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Formulation and evaluation of paracetamol tablets by using natural binders

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Abstract
Using two distinct natural binders aliv and basil a laboratory study was conducted to assess the impact of binder on the physico-chemical characteristics and quality of paracetamol tablets made via the wet granulation method. Tablets account for more than 70% of drug dosage forms due to their superior dose accuracy, stability, affordability, large-scale manufacturing, variety of drug release mechanisms, simplicity of transportation, and patient compliance. Binder is one of the primary components combined with the medication during tablet dosage form production, and it is crucial to the tablets' intended quality [14].
The aim of this study was to evaluate the binder effects of living powder and basil, which are used as food and pharmaceutical excipients due to their affordability, biocompatibility, and biodegradability. The physical characteristics of the tablets (weight, hardness, thickness, friability, content uniformity, disintegration, and dissolution) and granules (bulk density, tapped density, Carr's index, flow rate, and angle of repose) were evaluated [11]. All pre-compression and post-compression parameter results fell within an acceptable pharmacopoeia range. In dose form, aliv and basil work incredibly well as binders [10].

Keywords: Aliv, basil, binder, dissolution, disintegration, assay

Introduction
The primary uses of paracetamol are as an analgesic and an antipyretic [8]. Tablets are the most cost-effective, easily transportable, and patient-complied oral solid dosage forms available. Tablets are solid masses created by using a tablet machine to condense appropriately prepared medication (Granules). The amount that is labeled and the body's ability to absorb it are two factors that affect how clinically effective a tablet formulation is. The primary goal of an oral tablet is to enter the body through the gastrointestinal tract in a specific quantity to provide a therapeutic effect.
Excipients are materials that are used with the active ingredient in a medication to provide long-term stability and to bulk up solid formulations that contain potent active agents in small amounts. Examples of these materials include lubricants, binders, and disintegrants. Tablet quality is influenced by type, quantity, and method of adding binder. As a result, the final tablet performance is greatly influenced by the binder selection [1].
The primary component utilized in tablet formulation to improve granule cohesion is a binder [7]. This guarantees that, even after compression, the tablet will not break [5]. In order to make tablets with homogeneous medication content and consistent weight, the flowability qualities are crucial. To achieve physical stability and compaction of tablets, the compaction qualities are crucial [6].

Advantages
1. Improved granule cohesiveness and agglomeration.
2. No adverse effects.
3. More economical and effective.
4. Good hardness.

Materials
Basil seeds, Aliv seeds were purchased from market, Paracetamol, acetone, lactose, talc,

magnesium stearate,. All other reagents were of analytical quality [9].

Natural binders used in the formulation of tablets

Alive seed

Synonym: Halim seed

Biological source: Lepidium sativum

Family: Brassicaceae.

Uses

1. Increase defenses against infection.
2. Treat anemia.
3. Keep your skin well-hydrated.
4. Preventing dryness of skin.

Fig 1: Aliv seeds.

Basil seeds

Synonym: Sabja

Biological source: Ocimum bascilicum

Family: Lamiaceae

Uses

1. Serves as the body's natural coolant.
2. Lowers the levels of blood sugar.
3. Attenuates acidity.
4. Helpful for losing weight.
5. May lower the chance of developing heart disease.

Fig 2: Basil seeds

Paracetamol

It is one of the most effective over the counter Analgesic antipyretic drug.

Lactose

Work as a disintegrant and diluent. When there is relatively little medication in each tablet, the diluent is required to increase the weight. Fillers called diluent are used to give tablets the necessary weight.

Talc

Talc functions as a lubricant to lessen friction within the joint during compression and between the tablet and die wall while the tablet is being ejected.

Magnesium stearate

Magnesium stearate work as Glidant to increase the flow properties of granules.

Formula

Ingredients	(500mg) Quantity in mg for 1 tablet	(500mg) Quantity in gm for 40 tablet	Uses
Paracetamol	500 mg	20 gm	Drug
Lactose	187.5 mg	7.5 gm	Diluent/Disintegrent
Aliv/Basil	24 mg	0.96 gm	Binder
Talc	20 mg	0.8 gm	Glidant
Magnesium stearate	6 mg	0.24 gm	Lubricant
Distilled Water	Q.s	Q.s	Binding agent

Methodology

Powder preparation of the binders

- **Step 1:** Weigh five grams of basil and Aliv seeds.
- **Step 2:** Use a mortar and pestle to agitate it.
- **Step 3:** To create homogenous particles, pass it through filter number 80.
- **Step 4:** Add 10 ml of acetone to eliminate any lipids that may be present.

Wet Granulation

1. In a mortar and pestle, combine the lactose, paracetamol, and Aliv/Basil powder (Binder). Mix thoroughly, then strain the mixture through sieve no. 80 to create a homogenous mixture.
2. Include Q.S. distilled water, thoroughly combine, and create a moist mass.
3. To create the granules, pass the moist substance through sieve no. 20.
4. After that, the granules are dried for 30 minutes at 60 °C in a hot air oven.
5. Move the dried grains through sieve no. 30 to get uniform mixture.
6. Add Magnesium stearate and talc in it.

Tablet Compression

1. Then granules are compressed in tablet punching machine (According to size and shape).
2. Formation of 500mg paracetamol tablets (3).

Evaluation Parameters

Evaluation parameters of granules

Particle size distribution of the granule

After the granules were weighed and shaken for ten minutes, the particle size distribution of the granules was ascertained using mesh analysis with a stack of sieves. Using

gravimetric analysis, the granule counts on each sieve were determined [2]

Bulk Density: After being accurately measured on a chemical scale, 14.75g of granules were put into a 100 ml measuring cylinder. Three times, at intervals of two seconds, the cylinder was dropped from a height of 2.5 cm onto a wooden platform. The bulk volume is defined as the volume that the granules occupy [16].

Formula
Bulk Density = Mass of powder/Volume of powder

Tapped Density: The density that can be obtained by pouring or tapping a container containing a powder sample mechanically over 100 times [12].

Formula
Tapped Density = Mass of powder/Tapped Volume

Carr`s Index: Carr's index can be determined by bulk density and taped density measurement [13].

Formula
Carr`s Index = Tapped Density- Bulk Density/ Tapped Density

Hausner`s ratio: This is to determine exactly how much porosity-or void space a powder contains [4].

Formula
Hausner`s ratio = Tapped Density / Bulk Density

Angle of repose (°)
A retort stand was clamped over a blocked glass funnel with 14.75 grams of the granules within, 2 cm away from a flat surface. After that, the block was removed, allowing the granules to pass through the funnel opening, which had a diameter of roughly 1.5 cm. Both the radius and the height (h) of the heap that was created were recorded. The formula [4] was used to compute the angle of repose (°) was calculated according to the formula [4].

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

Where,
θ-Angle of repose
h – Height of the heap

Table 1: Evaluation tests of granules.

Parameters	Aliv	Basil
Bulk Density	0.513 gm/ml	0.493 gm/ml
Tapped Density	0.573 gm/ml	0.565 gm/ml
Carr`s Index	10.47%	12.74%
Hausner`s ratio	1.11%	1.14%
Angle of repose	28.81°	29.24°

Evaluation parameters of tablets
Weight Variation test: From each batch, twenty tablets were selected at random and subjected to an individual gravimetric assessment using an analytical balance. We computed the weight mean and standard deviation [5].

Formula

Weight Variation = (Iw-Aw)/Aw x 100% where, Iw = Individual weight of tablet
Aw = Average weight of tablet

Table 2: Weight variation test of the tablets.

No. of Tablets	Aliv	Basil
1	0.581	0.583
2	0.574	0.592
3	0.593	0.571
4	0.567	0.549
5	0.578	0.567
6	0.589	0.549
7	0.567	0.574
8	0.549	0.582
9	0.590	0.590
10	0.575	0.574
11	0.546	0.581
12	0.592	0.584
13	0.583	0.593
14	0.568	0.581
15	0.589	0.567
16	0.584	0.578
17	0.574	0.575
18	0.568	0.689
19	0.553	0.546
20	0.554	0.571

Weight variation test of basil and aliv tablet formulation was found to be 5%.

Hardness test
For this test, five tablets at random were selected from each formulation. The hardness was measured using a tablet hardness tester. The tester's tablet was positioned between the spindle and anvil, and the calibrated length was set to zero. The diametric compression force applied to the tablet was then measured in kg/units, and the position on the calibrated length at which the tablet broke was noted. Each batch's mean hardness was determined, and from there, the standard deviations and coefficient of variations were computed [15].

Table 3: Hardness test

No. of Tablets	Aliv	Basil
1	3.7 Kg/cm2	3.8 Kg/cm2
2	3.7 Kg/cm2	3.6 Kg/cm2
3	3.8 Kg/cm2	3.9 Kg/cm2
4	3.7 Kg/cm2	3.8 Kg/cm2
5	3.8 Kg/cm2	3.9 Kg/cm2

Dimension and thickness test
Using a vernier caliper and micrometer screw gauge, the diameter and thickness of the tablets were measured [2].

Table 4: Dimension and thickness test

No. of Tablets	Aliv	Basil
1	12 - 4 mm	12 - 4 mm
2	12 – 4 mm	12 - 4 mm
3	12 – 4 mm	12 - 4 mm
4	12 – 4 mm	12 - 4 mm
5	12 – 4 mm	12 - 4 mm

Friability test
The apparatus utilized for this test was the Friability Test apparatus. A total of twenty tablets were chosen at random,

dust-packed, and weighed using an electronic balance before being put inside the friabualtor. For four minutes, the machine ran at 25 rpm for 100 revolutions. Once more, the tablets were meticulously dedusted and weighed. For each pill formulation, the percentage losses were computed. Friability given as a percentage of weight loss. The test was conducted three times, and the average was found [15].

Formula
Weight loss = W1-W2/W1 x 100

Where
W1-Initial weight
W2- Final weight

Table 4: Friability test

Parameters	Aliv	Basil
Friability	0.2% w/w	0.7% w/w

Disintegration test

It was a Disintegration Test System machine. 900 ml of water that was kept at a constant 37 ºC was the disintegration medium that was utilized in the experiment. Six tablets were randomly chosen from each formulation and one was placed in each of the basket's cylindrical tubes before the discs were added to each basket. It was timed how long it took for each tablet to disintegrate into tiny pieces and escape through the mesh. For every batch, the mean disintegration time was determined [15].

Table 5: Disintegration test

No. of Tablets	For Aliv time in min	For Basil time in min
1	12.53 sec	11.58 sec
2	14.09 sec	12.10 sec
3	14.22 sec	12. 35 sec
4	13.49 sec	12. 02 sec
5	12.59 sec	11.47 sec
6	13.04 sec	12. 25 sec

Disintegration test of both aliv and basil formulation was passed. Tablets of both formulation were disintegrated within 15 min.

Dissolution test (Rotating paddle method)

The dissolving medium was phosphate buffer (pH 6.8). For one tablet of each formulation, a dissolution test was conducted. As per the protocol, six beakers containing 900ml of phosphate buffer (pH 6.8) were filled with the dissolution apparatus. Each formulation was given one tablet, which was then put in a beaker. After then, the paddle rotated at a certain speed. Five milliliter samples were taken out at certain intervals (t10, t20, t30, t40, t50, and t60), diluted six times, and then their paracetamol concentration was measured using spectrophotometry at 256 nm [15].

Phosphate buffer

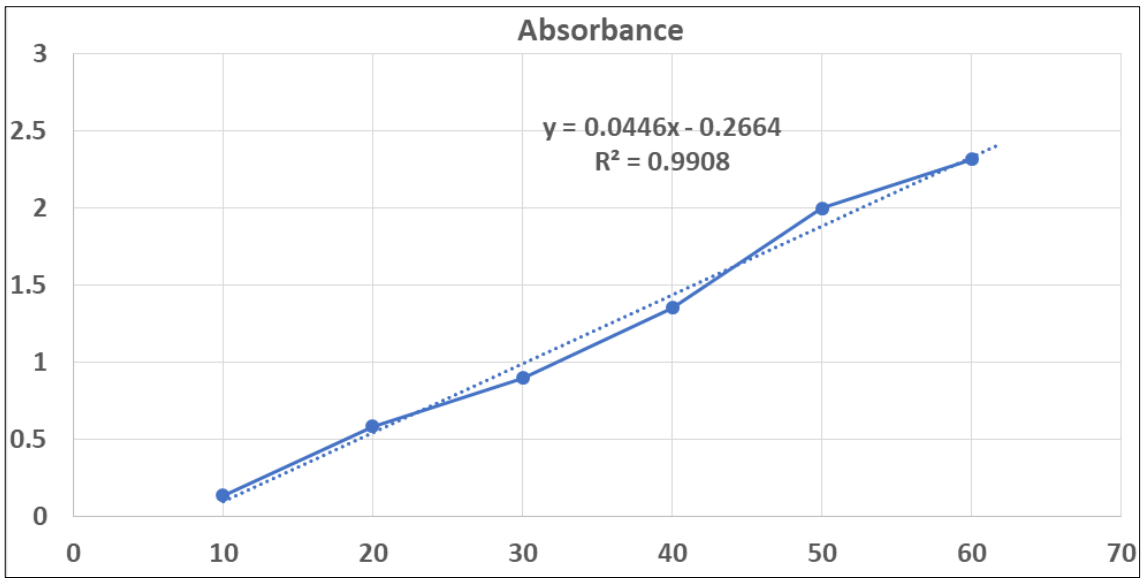
In a 200 ml volumetric flask, add 50 ml of 0.2 M potassium dihydrogen phosphate, the prescribed amount of 0.2 M sodium hydroxide (Found in the table), and distilled water to fill the remaining 200 ml [17].

Formula

Y = mx+c
M = slope
C = y-intercept

1. Concentration = Absorbance / Slope
2. Amount of drug release = Concentration * Volume of dissolution medium/1000
3. % drug release = Amount of drug release dilution factor/ Drug dose

Dissolution rate of Aliv

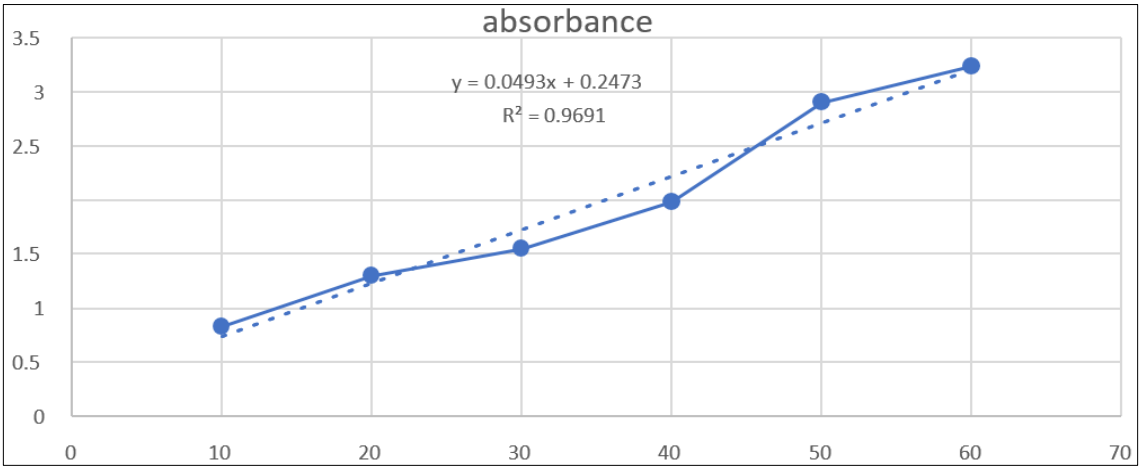


Graph 1: Dissolution rate of Aliv formulation

Table 6: Dissolution rate of Aliv formulation.

Sr. No	Time	Abs	Conc	Con*Dil.F	Conc in 900ml	Cumulative 900ml	Cumulative amount	% of drug release
1	10	0.314	1.3	13	11700	11700	11.7	2
2	20	0.584	2.1	24	18900	30600	30.6	6
3	30	0.898	3.3	33	29700	60300	60.3	12
4	40	1.352	5.9	59	53100	113400	113.4	22
5	50	1.999	7.5	75	67500	180900	108.9	36
6	60	2.314	10	100	90000	270900	270.9	54

Dissolution rate of Basil



Graph 2: Dissolution rate of Basil formulation

Table 7: Dissolution rate of Basil formulation

Sr. No	Time	Abs	Conc	Conc*Dil.F	Conc in 900ml	Cumulative 900ml	Cumulative amount	% of drug release
1	10	0.838	3.3	33	29700	29700	29.7	5
2	20	1.307	5.2	52	46800	76500	76.5	15
3	30	1.557	6.3	63	56700	133200	133.2	26
4	40	1.989	8.5	80	72000	205200	209.7	41
5	50	2.906	11	110	99000	304200	308.7	60
6	60	3.245	13	130	117000	421200	425.7	85

Assay of paracetamol tablets

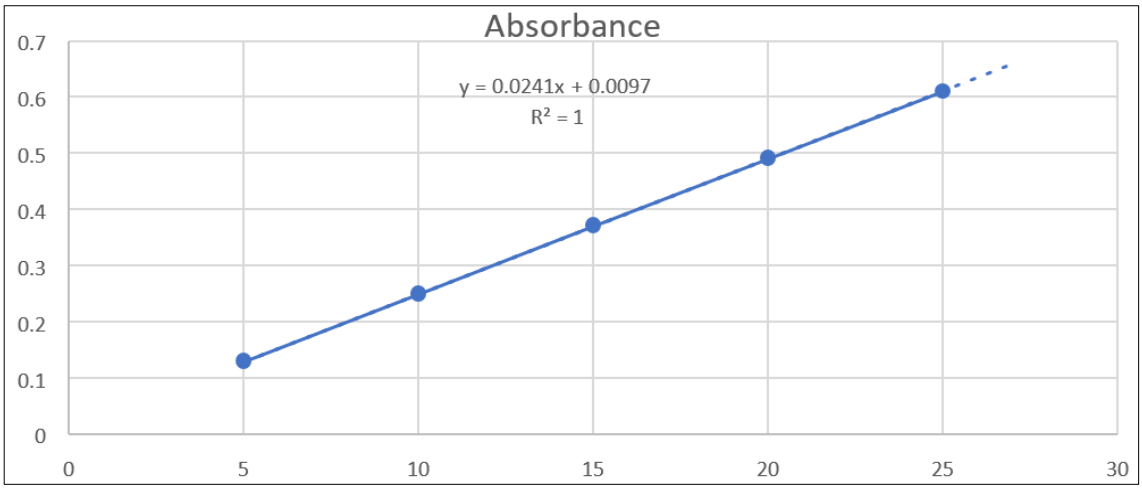
Break down and weigh ten tablets. Weigh an exact quantity of powder that is equal to around 10 milligrams of paracetamol. 10 milliliters of phosphate buffer should be placed in a clean beaker. Add the powdered paracetamol (10 mg) and dissolve. Transfer it into a 100 ml volumetric flask and use phosphate buffer to increase the volume. After the Whatman filter, filter the resultant solution. Fill a 10 ml volumetric flask with 5, 10, 15, 20, and 25 ppm of filtrate. At a maximum of roughly 256 nm, measure the absorbance of the resultant solution [18].

Formula

A = abc

% purity of paracetamol tablet = Practical concentration /concentration x 100

1. Assay of aliv formulation.

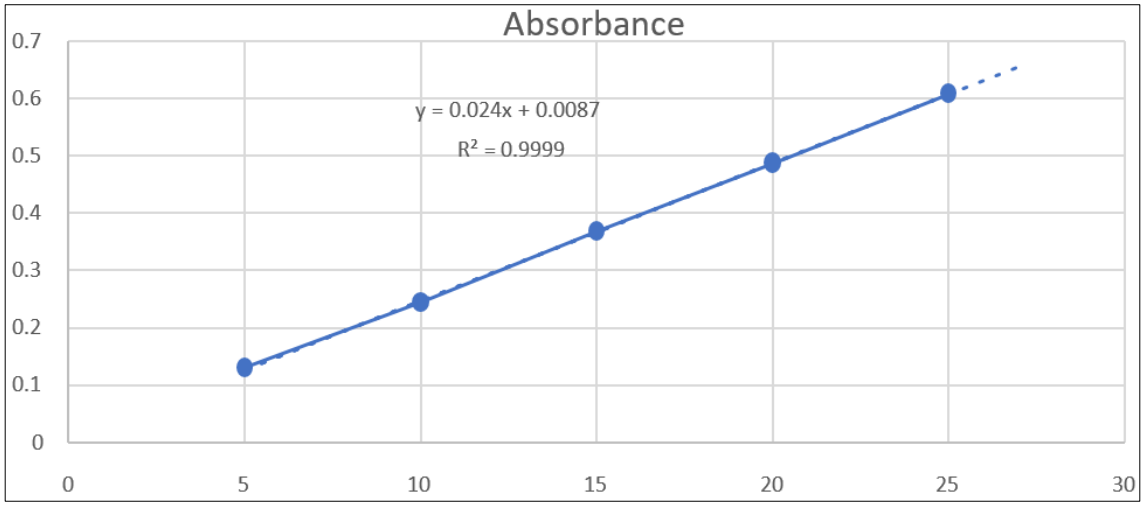


Graph 3: Calibration curve for Aliv formulation

Table 8: Assay of aliv formulation

Sr. No	Concentration	Absorbance	Practical Concentration	% purity of paracetamol tablet
1	5	0.13	5.3	106%
2	10	0.25	10.3	103%
3	15	0.371	15.3	102%
4	20	0.491	20.2	101%
5	25	0.611	25.2	100.8%

2. Assay of basil formulation



Graph 4: Calibration curve for Basil formulation

Table 9: Assay of basil formulation

Sr. No	Concentration	Absorbance	Practical Concentration	% purity of paracetamol tablet
1	5	0.131	5.4	108%
2	10	0.245	10.1	101%
3	15	0.369	15.2	101.3%
4	20	0.488	20.1	100.5%
5	25	0.609	25.1	100.4%

Both the formulation pass the assay test. The % purity of paracetamol tablets is between the range of 95% and 105%.

Conclusion

Aliv and Basil both the binders pass the evaluation tests. Basil show excellent property of binding. While Aliv show a good property of binding. Friability and hardness of Aliv was better than Basil. Also, disintegration of basil was good than that of aliv formulation. Aliv also pass the disintegration test but the basil formulation take less time to disintegrate the tablet than aliv formulation.

Dissolution of basil was performed better than aliv. It seems that at the same time the dissolution rate of tablet was more as compared to aliv. Weight variatrion and dimension test of the both the formulation were same. Both the binders aliv and basil pass the assay test.

Reference

1. Kulkarni VM, Babare SB, Joshi SK, Walode SG, Rudrapal M, Kakade AP, *et al*. Formulation and evaluation of paracetamol tablets using coconut oil as a binder. J Drug Deliv Ther. 2022;12(3):142-148.
2. Nep EI, Ngwuluka NC, Ogaji IJ. Formulation and evaluation of paracetamol tablets manufactured using the dried fruit of Phoenix dactylifera Linn as an excipient. Res Pharm Biotechnol. 2010;2(3):25-32.
3. Eraga SO, Iboi A, Eichie FE, Okenyehike EM, Cash-Torunarigha OE. Evaluation of Dacryodes edulis (Burseraceae) exudate as a binding agent in paracetamol matrix tablet formulation. East Cent Afr J Pharm Sci. 2015;18:10-17.
4. Ordu JI, Abidde TO, Okafo SE. Evaluation of the binding properties of gum obtained from dried leaves of *Corchorus olitorious* on metronidazole tablets formulation. Pharma Innovation J. 2018;7(5):688-694.
5. Desta KH, Tadese E, Molla F. Physicochemical characterization and evaluation of the binding effect of Acacia etbaica Schweinf gum in granule and tablet formulations. Biomed Res Int. 2021;2021:5571507.
6. Dey P, Kumar S, Anoop. Formulation and evaluation of paracetamol tablets to assess binding property of orange peel pectin. Int J Pharm Pharmaceut Res. 2019;16(2):1-8.
7. Zilhadia Z, Hidayatullah S, Amaliya S, Anggraeni Y, Harahap Y. Preparation and evaluation on paracetamol tablets using goatskin gelatin as a new binder; c2021 Jan 22.
8. Jackson C, Akpabio E, Umoh R, Adedoku M, Ubulom P, Ekpe G. Evaluation of Sesamum indicum gum as a binder in the formulation of paracetamol granules and tablets. Res Pharm Biotechnol. 2012;4(1):1-5.
9. Okafo SE, Agbamu E, Bazunu ON, Onoja OJ. Evaluation of the binding property of Irvingian

Gabonesis gum in paracetamol tablet formulations produced using two different disintegrants. Int. J Pharm Biomed Sci. 2023;3(2):38-44.
10. Roohullah ZI, Khan JA, Asim SM, Obaidullah BA. Preparation of paracetamol tablets using PVP-K30 and K90 as binders. Acta Pharm Turc. 2003:137-145.
11. Srivastava P, Malviya R, Kulkarni GT. Formulation and evaluation of paracetamol tablets to assess binding property of orange peel pectin. Indian J Pharm Sci. 2010;3(1):43-46.
12. Inamdar M, Momin M, Abhang P. Isolation and evaluation of fenugreek, flaxseed mucilages and its use as a pharmaceutical binder. Int. J Pharm Technol. 2012;4(3):4766-4777.
13. Nagpal M. Development and evaluation of fast dissolving tablets of valsartan using different binders. Am J Pharm Health Res. 2015;3(6):122-130.
14. Mali K, Dias RJ, Ghorpade V. Manufacturing and evaluation of paracetamol tablets; c2017 Apr.
15. Gunatilake SK, Adekol F. Effects of binder on the physico-chemical properties and the quality of paracetamol tablet. Der Pharma Chem. 2016;8(4):237-242.
16. Satyam G. Isolation and evaluation of the binding property of sago starch in paracetamol tablets. Int. J Pharm Res Dev. 2010;2(1):56-61.
17. Venkataswamy M. Dissolution study of paracetamol commercial tablet; c2018 Sep.
18. Mali KK. Assay of paracetamol tablet by UV spectrophotometer; c2023 Apr 23.