and Weight of Medicine Formulation

Some drugs have low amounts necessary for use; thus, there are challenges when trying to formulate such medicines. Diluent excipients ensure the drugs reach appropriate bulkiness and weight required during processing and packaging.[5]

2. Improving Powder Flow Properties

In the formulation of medicines, the powder must be able to flow freely to ensure that the contents are well filled during packaging in a capsule or tablet formulation. Excipients like glidants decrease particle-particle friction, thus improving powder flow properties.[6]

3. Improve Compressibility during Tablet Preparation

There are some active pharmaceutical ingredients that have poor compressibility characteristics, and therefore, they cannot form hard tablets by themselves. The excipients called binders increase the stickiness of particles, and this makes it possible to prepare solid tablets that have enough hardness and mechanical strength.[7]

4. Promote Rapid Disintegration of Tablets after Their Oral Ingestion

As soon as tablets get into the gastro-intestinal tract, they need to break into tiny pieces for the medication to be released. The disintegrating excipients are used for making sure that there is fast disintegration of a pill.[8]

5. Increase Dissolution of a Drug in Water

Some drugs have poor solubility in water, and thus, they are poorly bioavailable. There are some excipients that help in dissolving a drug faster.[9]

6. Protection of Active Drug Molecules against Degradation

Sometimes, there are chances that the drug molecules might be prone to degradation due to factors like moisture, oxygen, light, or even chemical processes. Excipients like antioxidants, preservatives, and stabilizers will prevent drug degradation during their manufacturing, storage, and usage.[10]

7. Enhancement of the Visual Appeal of Pharmaceutical Formulations

Excipients are used to provide color and shine to the formulations and increase their visual attractiveness.[11]

8. Removal of Undesirable Odors and Flavors of Drugs

Many times, drugs have an undesirable smell or bad flavor, and patients would not like to take these formulations. These excipients are added to reduce the bitterness of drugs.[12]

9. Increase Patient Compliance

Excipients increase the acceptability and convenience of the drug by means of better taste, appearance, swallow ability, and performance of the drug. This increases compliance of the patients with the prescribed regimen.[13]

10. Increase the Stability and Shelf-Life of the Product

Excipients are very important for keeping stability in the pharmaceutical product physically, chemically, and microbiologically. Excipients prevent degradation of the product and hence increase the shelf life of the medicine.[14]

1.3 Classification of Pharmaceutical Excipients1.3 Classification of Pharmaceutical Excipients

Pharmaceutical excipients can be classified according to their function in dosage forms:

1. Fillers or Diluents

2. Binders

3. Disintegrants

4. Lubricants

5. Glidants

6. Preservatives

7. Antioxidants

8. Sweetening Agents

9. Flavouring Agents

10. Coating Agents[15]

1.4 Advantages of Natural Excipients over Synthetic Excipients

1.4 Advantages of Natural Excipients over Synthetic Excipients

1. They are biodegradable and environmentally friendly.

2. They are obtained from renewable sources.

3. They exhibit great biocompatibility.

4. They have lower toxicity levels.

5. They are economical and easily accessible.

6. They constitute sustainable sources of raw materials.[16]

7. Improved patient acceptability.

8. Environmentally less burdensome.

9. Pharmaceutical multifunctionality.

10. Green pharmaceutical manufacturing suitability.[17]

1.5 Limitations of Synthetic Excipients

While excipients play a significant role in the formulation of drugs, there are also several limitations in their usage. One of the major disadvantages of using certain specialized excipients is that the process of manufacturing these excipients is very costly because they are used to deliver the drug at a controlled rate, mask tastes, and improve the stability of the drug among others. Such excipients make the pharmaceutical products expensive.

Another disadvantage of using excipients is that chemical processing is required in most cases in order to produce them.[18]

The use of some excipients may also pose certain environmental issues. Environmental pollution may arise as a consequence of the production and disposal of artificial substances, and in some cases, such excipients may be non-biodegradable and, thus, harmful to the environment. Some excipients may cause irritation, sensitivity, or even toxicity in some individuals. Despite the fact that excipients are usually pharmacologically inert substances, there are cases where some chemicals may cause allergic responses and adverse reactions depending on the dosage and the patient. In addition, another limitation of using excipients is associated with their low biodegradability. Most artificial excipients do not biodegrade easily due to their chemical structure.[19]

Significance of Pharmaceutical Excipients

1. Facilitate formulation development.

2. Improve quality of pharmaceutical products.

3. Ensure dose uniformity.

4. Enhance stability and shelf life.

5. Improve bioavailability.

6. Promote patient compliance.

7. Support large-scale manufacturing.

8. Ensure reproducibility of formulations.

9. Improve therapeutic performance.

10. Contribute to product safety and efficacy.[20]

1.6 Relevance of Natural Excipients in the Current Experiment

Due to increasing interest among researchers to use natural and environmentally friendly ingredients in formulations, the need to develop new excipients that are not only natural but also have multiple functionalities has increased. Brown Rice Flour has been proposed as a possible candidate for natural excipients because of the presence of high starch content, multifunctional nature, nutritional benefits, and swelling nature. Its ability to act as a filler, disintegrant, and lubricant can offer an environment-friendly alternative to synthetic excipients.[21]

2. MATERIAL AND METHODS:

Material:

Table 1. Materials Used in the Study

Sr. No.	Material	Function	Supplier/ Manufacturer	Location
1	Diclofenac Sodium	Active Pharmaceutical	Yarrow Chem Products Pvt. Ltd.	Mumbai, India

		Ingredient		
2	Brown Rice Flour	Natural Excipient	Local Market	Maharashtra, India
3	Microcrystalline Cellulose (MCC)	Filler	SD Fine Chem Ltd.	Mumbai, India
4	Lactose	Diluent	SD Fine Chem Ltd.	Mumbai, India
5	Croscarmellose Sodium (CCS)	Superdisintegrant	Signet Chemical Corporation Pvt. Ltd.	Mumbai, India
6	Polyvinylpyrrolidone K30 (PVP K30)	Binder	Loba Chemie Pvt. Ltd.	Mumbai, India
7	Starch	Binder/Disintegrant	SD Fine Chem Ltd.	Mumbai, India
8	Talc	Glidant	Loba Chemie Pvt. Ltd.	Mumbai, India
9	Magnesium Stearate	Lubricant	Signet Chemical Corporation Pvt. Ltd.	Mumbai, India
10	Potassium Dihydrogen Phosphate	Analytical Reagent	Loba Chemie Pvt. Ltd.	Mumbai, India
11	Sodium Hydroxide	Analytical Reagent	Loba Chemie Pvt. Ltd.	Mumbai, India
12	Distilled Water	Analytical Reagent	Prepared in Laboratory	—

2.2 Method of Preparation of Tablets by Wet Granulation Method

1. Weighing of Ingredients: All the ingredients, both drug and excipients, are weighed accurately as per requirement.
2. Sieving of Materials: The drug and excipients are sieved in order to get rid of any lumps and to obtain a uniform particle size.
3. Dry Blending: The active drug ingredient along with the excipients, like diluent and disintegrants, is blended in order to have a uniform powder blend.
4. Preparation of Binder Solution: The binding agent is made up in a suitable solvent, which is usually water, in order to obtain a binding solution.
5. Wet Granulation Process: Binding solution is gradually added to the powder blend and mixed continuously in order to form a wet mass.
6. Screening of Wet Mass: The wet mass is sieved to make wet granules having a uniform size.
7. Drying of Wet Granules: The wet granules are dried in order to attain the required moisture level in them.

8. Sizing of Granules: The granules after drying are subjected to further sizing through another finer mesh in order to break apart any agglomerates.[22]

9. Pre-lubrication of Granules: Pre-lubricants like talc are added to the dried granules to improve their flow characteristics.

10. Lubrication of Granules: Lubricants such as magnesium stearate are added to the granules to make them easy to compress.

11. Compression of Granules: The lubricated granules are now subjected to compression by means of a tableting machine.[23]

Table no. 5 (a): Trial batches

Batch	**Diclofena**	**BRF(Dr**	**MCC**	**Lacto**	**CCS**	**Starch**	**PVPK30**	**Talc**	**BRF(Pr**	**MgStea**	**BRF(Lu**	**TotalW**

	cSodium	**yMix)**		**se**					**e-Lub.)**	**rate**	**b.)**	**t.**
KK01	50	80.5	-	-	7.5	7.5	-	3	-	1.5	-	150
KK02	50	-	80.5	-	7.5	7.5	-	3	-	1.5	-	150
KK03	50	44	44	-	-	7.5	-	3	-	1.5	-	150
KK04	50	40.25	40.25	-	7.5	7.5	-	3	-	1.5	-	150
KK05	50	88	-	-	-	7.5	-	3	-	1.5	-	150
KK06	50	83.5	-	-	-	-	7.5	-	7.5	-	1.5	150
KK07	50	90.5	-	-	-	5	-	3	-	1.5	-	150
KK08	50	80.5	-	-	-	7.5	-	3	7.5	1.5	-	150
KK09	50	83	-	-	-	5	-	3	7.5	1.5	-	150
KK10	50	90	-	-	-	-	5	3	-	1.5	-	150
KK11	50	88.5	-	-	-	-	7.5	3	-	1.5	-	150
KK12	50	7.5	80.5	-	-	7.5	-	3	-	1.5	-	150
KK13	50	5	80.5	-	-	7.5	-	3	2.5	1.5	-	150
KK14	50	5	-	80.5	-	5	-	3	5	1.5	-	150
KK15	50	7.5	80.5	-	-	5	-	3	2.5	1.5	-	150
KK16	50	5	80.5	-	-	7.5	-	-	5.5	1.5	-	150
KK17	50	7.5	80.5	-	-	-	7.5	3	-	1.5	-	150
KK18	50	5	-	80.5	-	-	5	3	5	1.5	-	150
KK19	50	5	80.5	-	-	7.5	-	-	7.5	1.5	-	150
KK20	50	15	76	-	-	7.5	-	-	-	1.5	-	150
KK21	50	7.5	76	-	-	5	-	2.5	7.5	1.5	-	150
KK22	50	15	76	-	-	5	-	2.5	7.5	1.5	-	150
KK23	50	-	80.5	-	7.5	7.5	-	3	-	-	1.5	150
KK24	50	-	76	-	-	7.5	-	-	15.5	1.5	-	150
KK25	50	-	76	-	-	7.5	-	9	-	-	7.5	150
KK26	50	-	78.5	-	-	7.5	-	9	-	-	5	150
KK27	50	-	82.5	-	-	7.5	-	5	-	-	5	150
KK	50	-	85	-	-	7.5	-	2.5	-	-	5	150

28												
KK29	50	-	82.5	-	-	7.5	-	2.5	-	-	7.5	150
KK30	50	-	82.5	-	-	-	7.5	2.5	-	-	7.5	150
KK31	50	26.83	26.83	26.83	5	-	5	3	5.01	1.5	-	150
KK32	50	26.83	26.83	26.83	5	5	-	3	5.01	-	1.5	150

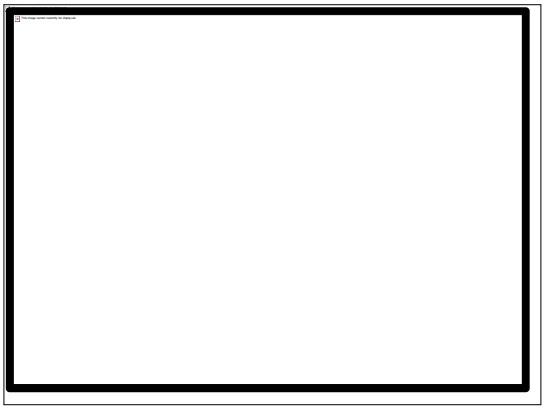

Fig no. 2 Formulation of diclofenac tablets using natural excipients.

3. RESULT AND DISCUSSION:

3.1 Pre-formulation studies for the tablets:

1. FT-IR studies:

FTIR analysis was performed to study the compatibility between Diclofenac Sodium and Brown Rice Flour. Samples of pure drug, Brown Rice Flour, and their physical mixtures were finely triturated and mixed with potassium bromide (KBr). The mixture was compressed into pellets and scanned using an FTIR spectrophotometer in the range of 4000–400 cm^{-1}. The obtained spectra were compared for any shift, disappearance, or appearance of new peaks indicating interaction[24]

Fig. no. 11: FTIR of Brown Rice Flour

Table: Major FTIR Peaks of Brown Rice Flour

Functional Group	Characteristic Peak (cm^{-1})
O–H Stretching	3270–3400
C–H Stretching	2920–2935
C=O Stretching	1630–1650
C–O Stretching	1020–1150

FTIR OF BROWN RICE FLOUR & DICLOFENAC SODIUM

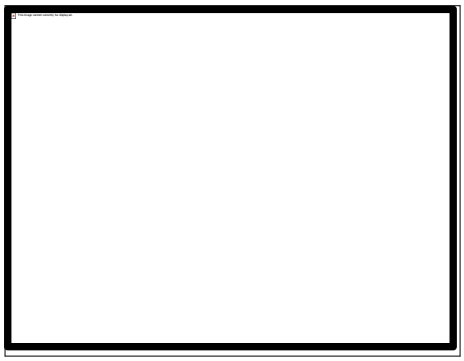

Fig. no. 12: FTIR of Brown Rice Flour and Diclofenac

Table: Major FTIR Peaks of Diclofenac Sodium

Functional Group	Characteristic Peak (cm^{-1})
N–H Stretching	3380–3395
Aromatic C–H Stretching	3060–3070
C=O / COO^- Stretching	1570–1605
Aromatic C=C Stretching	1450–1500
C–Cl Stretching	740–760

FTIR Compatibility Result

Sample	Observation
Brown Rice Flour	Characteristic peaks observed
Diclofenac Sodium	Characteristic peaks observed
Brown Rice Flour + Diclofenac Sodium	All major peaks retained without significant shift

There were no significant changes to the characteristic peaks of Diclofenac Sodium when mixed with Brown Rice Flour, which indicates a

good compatibility and no reaction at all between the two. The results of FTIR analysis proved that there was no reaction between Diclofenac Sodium and Brown Rice Flour. This was shown by the lack of any significant change in the characteristic peaks of the drug.

3.2 Evaluation of all the 32 batches:

Table A. Pre-Formulation Evaluation (Granular Characteristics)

Batch	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)	Flow Property
KK01	0.50	0.58	12.00	1.13	32	Good
KK02	0.42	0.45	6.66	1.07	34	Good
KK03	0.50	0.53	5.66	1.06	27	Excellent
KK04	0.53	0.62	14.50	1.16	31	Good
KK05	0.66	0.71	7.40	1.07	26	Excellent
KK06	0.55	0.58	5.17	1.05	29	Excellent
KK07	0.51	0.60	15.03	1.17	35	Good
KK08	0.43	0.49	12.24	1.09	25	Excellent
KK09	0.53	0.62	14.50	1.16	31	Good
KK10	0.49	0.56	12.50	1.14	33	Good
KK11	0.63	0.73	13.69	1.15	33	Good
KK12	0.46	0.50	8.00	1.08	31	Good
KK13	0.47	0.50	8.00	1.06	26	Excellent
KK14	0.52	0.60	13.33	1.15	34	Good
KK15	0.42	0.49	14.28	1.16	35	Good
KK16	0.63	0.77	18.18	1.22	37	Fair
KK17	0.49	0.59	16.94	1.22	38	Fair
KK18	0.65	0.75	13.33	1.15	32	Good
KK19	0.50	0.58	13.79	1.16	31	Good
KK20	0.52	0.60	13.33	1.15	34	Good
KK21	0.47	0.55	14.54	1.17	35	Good
KK22	0.42	0.49	14.28	1.16	32	Good
KK23	0.47	0.55	14.54	1.17	31	Good
KK24	0.52	0.61	14.75	1.17	33	Good
KK25	0.54	0.63	14.28	1.16	35	Good
KK26	0.53	0.60	11.66	1.13	31	Good
KK27	0.47	0.55	14.54	1.17	33	Good
KK28	0.51	0.58	12.06	1.13	34	Good
KK29	0.53	0.62	14.50	1.16	31	Good
KK30	0.49	0.59	16.94	1.20	37	Fair
KK31	0.55	0.70	21.42	1.27	41	Passable
KK32	0.48	0.61	21.31	1.27	42	Passable

Table B. Post-Formulation Evaluation (IPQC Evaluation of Tablets)

Batch	Hardness	Thickness	Disintegration	Friability	Drug Re	Assay	Weight

	(kg/cm²)	(mm)	Time	(%)	lease (%)	(%)	(mg)
KK01	8	6	4 min	Nil	75.80	95	152
KK02	7	8	45 sec	Nil	70.85	92	154
KK03	6.5	8	25 sec	0.01	75.35	94	142
KK04	7	8	42 sec	Nil	78.40	91	145
KK05	6	6	13 min	Nil	76.00	93	155
KK06	7	6	3 min	Nil	78.00	92	149
KK07	8.5	8	14 min	Nil	75.60	90	152
KK08	6	7	6 min	0.02	75.60	90	154
KK09	6	8	4 min	Nil	72.00	98	148
KK10	8	8	14 min	Nil	69.00	92	155
KK11	7	8	14.5 min	Nil	74.50	95	145
KK12	7	9	36 sec	Nil	71.41	95	150
KK13	8	8	1 min 5 sec	Nil	79.92	98	153
KK14	6	8	45 sec	0.02	71.41	95	155
KK15	8.5	8	46 sec	Nil	72.79	93	152
KK16	6	8	41 sec	Nil	110.95	95	145
KK17	11	8	13 min	0.01	74.35	91	149
KK18	8	8	6 min	Nil	66.39	96	152
KK19	8	8	50 sec	Nil	76.00	96	153
KK20	7	6	1.3 min	Nil	71.00	95	150
KK21	6	6	40 sec	Nil	78.00	97	146
KK22	6	6	1.1 min	Nil	70.00	91	153
KK23	6	6	40 sec	Nil	78.00	97	152
KK24	7	6	3 min	0.03	76.00	93	155
KK25	5	8	2.5 min	0.02	80.00	93	153
KK26	6	7	2 min	Nil	85.00	94	154
KK27	7	6	6 min	Nil	79.00	94	152
KK28	6	6	4 min	Nil	83.00	92	150
KK29	5	6	3.4 min	Nil	78.50	98	148
KK30	6	6	3.2 min	Nil	74.00	91	155
KK31	9	7	3 min 3 sec	Nil	17.58	92	150
KK32	9	8	4 min	0.02	75.87	98	148

3.3 Pre-Evaluation (Granule Evaluation) Parameters of Optimized Batch

1. Angle of Repose

Procedure: Granules were allowed to flow through a funnel to form a cone, and the angle between the surface of the pile and horizontal plane was calculated.[25]

Result:

Batch	Angle of Repose
KK01 (Filler)	32°
KK13 (Disintegrant)	26°
KK26 (Lubricant)	31°

Flow property: KK01 – Good; KK13 and KK26 – Excellent.

2. Bulk Density

Procedure: 10 g granules were poured into a

graduated cylinder and the occupied volume was recorded. Bulk density was calculated as weight divided by bulk volume.[26]

Result:

Batch	Bulk Density (g/ml)
KK01	0.53
KK13	0.46
KK26	0.53

3. Tapped Density

Procedure: The graduated cylinder containing granules was tapped until constant volume was obtained and tapped density was calculated.[27]

Result:

Batch	Tapped Density (g/ml)
KK01	0.62
KK13	0.50
KK26	0.60

4. Carr's Compressibility Index

Procedure: Carr's index was calculated using bulk density and tapped density values to determine flowability and compressibility of granules.[28]

Result:

Batch	Carr's Index (%)
KK01	14.5
KK13	8.0
KK26	11.66

5. Hausner's Ratio

Procedure: Hausner's ratio was calculated by dividing tapped density by bulk density.[29]

Result:

Batch	Hausner's Ratio
KK01	1.16
KK13	1.06
KK26	1.13

3.4 Evaluation Parameters of Optimized Tablets (IPQC Evaluation)

Table: Evaluation Parameters of Optimized Diclofenac Sodium Tablet Formulations

Sr. No.	Evaluation Parameter	Procedure	KK01 (BRF as Filler)	KK13 (BRF as Disintegrant)	KK26 (BRF as Lubricant)
1	Thickness (mm)	Ten tablets were selected randomly and thickness was measured using a Vernier caliper.	6	8	8
2	Hardness (kg/cm²)	Hardness was measured using a Monsanto hardness tester.	7	8	8
3	Friability (%)	Six tablets were rotated in a Roche friabilator at 25 rpm for 4 min and percent friability was calculated.	Nil	Nil	Nil
4	Disintegration Time	Six tablets were tested using the IP disintegration apparatus and disintegration time was recorded.	3.5 min	1 min	1 min 2 sec
5	In-Vitro Drug Release (%)	Dissolution study was performed and cumulative	76.00	80.92	84.00

		drug release was measured after 30 min.			
6	Assay (%)	Drug content was determined and expressed as percentage assay of Diclofenac Sodium.	96	97	94
7	Weight Variation (mg)	Twenty tablets were weighed individually and compared with IP limits.	145	150	154

All formulations complied with the pharmacopoeia requirements for weight variation (150 ± 10%) and exhibited acceptable tablet characteristics. Among the optimized batches, KK13 showed the fastest disintegration, whereas KK26 exhibited the highest drug release.

3.3 Validation Study of Optimized Batches (KK01, KK13 and KK26)

The optimized formulations were prepared repeatedly (R1–R5) to confirm the reproducibility and reliability of the formulation process. The validation batches were evaluated for hardness, thickness, friability, disintegration time, drug release, assay, and weight variation.[30]

Sr. No.	Validation Parameter	Procedure	Result
1	Thickness	Ten tablets from each validation batch were measured using a Vernier caliper.	Thickness remained consistent within acceptable limits for all validation batches.
2	Hardness	Tablet hardness was determined using a Monsanto hardness tester.	All validation batches showed uniform hardness indicating good mechanical strength.
3	Friability	Tablets were rotated in a Roche friabilator at 25 rpm for 4 min and percentage weight loss was calculated.	Friability was negligible and within the IP limit (<1%) for all batches.
4	Weight Variation	Twenty tablets were weighed individually and compared with the average weight.	All validation batches complied with IP specifications for weight variation.
5	Disintegration Test	Six tablets were tested using the IP disintegration apparatus and disintegration time was recorded.	KK01: 3–4 min; KK13: 1–1.05 min; KK26: 1–1.05 min, showing reproducible disintegration behavior.
6	Assay	Drug content was determined and expressed as percentage of labeled amount.	Drug content of all validation batches was within the acceptable range of 90–110%.
7	In-vitro Dissolution Study	Drug release was evaluated using USP Type-II dissolution	KK01 showed ~76% release, KK13 ~80%, and

		apparatus in phosphate buffer pH 6.8.	KK26 ~84–85% release within 30 min.
8	Reproducibility Study	Five replicate batches (R1–R5) of optimized formulations were prepared and evaluated.	Results showed minimal batch-to-batch variation, confirming formulation reproducibility and process reliability.

The validation batches (R1–R5) of optimized formulations KK01, KK13, and KK26 demonstrated consistent tablet characteristics, satisfactory drug release, and reproducible performance, confirming the reliability of Brown Rice Flour as a pharmaceutical excipient.

3.5 Stability Studies

Procedure

The optimized Immediate Release (I.R.) tablet batches (KK01, KK13 and KK26) were packed in suitable containers and stored at **40 ± 2°C / 75 ± 5% RH for 28 days** (accelerated condition) and at **2–8°C for 24 hours** (refrigerated condition). After one month, the formulations were evaluated for pre-compression and post-compression parameters. No significant changes were observed, indicating good stability of the formulations.[31]

Stability Study Results of Optimized Batches

Parameter	**KK01 (Initial)**	**KK01 (After 28 Days)**	**KK13 (Initial)**	**KK13 (After 28 Days)**	**KK26 (Initial)**	**KK26 (After 28 Days)**
Angle of Repose (°)	28.6	28.8	27.9	28.1	29.2	29.4
Bulk Density (g/ml)	0.48	0.48	0.49	0.49	0.47	0.47
Tapped Density (g/ml)	0.56	0.56	0.57	0.57	0.55	0.55
Carr's Index (%)	14.28	14.30	14.03	14.05	14.54	14.56
Hausner's Ratio	1.1 6	1.1 6	1.1 6	1.1 6	1.1 7	1.1 7
Size & Shape	Circular	Circular	Circular	Circular	Circular	Circular
Weight Variation (mg)	150.1 ± 1.8	150.0 ± 1.9	149.8 ± 1.6	149.7 ± 1.7	150.3 ± 1.5	150.2 ± 1.6
Thickness (mm)	6.0	6.0	8.0	8.0	8.0	8.0
Hardness (kg/cm^2)	4.2	4.1	4.5	4.4	4.3	4.2
Friability (%)	0.58	0.60	0.52	0.54	0.55	0.57
Disintegration Time (sec)	62	64	48	50	70	72
Drug Release at 30 min (%)	98.4	97.9	99.1	98.7	97.6	97.1
Assay (%)	99.4	99.1	99.8	99.5	99.2	98.9

No change in the angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, weight variation, thickness, hardness, friability, disintegration time, drug release and assay values were noted when I.R. tablets were stored under accelerated and refrigerated conditions, proving the stability of optimized I.R. tablet formulations (KK01, KK13 and KK26) over the duration of the experiment.

4. CONCLUSION:

Among all the optimized formulations, Batch KK13 exhibited favorable tablet properties such as fast disintegration, hardness, friability, uniformity, good drug release, etc., making it the best optimized batch. Hence KK13 was found to be the best optimized formulation among the formulations screened and tested. The current investigation assessed the feasibility of using Brown Rice Flour as a natural excipient in the formulation of Diclofenac Sodium Immediate Release Tablets. Brown Rice Flour has been used as a filler, disintegrating agent, and lubricant in the development of 32 formulations. FTIR results showed compatibility of Diclofenac Sodium with Brown Rice Flour, implying that no interactions occurred between the drug and the excipients.

All of the formulations tested were found to have better performance by Batch KK13, where Brown Rice Flour is used as the disintegrant (both intra- and extra-granularly). Batch KK13 possesses suitable

flowability, appropriate mechanical strength, fast disintegration, efficient drug release, and storage stability even under accelerated conditions. Further investigations into the stability of the formulation indicated that no changes occurred in either physical properties or drug release.

As such, it can be concluded that Brown Rice Flour has the ability to act as a multifunctional natural excipient. The outstanding properties of Brown Rice Flour as a disintegrant in Batch KK13 indicate that it can be used as a safe, economical, and sustainable alternative to artificial excipients for immediate-release tablets.

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6. CONFLICTS OF INTEREST:

The authors declare that there is no conflict of interest regarding the publication of this research work. The study was conducted solely for academic and scientific purposes, and no financial or commercial interests influenced the research outcomes.

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