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"Formulation and Evaluation of Dispersible Tablet of Kayam Churna"-An Experimental Study

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ABSTRACT: Ayurvedic medications are essential in gastrointestinal issues due to their safety and efficacy. Kayam churna is a prevalent Ayurvedic remedy for constipation. It is not a conventional Ayurvedic medication. It is a proprietary Ayurvedic medicine. Kayam churna comes in powder and tablet form, although disintegration was a concern. Thus, the major goal of the study is to develop and assess the disintegrating tablet of Kayam Churna. The goal is to adjust the concentration of different disintegrating agents to improve the disintegration rate and solubility of Kayam Churna dispersible tablets. In this investigation, mouth-dissolving tablets were made using the compression method with sodium starch glycolate, crospovidone, and croscarmellose as super disintegrants. The developed tablets were evaluated using a variety of characteristics, including particle size analysis, weight variation, friability test, hardness test, disintegration test, and stability research. All the preformulation and precompression micromeritics parameter of F1-F10 formulations were within the prescribed limits. The formulation of sodium starch glycolate (F2- F4) showed the best result compared to crospovidone (F5–F7) and croscarmellose (F8-F10) formulations. The concentration of super disintegrating agent is in increasing from F2-F4, F5-F7, and F8-F10 and among those F4, F7, F10 disintegration time was less and F4 having the highest concentration of sodium starch glycolate showed the best result among all the formulations. In comparison to all other formulations, the F4 formulation demonstrated a decreased disintegration time. Additionally, the evaluation test showed that the formulation's diameter, thickness, hardness, weight variation, friability, and disintegration time were all within the as per IP.

KEYWORDS: Ayurvedic medicine, Kayam churna, Wet granulation, Super disintegrating agent.

I. INTRODUCTION

It is an ayurvedic formulation made up of seven ingredients, Senna leaves (Cassia angustifolia), Black Salt, Mulethi (Glycyrrhiza glabra), Nishoth (Operculina turpethum), Ajwain (Trachyspermum ammi), Haritaki (Terminalia chebula), and Svarjikshara (Sodium bicarbonate), with Senna serving as the main ingredient. It has been widely used for decades to treat a variety of gastrointestinal disorders, including constipation, gastritis, diarrhea, heartburn, peptic ulcers, gastroesophageal reflux disease, and other related disorders (Ayurvedic Pharmacopoeia of India). Because of this herbal product's powerful laxative and digestive properties, ingesting it in specified proportions can assist improve digestion and alleviate constipation.[1] In the Ayurvedic medical system, churna refers to a drug or drug in the shape of a fine powder. The medications listed in Patha were adequately washed, dried, powdered, and sieved. Churna flows freely and retains its effect for one year when stored in an airtight container. Examples are Triphala churna, Trikatu churna, Drakeshadi churna, and Sudharsana churna. Churna expression is comparable to powder formulations in the system of regulated medicine (allopathic drugs).[2] Churna has recently been made into tablets to make it easier to administer doses. These drugs are typically administered due to their particle size. The smaller the particle size, the higher the absorption rate from gastro intestinal tract, and thus maximum the bioavailability. Ayurvedic doctors use it to treat conditions like diabetes, indigestion, and constipation. Indigestion is a prevalent ailment affecting the general population, and allergic systemic antacids are typically prescribed. Because utilizing such metal contains antacids, which can produce negative effects such as Alzheimer's disease over time, we identified a solution that can almost certainly heal indigestion. That is why we make churna from natural substances that humans routinely utilize for curative purposes.[3] ODTs are also known as orodispersible tablets, mouth-

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dissolving tablets, rapimelts, melt-in-mouth tablets, fast-disintegrating tablets and rapid-dissolving tablets.[4] ODTs are solid unit dosage forms/entities containing medicinal substances which that disintegrate or dissolve rapidly in the oral cavity usually within a few seconds even without the need of water or chewing. As the tablet disintegrates in the mouth, this can enhance the clinical effect of drug through pregastric absorption from the mouth, pharynx and esophagus.[5,6] In such cases, the bioavailability of drug is significantly enhanced by avoiding first-pass hepatic metabolism than those observed with conventional tablets. ODTs also combine the advantages of both liquid and conventional tablet formulations allowing the ease of swallowing in the form of liquid.[7] The advantages of these dosage forms are continuously and increasingly being identified in both pharmaceutical industries as well as in academia The objective of the present article is to highlight the development of ODTs, their significance, ideal characteristics, various techniques and aspects related to design and formulation, marketed preparations and future prospective.[8]

II. MATERIALS AND METHODES

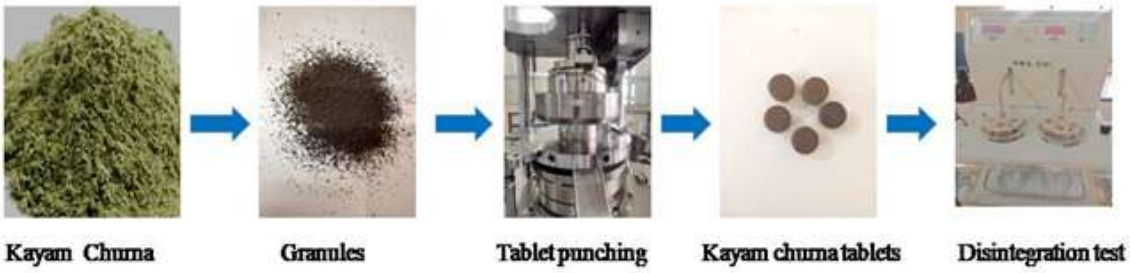

Figure1: Formulation of dispersible tablets from Kayam Churna

Material:

Kayam churna was obtained from Patanjali ayurvedic medicine shops, Lactose, Magnesium stearate, Talc, Starch, Gelatin, Sodium starch glycolate, Crosscarmellose, Crospovidone and other chemical and solvents were procured from market used in formulation of Dispersible tablet of Kayam churna.

Methods:

PREFORMULATION STUDIES:

Goals of Preformulation:

The main goal of the study is to establish the physicochemical parameters of a new drug (CHURNA). To determine its physical properties and compatibility with standard excipients. Providing scientific data to support the dosage form design and evaluation of the product efficacy and stability.[9]

PARTICLE SIZE ANALYSIS:

Procedure:

The standard sieve set (sieve nos. 10, 22, 36, 44, 65, 80, 100, and 120) is chosen and positioned so that the finest particles are at the bottom and the coarsest remain at the top. Weight of material around 50g, placed it on the coarsest sieve 10. Place the aforementioned sieves on a hand sieve shaker and give it a 20-minute shake. Collect and weigh all the sample retained on each sieve. Report the weights on each sieve against corresponding sieve number.

Ocular microscopy: The optical microscope, also referred to as a light microscope, is a type of microscope that commonly uses visible light and a system of lenses to generate magnified images of small objects.

Standard stage micrometer:

A Stage Micrometer is essentially a microscope slide with a finely split scale marked on the surface. The scale is of known real length and is used to calibrate optical devices using eyepiece graticule patterns.

Procedure:

C**ounting of the sample:**

A small portion of the given sample transferred to a clean slide one (or) two drops of liquid paraffin is added to the slide. The sample is dispersed uniformly with the help of a brush and particles should be in dependent and distribution should be uniform. The cover slip is placed carefully entrancement of air bubbles is avoided. The slide is placed on the stage of the microscope.

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Measurement of particle size:

The light microscope can show the precise shape and size of each particle. When combined with a camera, the light microscope may capture images of the particles. It can also be used with a computer and image analysis software to estimate shape and size.[10]

Micromeritics:

Pre- Formulation parameter

The powder blends of all the six formulations were studied for their granule properties such as Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of repose by standard methods.[11]

Angle of repose:

The flow parameters of the mix (before to compression) were determined using angle of repose, Carr's index, and Hausner ratio. To determine static angle of repose (θ), the blend was poured through the walls of a funnel. The lower tip was set at a height of 2.0 cm above the hard surface[11]. The blends were poured until the higher tip of the pile surface contacted the lower tip of the funnel. The angle of repose was calculated as $\tan^{-1}$ of (the height of the pile divided by the radius of its base). The angle of repose (θ) [12] , was computed using equation 1.

Angle of repose (Θ) = $\tan^{-1}$ h/r … (1)

Where, Θ =is the angle of repose,
r = is the radius in (cm)
h= is the height in (cm)

Bulk density:

The loose bulk density (LBD) of powder blends was determined using the following equation.[13]

Loose Bulk Density (LBD) = Total weight of powder/ Total volume of powder … (2)

Tapped density:

The tapped bulk densities (TBD) of powder blends were determined using the following equation.[13]

TBD (Tapped Bulk Density) = Total weight of Powder/Tapped Volume of tapped powder. … (3)

Carr's Comprexibilty index:

The powder's ability to be compressed is measured by the Hausner ratio and compressibility index. The evaluation of the tablet blend's packing ability was based on changes in volume, which result from the packing rearranging during tapping. It was stated that equation 14 was used to construct Carr's compressibility index.[14]

Carr's index = [Tapped density - Bulk density/Tapped density] X 100 … (4)

Hausner's ratio:

The Hausner ratio is a measure of powder flow easiness that is not direct. The formula for calculating Hausner ratio by using following equation 5.[15]

Hausner ratio = D_t / D_b ... (5)

Where, D_t = Tapped density
D_b =Bulk density

Moisture content

Moisture content indicates water containt in the product was calculated by using the eqn. 6.[11]

Moisture content = W2 – W3 / W3– W1 … (6)

Where,
W1=Weight of sample
W2=Weight of wet sample + Petri plate
W3=Weight of dry sample + Petri plate

TABLET NO.1: FORMULATION (F1-F10)

	FORMULATIONS CODE									
Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Churna	250	250	250	250	250	250	250	250	250	250
Lactose IP	27	25	23	21	25	23	21	25	23	21
Starch paste + 5%+Gelatin	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Sod. starch glycolate IP	---	2	4	6	---	---	---	---	---	---
Cross	---	---	---	---	2	4	6	---	---	---

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povidone IP										
Croscarmellose IP	---	---	---	---	---	---	---	**2**	**4**	**6**
Talc IP	1	1	1	1	1	1	1	1	1	1
Mg.Sterate IP	2	2	2	2	2	2	2	2	2	2
Total weight (mg)	280	280	280	280	280	280	280	280	280	280

KAYAM CHURNA GRANULES:

Procedure:

Weigh all the ingredients and blend them. Wet granules are prepared by adding the binders solution i.e. granulating agent (starch paste + gelatin). Dry the granules in a hot air oven at 60^0C. Screening of dried sample through the mesh no.40. Mix other ingredients, lubricant (magnesium stearate), and glidant (talc) by blending with granules.

POST-COMPRESSION PARAMETER STUDIES:

Thickness:

Tablet thickness can be measured with a vernier caliper, thickness gauge, or automated device (an automated weight, hardness, thickness, and tablet diameter test equipment). The thickness of the tablet should be kept within a ±5% range of a standard value, depending on its size.[16]

Diameter:

It was measured by using vernier calliper scale.[17] A micrometer is the tool used to measure a tablet's thickness. If the batch is within the standard deviation of +/- 5%, it may be considered acceptable.

Hardness:

A tablet's hardness reveals how well it can tolerate handling-related mechanical shocks. The Monsanto hardness tester[18] was used to measure the tablets' hardness. It is stated as kg/cm^2. The hardness of three tablet was measured after they were chosen at random.[19]

Weight variation:

From each batch, twenty tablets were chosen at random, and the average weight was determined. Next, in order to determine the weight variation of the tablets, each tablet was weighed individually and the weight of each was compared to the average weight.[20]

Friability:

The friability of tablets was assessed using the Roche Friabilator. It's expressed as a percentage (%). Twenty tablets were initially weighed and put to the Friabilator. The Friabilator was run at 25 rpm for 4 minutes, or up to 100 rotations. The tablets were weighed again. The percentage friability was then estimated using the following formula.[21]

The percentage friability was calculated as eqn.7

Friability (%) =W1-W2/W1 X 100 … (7)

Where, W1= Initial weight of tablet (Before operation or Tumbling) &

W2= Final weight of tablet (After operation or Tumbling)

Percentages Friability of tablets less than 1 % are considered acceptable.

Disintegration studies:

The process of breaking down a tablet into smaller bits is known as disintegration. A tablet's in vitro disintegration time was assessed using a disintegration test instrument designed to meet I.P. requirements. Place one tablet in each of the basket's six tubes. Fill each tube with a disc and use pH 6.8 (simulated saliva fluid) as the immersion liquid at $37^0\pm 2^0$C. To maintain a pH of 6.8 and a temperature of $37^0\pm 2^0$C, raise and lower the assembly at a rate of 30 cycles per minute. The duration in seconds required for the tablet to completely disintegrate and leave no palpable mass in the instrument was measured and recorded.[22]

Stability studies:

The goal of stability testing is to provide evidence on how the quality of a drug substance or drug product varies over time as a result of a variety of environmental factors such as temperature, humidity, and light, as well as to establish a re-test period or a shelf life for the drug.

III. RESULT AND DISCUSSION:

All the formulations, F1-F10 were prepared by wet granulation technique. F2-F10 formulation were prepared using three different

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superdinsintegrants such as Sodium starch glycolate, Croscarmellose sodium, Crospovidone. Lactose is used as diluent. Talc is used as glidant to improve the flow property of the formulation. Magnesium stearate is used as a Lubricant to aid in the tableting process during the preparation of tablets. A combination of Starch paste (5%) and gelatin is used as a Granulating agent to hold the API with other excipients. The formulations F2, F3 and F4 have Sodium starch glycolate at a concentration of 2mg, 4mg, and 6mg respectively. F5, F6, and F7 have Crospovidone at a concentration of 2mg, 4mg, and 6mg respectively. F8, F9, and F10 have croscarmellose at a concentration of 2mg, 4mg, and 6mg respectively. For each formulation, a blend of drugs and excipients was prepared and evaluated for various parameters like angle of repose, bulk density, tapped density, Hausner ratio, and compressibility index. Using the bulk and tapped density data, Hausner's ratio and compressibility index was calculated. The powder blend of all the formulations had Hausner's ratio of 1.128 or less indicating good flowability. The compressibility index was found between 10 to 15 % and the compressibility flowability correlation data indicated a fairly good flowability of the blend. The good flowability of blend was also made evident with the angle of repose 30.45, which is below 30° indicating excellent flowability (Table 3). Tablets were prepared using the compression technique. Since the powder material was free-flowing, tablets were obtained of uniform weight due to uniform die fill, with acceptable weight variations as per pharmaceutical specifications. The hardness of the tablets is between 1.01.5kg/cm^2. The hardness of the tablet was found to be satisfactory so that the tablet will resist mechanical shock during transportation and storage. The friability of the table was found below 1 % (I.e. 0.2-0.8%) and good mechanical resistance of tablets.

PREFORMULATION STUDIES:

TABLE NO 2: PARTICLE SIZE ANALYSIS

size group	Mean of size range(d)	No. of particles in each size (n)	Geometrical mean	n X d	n X d^2
0-20	10	45	22.5	450	4500
20-40	30	113	56.5	3390	101700
40-60	50	193	96.5	9650	482500
60-80	70	118	59	8260	578200
80-100	90	31	15.5	2790	251100
		$\sum$ n = 500		$\sum$(nd)=24540	

MICROMERITICS:

PRE COMPRESSION STUDIES

TABLE NO. 3: RESULT OF MICROMERITICS STUDIES

	FORMULATIONS CODE									
PARAMETERS	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Angle of repose(Θ)	**30.45^0**	**23.30^0**	**22.45^0**	**22.89^0**	**22.75^0**	**21.54^0**	**21.68^0**	**23.65^0**	**22.95^0**	**22.60^0**
Bulk density (gm/ml)	**0.35**	**0.36**	**0.37**	**0.35**	**0.36**	**0.36**	**0.39**	**0.40**	**0.36**	**0.39**
Tapped density (gm/ml)	**0.505**	**0.56**	**0.55**	**0.52**	**0.57**	**0.54**	**0.53**	**0.60**	**0.58**	**0.59**
Moisture	**5.48**	**6.34**	**6.25**	**5.89**	**5.97**	**6.55**	**6.98**	**7.02**	**5.54**	**6.75**

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e cont ent (%)										
Hausner's ratio (gm/ml)	**1.428**	**1.55**	**1.487**	**1.485**	**1.58**	**1.5**	**1.35**	**1.5**	**1.61**	**1.51**
Compressiblity index (%)	**30**	**35.71**	**32.72**	**32.69**	**36.84**	**33.33**	**26.41**	**33.33**	**37.93**	**33.89**

The disintegration time of the formulation was ranging from 2- 8 minutes. The disintegration time decreases as the concentration of super disintegrants increases. The in vitro disintegration time of all formulated tablets was found to be less than 10 minutes (Table 4).

3) POST COMPRESSION STUDIES:

TABLE NO.4: RESULTS OF POSTCOMPRESSION STUDIES

	FORMULATIONS CODE									
PARAMETERS	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Diameter (mm)	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Thickness (mm)	8.2	8.2	8.2	8.2	8.2	8.2	8.2	8.2	8.2	8.2
Hardness(kg/cm^2)	1.5	1.2	1.3	1.0	1.5	1.5	1.3	1.5	1.2	1.0
Weight variation(mg)	8	8.54	7.94	7.99	6.56	7.13	5.86	7.37	8.05	8.98
Friability (%)	0.6	0.5	0.43	0.26	0.75	0.48	0.65	0.33	0.56	0.64
DisintegrationTest(Min)	20	4	3.27	2	7	5.26	4.65	8	7.15	6.30

From F2 to F10 formulations of disintegration of kayam churna tablets were in the range of 2 to 8min.

Sodium starch glycolate[23] was found to be the best formulation (i.e.F4) which contains 6mg, and showed 2min of disintegration as compared to crospovidone and croscarmilose.

Thus Kayam churna disintegrating property was observed in the following hierarchy.

Sodium starch glycolate > Crospovidone > Croscarmellose.

IV. CONCLUSION

The formulation study results of kayam churna were found to be powder was not free flowing andparticle sizes were in the range of 50-55 µm.

The formulation of kayam churna powder was subjected to wet granulation with various concentrations of super disintegrants. The disintegration time for all formulations was in range of 2 minutes to 8 minutes but without a super disintegrating agent, it was found to be 20 min. The addition of superdisintegrants concludes that Kayam churna tablet showed accelerated disintegration properties. Among the three super disintegrating agents, sodium starch glycolate conformed promising results as compared to other super disintegrating agents.

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