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Formulation and evaluation of dispersible tablet from poly herbal churna for digestive property

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Abstract
Objective: The aim of the present study was to transform Ayurvedic formulation into modern dosage form such as poly-herbal dispersible tablet without altering the chemical properties of the original formulation.
Methods: Poly-herbal churna was prepared and then poly-herbal dispersible tablet was formulated. Standardization parameters such as loss on drying, ash value, extractive value was performed for churna. The evaluation of raw materials, polyherbal churna, polyherbal extract and dispersible tablet was done using preliminary phytochemical tests. The dispersible tablet was formulated and evaluated for pre and post compression parameters. Determination of digestive property done by amylolytic, lipolytic, protiolytic activity.
Results: The standardization parameters showed the results within the standard limits, thus confirming the quality and purity of the raw materials. The pre and post compression parameters for poly-herbal dispersible tablet formulation resulted within the acceptance range.

Keywords: Polyherbal churna, dispersible tablet, digestive property

Introduction
The World Health Organization (WHO) has noted that there has been a significant growth in awareness of Ayurvedic treatments in recent years. Medicinal plants, animals, and minerals are used in Ayurvedic preparations. Traditional medicines are defined by the WHO as "health practices, techniques, knowledge, and belief."According to the WHO, nearly 80% of people in under-developed nations rely only on traditional medicine for their primary health care [1].
"The ingredients of these churna were Turmeric *(Curcuma longa)* Ginger (*Zingiber officinale*), Cinnamon *(Cinnamomum zeylanicum)* and Fennel (*Foeniculum vulgare*)."
Turmeric (curcuma) is commonly used for conditions involving pain and inflammation, such as osteoarthritis. It is also used for hay fever, depression, high cholesterol, a type of liver disease, and itching. Ginger it is commonly used as digestion and various types of stomach problems. Fennel is used for various digestive problems including heartburn, intestinal gas, bloting, loss of appetite. This is mainly used as a carminative. Cinnamon contains cinnamaldehyde, It has anti-viral, anti-bacterial and anti-fungal properties and is mostly used as carminative [1].
Many churnas have been directly turned into tablets, vati, and chewable tablets in the past, but no dispersible churna tablet has been reported to date. Aside from that, other enhancements are needed to improve their utility, such as bioavailability, dosage-regimens, popularity, and patient acceptance. Due to their short shelf lives, churna and vati dosage forms have a short shelf life.
Basically, in herbals or Ayurvedic medicines, formulations are in either liquid, semi – solid or solid forms. Among these formulation churna is a mixture of powdered herbs, which shows particular activity and is used for the treatment of various diseases. Churna is used normally to treat indigestion, constipation, anti- diabetes, carminative, purgatives etc. It is very popular, effective Ayurvedic formulation and demand for rational uses, but due to its pungeny taste its compliance is poor. So, there should be some improvement in the organoleptic properties and better compliance of patients and avoidance of dose variation,therefore dispersible tablets can be preffered. Churna is normally administered in specific dose as per the guidance of the physician which mainly depends on the age groups [2].
Certain formulations are voluminous and promt many problems during oral administration. Hence, poor patient's compliance is a major hurdle in the use of traditional medicines in their original form. Hence the study is being taken up to formulate polyherbal tablet using the prepared churna as, to overcome the dose variation, patient compliance and the ease of administration for the digestive property [3].

An earlier research on the digestive and carminative properties of the substances in question inspired us to create and test digestive enzyme activity, namely amylolytic, lipolytic, and proteolytic activity in comparison with GASEX (marketed formulation) used as a digestive agent [3].

Materials and methods

Materials

Plant Collection and Identification: Turmeric (CRF/Auth/2020/0ct/46), ginger (CRF/Auth/2020/0ct/47), cinnamon (CRF/Auth/2020/0ct/48) and fennel (CRF/Auth/2020/0ct/49) was collected from the Shri B.M.K Ayurvedic College of Belagavi, Karnataka, India. The plant materials was subjected for authentication by Dr, Ajit Lingayat Central Research Facility. Excipients used were of pharmaceutical grade: Anhydrous lactose (filler-binder), Sodium starch glycolate (super disintegrate), Crosscarmellose Sodium (super disintegrate), Talc (Adsorbent), Magnesium Stearate (Lubricant), Aerosil (Glidant), Stevia (Sweetener), Effervescent Base (Effervescent agent).

Methods

Preparation of poly-herbal churna

Curcumin, ginger, cinnamon and fennel are the four primary constituents in a 2:2:1:1 ratio. All of the components were weighed and sieved individually with a no. 85# sieve. The aforesaid sieved materials were then triturated to produce a homogeneous blend, which was then stored in an airtight container [5].

Preparation of extract

The extraction process was performed on the prepared Poly-herbal churna. The quantity of churna was precisely weighed. In a 500ml conical flask, macerated with 30% alcohol. For a period of two to three days, with frequent shaking. The aforesaid combination was then filtered, with the filtration being done under vacuum with a Rotary Evaporator. The concentrated extract was dried and kept in an airtight container.

Preliminary phytochemical screening

The Poly-herbal churna and Poly-herbal churna extract was subjected to phytochemical tests to assess the qualitative chemical composition by standard methods for Alkoloids, Tannins,Saponins,Carbohydrates,flevenoids,Steriods,Triterpinoids etc. [5]

Physico-chemical investigation

Poly-herbal churna and poly-herbal churna extract was subjected to physio-chemical investigation to assess the qualitative chemical composition by standard method Ash value (total ash values, acid insoluble ash, Water soluble ash) Extractice value (alcohol extractive value and water soluble extractive value) And lose on drying.

Ash values

A) Total ash

Accurately a Weighed 2 gram of sample was incinerated in a crucible at a temperature 500-600ºC in a muffle furnace till carbon free ash was obtained. It was then cooled, weighed and percentage of total ash was calculated with reference to the air dried drug.

B) Acid insoluble ash

The ash was then heated for 5 minutes with 25ml of (70 g/l) hydrochloric acid before being filtered through an ash-free filter paper. Insoluble debris stuck to filter paper was washed away with hot water and burned to a consistent weight in a muffle furnace. The proportion of acid- insoluble ash was estimated using air dried medication as a reference.

C) Water-soluble ash

The above-mentioned ash was boiled for 5 minutes with 25ml of water, and insoluble materials collected on an ash-free filter paper was washed with hot water before being burned in a muffle furnace for 15 minutes at a temperature not exceeding 450oC. “The weight of water-soluble ash was calculated by subtracting the weight of ash from the weight of water insoluble matter.” Refer was used to calculate the proportion of water- soluble ash.

Extractive value

a) Alcohol soluble extractive

The weighed accurately 4grams of sample was macerated with 100ml of alcohol in conical flask for 24hour, with frequent shaking at an interval of 6hours. It was then allowed to stand for 18hours and filtered rapidly to prevent any loss during evaporation. 25ml of filtrate was evaporated until it dries in a porcelain dish and dried at 105ºC to a constant weight. The percentage of alcohol soluble extract was calculated with reference to air-dried material.

Extractive value

b) Alcohol soluble extractive

The weighed accurately 4grams of sample was macerated with 100ml of alcohol in conical flask for 24hour, with frequent shaking at an interval of 6hours. It was then allowed to stand for 18hours and filtered rapidly to prevent any loss during evaporation. 25ml of filtrate was evaporated until it dries in a porcelain dish and dried at 105ºC to a constant weight. The percentage of alcohol soluble extract was calculated with reference to air-dried material.

Preparation of polyherbal dispersible tablet

Direct compression technique was adopted for the polyherbal dispersible tablet. The Polyherbal churna extract was correctly weighed and passed through filter No.85 and 120 independently, with 20% overages and excipients. Poly-herbal extract was triturated with a precisely weighed quantity of anhydrous lactose due to its hygroscopicity.

Table 6: Formulation trial table

Sr. No.	Ingredients	F1	F2	F3	F4
1	Polyherbal extract	600mg	600mg	600mg	600mg
2	Anhydrous lactose	50mg	50mg	50mg	50mg
3	Sodium Starch Glycolate	10mg	20mg	10mg	20mg
4	Crosscarmellose Sodium	20mg	10mg	10mg	20mg
5	Talc	1mg	1mg	1mg	1mg
6	Magnesium Stearate	1mg	1mg	1mg	1mg
7	Aerosil	5mg	5mg	5mg	5mg
8	Stevia	7mg	7mg	7mg	7mg
9	Effervescent base	100mg	100mg	100mg	100mg
	Total weight of the tablet	794mg	794mg	784mg	804mg

Pre-compression studies (micrometrics study)

a) Bulk density

The bulk density of each formulation batch's powder blend was assessed using the measuring cylinder method. In triplicates, the volume of loose powder was measured and recorded. Bulk densities of batches were calculated using following formula:

LBD = Weight of the power (M) / Volume of packing (Vb)

b) Tapped bulk density
The bulk density process was verified by tapping the measuring cylinder 15 times on a soft surface until a constant volume was seen and recorded in triplicates using following formula Tapped was determined.
TBD= Weight of the power (M) / Volume of tapped packing (Vb)

c) Carr's Compressibility Index
Using BD/TBD data Carr's index was determined. It was calculated using the following formula:

Carr´s Index = (TBD – LBD)/TBD

d) Hausner's Ratio
It is used to measure the inter-particle friction which shows the flow of the blend. The ideal range of the blend should be 1.2-1.5. It is found out by the following formula using the BD/TBD data in triplicates.

Hausner´s ratio = TBBD/LBD

e) Angle of repose
Angle of repose was calculated using the funnel method, which involved pouring a correctly weighed blend into a funnel. The funnel height was adjusted until the tip of the funnel just touched the apex of the heap or the blend's head. The mixture was then allowed to run freely through the funnel and onto the horizontal surface. The powder's diameter was measured, and the angle of repose θ was calculated.

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

where, h= height of powder cone r = radius of the powder cone

Post-compression parameters
For the Unofficial and Official Quality Control tests, the tablet from all batches were evaluated as follows: -

a) **Thickness**: Vernier caliper was used to measure the thickness of the tablets. Average values were observed of three tablets from each batch.
b) **Diameter:** Vernier caliper was used to measure the diameter of the tablets. Average values were observed of three tablets from each batch.
c) **Hardness:** It also affects the dissolution and disintegration times and may have an impact on bioavailability of the tablet. Tablets were randomly selected from each formulation batch and its hardness was tested using Monsanto Hardness Tester that indicates the crushing strength of the tablets.
d) **Friability:** The ability of tablets to withstand abrasion and mechanical shock at the time of packing and transport known as friability. It was determined by using calibrated Roche friabilitor.10 tablets were pre-weighed and placed in the friabilator which was allowed to run for 100 revolutions. Then, tablets were dedusted and reweighed. Acceptability range is less than 1%.

% Friability = Intial wt – final weight / intial weight*100

b) Weight Variation: The weight of every tablet in a batch should be in a uniform weight. The weight variation should be within permissible limits. 20 tablets were randomly picked up and weighed, the individual weight and their average weight of the tablets was calculated. Each tablet was determined with percentage deviation of its weight from its average weight.

% Deviation = Individual wt - Average wt/Individual wt*100

a) **Wetting Time and Water absorption ratio:** Wetting time is the time required to measure the wetting of the tablet completely. A water soluble dye i.e. amaranth was put into 6ml of water in a small petri dish with twice folded tissue paper on it. On that tissue paper the tablet was kept and the required time that reaches the upper surface of the tablet was observed by reweighing it.
R= Wb-Wa / Wa

Where, "Wb= weight of the tablet before absorption of water" Wa=weight of the tablet after absorption of water

R= water absorption ratio

b) ***In vitro* dispersion time:** 100 ml of water was taken in the beaker and two tablets were put into it determine the complete dispersion time.
c) ***In vitro* disintegration time:** Disintegration is the breakdown process of the tablet into tiny particles. In disintegration apparatus there are 6 baskets in which one tablet each was placed and it was kept in a beaker filled with 900ml of water at maintained temperature 37 ºC. The time in minutes determines the disintegration of the tablet. Generally, disintegration time must be within 3 minutes.

Determination of digestive property
About 100mg of accurately weighed quantity of dispersible tablet was mixed with 20 percent aqueous glycerol and phosphate buffer (pH7.8) in 1:4 ratio and filtered, the filtrate was used as enzyme source. The standard solution of GASEX was prepared in the same way as that of the test sample.

a) **Amylolytic activity:** 1 mL of dispersible tablet and 1 mL of GASEX tablet were incubated separately for 15 minutes at 27°C before being added to 1 mL of substrate (soluble starch 1 percent in phosphate buffer). By adding 2ml of DNS reagent and heating for 5 minutes, the enzyme reaction was stopped. At 520nm, the absorbance was measured.
b) **Lipolytic activity:** Substrate Solution Preparation 2 mL castor oil was neutralised to pH 7 and mixed well with 25 mL water in the presence of 100 mL bile salts (sodium taurocholate) to form an emulsion.
c) Procedure: Add 5 mL of pH 7 phosphate buffer to 20 mL of substrate. In a magnetic stirrer, the contents were steadily stirred while maintaining a temperature of 35 0C. The electrodes of the pH metre were dipped in the reaction mixture, and the pH was set to 7. The enzyme extract (0.5ml) was immediately added, and the pH was checked. The timer was set for a pH reading of 7 at zero time [6]"

$$\text{Lipolytic Activity} = \frac{\text{Volume of alkali x Strength of alkali}}{\text{Weight of sample x Time in minutes}}$$

c) Proteolytic activity: Preparation of the Substrate Solution In 200 mL of warm milk, acetic acid was added until caesin

precipitated. The precipitate was then removed, dried, and pulverised. One gm of prepared caesin was diluted to 100ml in distilled water.

Procedure: 1ml substrate solution, 1ml of phosphate buffer (Ph 7.6) and 1ml calcium chloride. After 1 hour of incubation with 3ml of 5% trichloroacetic acid solution, the digestion was halted. Centrifugation was used to remove the precipitate after 10 minutes, and one fraction of the supernatant was combined with 5ml Lowry's reagent. After that, the mixture was stained with dilute Folin-Ciocalteau reagent (1:2) and the optical density was measured at 650 nm. The proteolytic activity was then estimated in milligrammes of tyrosine using the standard curve. Protien was measured using a conventional method, and the results were expressed as specific activity in milligrammes of released tyrosine per milligramme of dissolved protien per hour at 37 °C.

Results and discussion

Phyto-chemical results

Table 2: Phyto-chemical Investigation

Sr. No.	Phytohemical test	Test	Polyherbal churna	Polyherbal extract
1	Saponins	Foam test	+	+
2	Tannins	Lead acetate	+	+
3	Carbohydrates	Molisch's test	+	+
		Fehling's test	+	+
4	Alkaloids	Mayer's test	+	+
		Dragendroff's test	+	+
		Wager's test	+	+
		Hager's test	+	+
5	Flavanoids	Shinoda test	+	+
		NaOH + Conc. H_2SO_4	+	+
6	Steroids	Salkowski's	+	+
		Libermann & Buchard	+	+
7	Triterpenes	Salkowski's	+	+
8	Phenols	Ferric chloride test	+	+

Physiochemical Parameters

Table 3: Physiochemical Parameters of Polyherbal churna.

Sr. No	Physico-chemical Parameters (%w/w)	Polyherbal Churna
1.	Total ash	4.34±1.02
2.	Acid Insoluble ash	0.25±0.05
3.	Water soluble ash	2.17±0.07
4.	Alcohol Soluble Extractive value	9.32±0.25
5.	Water Soluble Extractive value	11.90±0.31
6.	Loss on drying	9.7±0.20

Polyherbal dispersible tablet formulation

The polyherbal dispersible tablet formulations were further evaluated by pre- compression and post- compression parameters.

Pre-compression studies (micrometrics study)

The powder blend prepared by direct compression method was studied for several properties prior the compression.

Table 4: Pre-compression evaluation for polyherbal formulation of dispersible tablet

Pre- compression	F1	F2	F3	F4
Bulk density (g/cm^3)	0.63±0.011	0.65±0.014	0.62±0.010	0.63±0.012
Tapped Density (g/cm^3)	0.52±0.008	0.51±0.006	0.50±0.011	0.53±0.013
Carr's Compressibility index	20.39±1.79	26.54±4.20	19.68±1.45	18.66±1.27
Hausner's ratio	0.83±0.012	0.79±0.026	0.75±0.008	0.84±0.008
Angle of Repose (ɵ)	31.08±0.48	31.1±0.714	32.40±0.202	29.64±0.202

Data are expressed as Mean ± SD (n=3)

The powder blend for all formulations batches (F1 to F4) showed the bulk density between 0.62- 0.65 g/cm^3 and tapped density angle was between 0.50-0.53 g/cm^3, Carr's Compressibility index and Hausner's ratio was found in the range of 18.6-26.5 and 0.75-0.84 respectively. Angle of repose varied from 29.6º-32.4. The results of pre-compression data showed that all the formulated formulations were having the good flow properties and compressibilities. For large scale production of tablets free flowing and compressibilities parameters are essential for quality of tablets without weight variation and thickness. The powder blend of all formulation batches performed well in the pre-compression studies [13].

Post-compression studies

Formulation batches (F1-F4) were prepared with direct compression method by varying the concentration of Sodium Starch Glycolate (Super disintegrant). After compression of the dispersible tablets, they were evaluated for various physical parameters.

All the formulated batches were subjected for post compression parameters. Thickness and diameter of all the batches were within the range without affecting the final packing. The mechanical strength of the tablets was within the acceptable ranges without breakages or chipping this was confirmed by the hardness test and friability test. Friability

tests results of the formulations were within 1%. Weight variation test results showed that all formulation were within the ranges of ±5%. The wetting time, water absorption ratio and *In vitro*-disintegration tests are interrelated to evaluate the possible the possible shortest time to disintegrate the dispersible tablet. "The disintegration time for all the formulations was having the less than 1minute." European Pharmacopoeia specified that the dispersible tablets should have disintegration time within 3minutes. The results of the formulated tablets were less than 50secs, thus the effect of Super- disintegrant agent with optimized range produced lowest disintegration time with the aid of effervescent base [13].

Table 5: Post-compression evaluation for polyherbal formulation of dispersible tablet

Formulation batch	F1	F2	F3	F4
Thickness (mm)	5.6±0.08	5.6±0.06	5.5±0.11	5.4±0.15
Diameter (mm)	10.1±2.25	12.3±0.03	11.5±0.12	12.2±0.15
Hardness (kg/cm^2)	1.4±0.06	1.4±0.08	1.35±0.04	1.5±0.13
Friability (%)	0.29±0.09	0.31±0.06	0.30±0.08	0.31±0.05
Weight variation (mg)	789-799	789-799	779-789	799-809
Wetting time (secs)	10±2.04	11.10±3.63	10.7±4.02	9.27±1.27
Water Absorption Ratio (secs)	0.70±0.03	0.73±0.02	0.79±0.06	0.65±0.08
In vitro dispersion time (secs)	41±3.60	39±5.98	47±6.21	32±2.51
In vitro disintegration time (mins)	11.86±0.36	9.18±0.49	10.35±0.40	7.33±0.19

All the formulation batches were evaluated for physical appearance and color. The general appearance of all tablet were found to be round biconvex in shape, brown in color, smooth texture and odorless.

From the post compression studies; the hardness of the tablets was found to be within 1.3-1.5 kg/cm^2. Thickness and diameter ranges between 5.4-5.6 mm and 10.1-12.3 mm respectively. The friability of the tablets was found to be 0.29-0.31% and the average weights of the tablets were in the range of 789-809mg. The wetting time were found to be 9.2-11.1 secs similarly water absorption ratio ranged around 0.65-0.73 sec. *In vitro* dispersion time and *In vitro* disintegration time was found to be in the range of 32-47secs and 7.3-11.8 mins respectively [11].

In vitro Digestive property studies

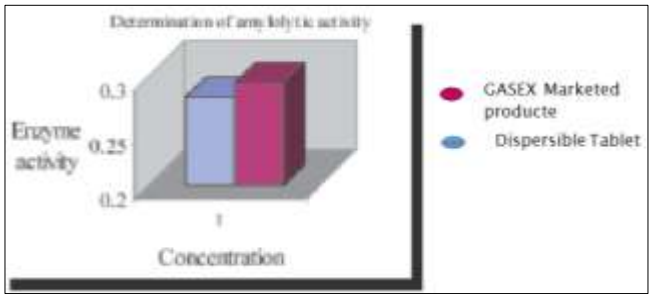

Fig 1: Determination of Digestive property by amylolytic

The amylolytic activity of the dispersible tablet was found to be 0.274mg/ml while that of GASEX was found to be 0.29 mg/ml.

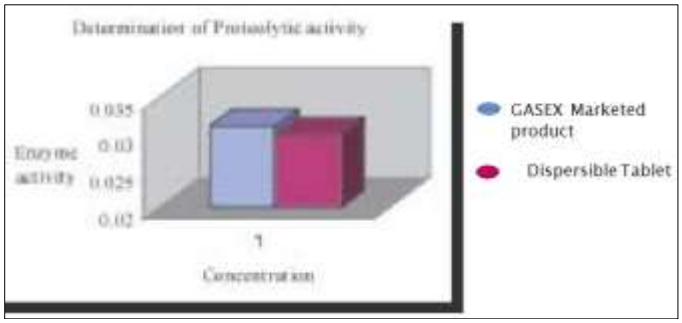

Fig 2: Determination of Digestive property by Proteolytic

Dispersible tablet has a lipolytic activity of 0.01634, while GASEX has a lipolytic activity of 0.02151.

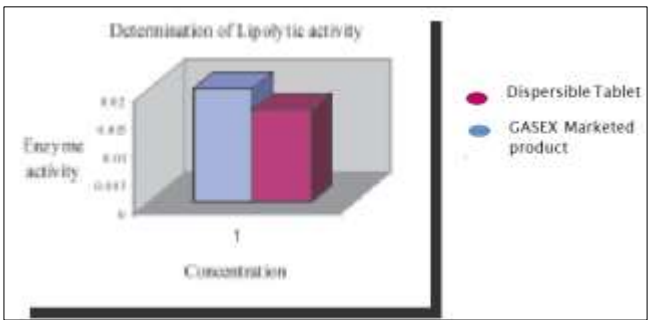

Fig 3: Determination of Digestive property by Lipolytic

The proteolytic activity of dispersible tablet was found to be 0.029 mg/ml while that of GASEX tablet was found to be 0.032 mg/ml.

Summary and conclusion

Summary

The usage and demand of herbal medicinal products has been increased all over the world because of their fewer side effects and proper therapeutic effects. Among all ayurvedic formulations, churna is one of them which contain the mixture of powdered herbs. Polyherbal churna has various traditional medicinal uses such as bio-enhancer, chemo- protective, anti-viral, expectorant, digestive property, fat- burner, etc. The shelf-life of churnas is very less due to which ayurvedic pharmacies manufacture in small batches. They are too voluminous which creates problem while administrating orally. All these factors show poor patient compliance and therefore, therein reduced contribution of traditional medicines in healthcare system. Polyherbal churna was prepared using turmeric,cinnamon,fennel and ginger. Further, Polyherbal churn was converted into hydro-alcoholic (30% alcohol) extract. The raw materials, polyherbal churna and polyherbal extract were subjected to further analysis. Preliminary phytochemical screening was performed to determine various phytoconstituents. The results showed the presence of Saponins, Tannins, Carbohydrates, Alkaloids, flavonoids, Steriods, Triterpenes and Phenols in all the samples indicate no net loss of phytoconstituents. Physico-chemical tests such as ash values, extractive values and loss

on drying were performed which confirmed the quality and purity of the samples. The Dispersible tablet of Poly-herbal extract was formulated using effervescent base by direct compression method. Four formulations were tried by varying the concentration of sodium starch glycolate. Effervescent base was used to increase the dispersion time and disintegration time. All the trials were subjected to pre-compression studies like Bulk density, Tap density, Angle of repose, Compressibility index and Hausner's ratio. The pre-compression studies showed good results. Further, the tablet batches were subjected to post-compression parameters such as Thickness, Hardness, Diameter, Hardness, Friability, and Weight variation, wetting time, Water –absorption time, In-Dispersion time and *In vitro* disintegration time. Based on results obtained F4 was selected as the optimized formulation which showed the dispersion time 32±2.51, friability 0.31±0.05 and *In vitro* disintegration 7.33±0.19.

The biological activity of dispersible tablet was assessed by comparing it to commercially available amylolytic, lipolytic, and proteolytic enzymes. Formulation GASEX tablet the enzyme amylase is involved in the amylolytic action. The conversion of starch to maltose caused by the action of Amylase is a type of enzyme. The measurement of amylolytic activity brings out dispersiblr tablets capacity to digest starch. The amylolytic activity of formed dispersible tablet was found to be 1.4 percent higher than that of the commercial formulation GASEX tablet in the current investigation. As a result, the prepared dispersible tablet was thought to have the ability to digest starch. Lipolytic activity is another enzymatic activity that involves the lipase enzyme breaking down lipids into fatty acids. The ability of a chemical to breakdown lipids is determined by measuring lipolytic activity. The lipolytic activity of compounded dispersible tablet was found to be slightly lower than that of GASEX tablet in this investigation. Proteolytic activity is an enzymatic activity in which the protease enzyme breaks down proteins into amino acids. The ability of a chemical to breakdown proteins can be determined by measuring its proteolytic activity. "It was determined in the current investigation utilising the folin- ciocalteau method, in which the phenolic group present in the released aminoacid, tyrosine, forms a compound with the reagents supplied and absorbs at 660nm." The intensity of colour depends on the amount of aromatic aminoacids present and hence gives the proteolytic activity of dispersible tablet. In the present study the proteolytic activity of formulated dispersible tablet was found to be almost equal to that of marketed formulation GASEX tablet.

Conclusion

The present study the Ayurvedic formulation polyherbal churna was converted into a modern dosage form i.e. polyherbal dispersible tablet. It can be concluded that the prepared dispersible tablet of polyherbal churna has overcome the disadvantages of churna such as poor patient compliance, pungent taste without altering its dose and chemical properties. There was no net loss of phytoconstituents present in churna during the process of conversion into polyherbal dispersible tablet. The *in vitro* assessment of enzymatic activity performed using the methods above reveals that the prepared dispersible tablet has the nearby same ability to digest carbohydrates, lipids, and proteins as the commercially available GASEX tablet.

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