Original Article

Formulation And Evaluation Of Nutraceuticals Of Curculigo Orchiode Root Extract

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Abstract

The goal of the current study was to create and assess nutritional tablets that contained various combinations of herbal medications.. The dietary supplement tablet that contains super tab 11SD diluents binder and containingnatural drug curculigo orchiode root extract It was made using the direct compression technique. The compressed formulations were evaluated using various criteria, including appearenace, thickening, varying weight, hardness, and friability. All of the nutraceuticals tablet's evaluation parameters produced findings that fell within the allowed range. Nutraceutical pre-formulation studies were determined to be within permissible limits. It was discovered that 92.11% of the herbal medicine from the enhanced nutraceutical formulation was released in vitro. The current investigation produced important findings. The results of the current study unequivocally demonstrated that nutraceuticals might be used to promote the body's health.

Key words: Direct compression, Nutraceutical, In vitro drug release

INTRODUCTION

Tablets are defined as unit dose, temper evident solid preparations containing one or more active ingredients. Conventional drug delivery systems like tablets and capsules often dissolve rapidly in the gastrointestinal tract for absorption into the bloodstream give rise to inordinately high drug concentrations in plasma [1]. The concept of making utility of food as health promoting factor beyond its nutritional value is gaining acceptance with in public arena and among scientific community. Nutraceuticals contain health- supporting ingredients or natural components that have an ability health benefit for the body. [2] A „nutraceutical" is a product isolated or purified from foods that is generally sold in medicinal forms not usually connected with food. A nutraceutical is bearing to have a physiological benefit or give protection against chronic disease. Term coined by Dr. Stephen L De Felice, Founder and Chairman of the Foundation for Innovation in Medicine, New Jersey, USA. Nutraceuticals sometimes referred as "functional foods", have caused heated debate because they change the traditional dividing line between food, and medicine.

The nutraceuticals normally contains required amount of lipids, protein, carbohydrates, vitamins, minerals and other necessary nutrients depending upon their emphases. Nutraceuticals in the market contains both traditional foods and non-traditional. When a supplement tablet is ingested, the body must digest and absorb the nutrients. Nutraceutical may include a whole area of products like isolated nutrients, dietary supplements, herbal products and other processed foods. [5] The growing disapproval among the patients about the synthetic therapeutic agents and affect about their toxicological profile gave birth to the "Dietary Supplements Health and Education Act" (DSHEA) in USA in 1994. [5, 6] The concept behind the mode of action of nutraceutical dosage form is to provide functional benefits by enhancing the supply of natural building blocks. It works in to two ways that is to minimize diseases sign or to improve body performance. [2, 3]

MATERIALS AND METHODS

Curculigo orchiode root was collected from Amazon online market. Supertab11SD, Primogel, magnesium stearate, and talc, among other substances, were all obtained from local pharmaceutical company Himalaya. Analytical-grade substances were employed throughout.

METHOD:

Using the direct compression approach, a nutraceutical tablet containing the natural remedy curculigo orchiode root was created. Talc, primogel, supertab11SD, and magnesium stearate were among the other substances used. The API and other excipients were weighed in accordance with table 1 and passed through sieve number 20. Following geometric mixing, all ingredients—excluding glidant and lubricant—were fully combined for 15 minutes. The final powder mix

was evaluated before to compaction, and the findings of the examination of pre compression parameters are provided in table..

Table 1: formulation for direct compression manufacturing of herbal tablets

S.No.	Ingredient	Purpose	Herbal Tablet (500mg)
1.	Hydroalcoholic extract of CO	API	300
2.	Super tab 11SD	Diluent- Binder	144
3.	Primojel	Super disintegrant	50
4.	Magnesium Stearate	Lubricant	3
5.	Talc	Glidant	3

EVALUATION OF NUTRACEUTICAL TABLETS

a.Pre-formulation studies:

Determining specific basic physical and chemical characteristics of the drug molecule as well as additional divided characteristics of the medication powder is crucial. Several of the subsequent actions and strategies in the formulation development process are determined by this knowledge. The preformulation stage is the first one..

In preformulation, the physicochemical characteristics of the drug material are characterised using biopharmaceutical concepts in order to create the best drug delivery system.

All of the extracts in the current study were evaluated for their micromechanical characteristics, such as bulk density, Carr's index, Hauster ratio, and angle of repose, as well as their organoleptic features, solubility, loss upon drying, and compatibility with excipients.

1. Organoleptic properties

On the based on visual and sensual, the color and odor of the extracts were determined.

2. Compatibility study

Individual hydroalcoholic extracts and the excipients utilised in the current investigation were tested for compatibility in a 1:1 ratio at 40 2 °C, 75 5% relative humidity, and 5 1 °C for refrigeration in airtight containers. At 7, 15, and 30 day intervals, triplicate samples were taken out and looked at physically for evidence of degradation..

3. Bulk density

Knowledge of absolute and bulk density of the drug substance is very useful in having some idea as to the size of final dosage form. The density of solids also of affects their flow properties, Carr's compressibility index, Hausner ratio can be used to predict the flow properties based on density measurement.

The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume including the contribution of the interparticulate void volume. The bulk density is grams per cubic centimetre (g/cm3). Bulk density was determined by taking the known mass of the extracts and transferred to 100 ml graduated measuring cylinder and tapped to constant volume. The experiment was repeated in triplicate. Bulk density was calculated using the following formula.

4. Carr's compressibility index

The Hausner ratio and Compressibility Index are indicators of an extract's susceptibility to be compressed. Because of this, they serve as indicators of the relative significance of particle interactions.. Such interactions are typically less significant and the values of the bulk and tapped densities will be closer in a free-flowing powder. There are usually more particle interactions in poorly flowing materials, which results in a larger discrepancy between the bulk and tapped densities.

The Compressibility Index and the Hausner Ratio both reflect these variations.

Carr's compressibility index is a straightforward test that assesses the flowability of extract by contrasting the density of powder while it is poured, tapered, and plucked down at different rates.

Tapped density - Poured density multiplied by 100 / Tapped density yields Carr's compressibility index.

5. Hausner ratio

The formula below is used to calculate it.
Tapped density /pore density is the Hausner ratio.

6. Percentage of fines

The percentage of fines indicates how much powder is still inside each granule. When there is free space in the die

cavity when employing 100% granules, maintaining the hardness of the tablet becomes difficult. Moreover, following compression, air causes the tablets to shatter. The sieve method can be used to calculate the percentage of particles.
After lubrication, a known mass of the mixed granules was run through British Standard Sieve Series mesh no. 80. The sample's weight and amount that made it past the filter were recorded.
The percentage fine amount was calculated using the formula below:
Fines percentage equals fines weight divided by total granule weight multiplied by 100.

B.Post compressional studies of prepared nutraceuticals:

1. Physical appearance: Shape, colour, texture, and odour of the tablet were studied visually.

2. Test for Friability

It gauges the potency of tablets. Take a sample of 10 whole tablets for tablets with an average weight of more than 0.65 g and a sample of entire tablets for tablets with an average weight of 0.65 g or less. The Roche Friabilator was used to conduct the friability test. In the beginning, ten tablets were weighed and placed in a spinning drum. Then, 100 falls of 6 inches in height were inflicted upon them (25 rpm for four minutes). The tablets were dedusted with a camel hair brush after the rotations were finished, and then they were weighed. For the majority of tablets, a maximum weight loss of not more than 1.0 percent (from a single test or from the mean of the three tests) is allowed. The formula below was used to compute the percentage loss in weight or friability (F), and the results are shown in the table.
(Start weight -Final weight / Final weight) x 100 = % Friability

3.. Hardness

Consumer approval depends on the tablet's adequate hardness, resistance to powdering, and friability. It affects drug release and tablet breakdown as well. Using a Pfizer hardness tester, the hardness of ten tablets that were randomly chosen was determined. The outcomes are shown in a table.

4. Uniformity of weight

Twenty tablets were randomly chosen, weighed together, and then individually to ensure weight consistency. The results are shown in the table along with the mean and standard deviation. If no more than two of the individual weights stray from the average weight by more than the % and no weights deviate by more than twice the percentage listed below, the prepared tablets pass the test..

5. Thickness:

Vernier callipers were used to calculate the tablet's thickness. Six tablets were utilised for this test, and the thickness of each tablet was measured between two jaws vertically and expressed in mm.

6. Disintegration

Disintegration is the breakdown of a tablet into smaller pieces or grains. Six glass tubes, each three inches long and open at the top, are placed against a ten-mesh screen at the bottom of the basket rack to test the disintegration. One tablet is placed in each tube and the basket rack is set up in a one-liter beaker of water at 37+2°C to test the disintegration time. The basket rack is positioned so that the tablet remains 2.5 cm below the surface of the liquid on its upward movement and descends not closer than 2.5 cm from the beaker's bottom. The basket housing the tablets is moved up and down across a distance of 5–6 cm using a typical motor-driven device at a frequency of 28–32 cycles per minute. Modified release tablets and tablets intended for oral usage are not eligible for this test. Although the majority of tablets have a maximum disintegration period of 30 minutes, uncoated tablets can disintegrate in as little as 5 minutes. The breakdown time of enteric-coated pills is greater than one hour.

In Vitro Dissolution Studies:

An eight station dissolution test equipment with paddles and 900 cc of a 6.8 pH phosphate buffer as the dissolution medium were used to conduct in vitro dissolution studies on all of the different formulations. Formulations C1 to C3 produced with xanthum gum at 10- 40 mg were observed to release 90% of the drug within 4 hours. Formulations C5 to C7 made with a karaya gum ratio of 10 to 40 mg failed to prolong the drug release for up to 12 hours. It was found that Formulation C8, which contains 40 mg of karaya gum, can prolong the time that the drug is released by up to 12 hours. Formulation C8 delivered roughly 92.11 percent of the medication throughout a 12-hour period, and it.

RESULTS AND DISCUSSIONS

Table2: final powder blend for pre compression parameters were shown in the dissolving profiles.

S.No.	Compression parameter before	Observation
1.	Organoleptic properties	brown substance that was free-flowing and odorous.
2.	fines percentage.	17% w/w
3.	Volume density	0.46 g/cm3
4.	Angle of repose	32.42°
5.	Hausener ratio	1.156
6.	Carr index	13.35%

Table3: Evaluation of herbal tablets for post compression parameters

S.No.	Post compression parameter	Observation/Result
1.	Physical appearance	Pale brown, round shaped tablets with characteristic odor
2.	Hardness	5.2±0.15 kg/cm^2
3.	Friability	0.72±0.37%
4.	Weight uniformity	499±0.71 mg
5.	Thickness	18±0.52 mm
6.	Time of disintegration	9.31±0.26 minutes

Table 4: Composition of Controlled Release Herbal tablets by direct compression technique

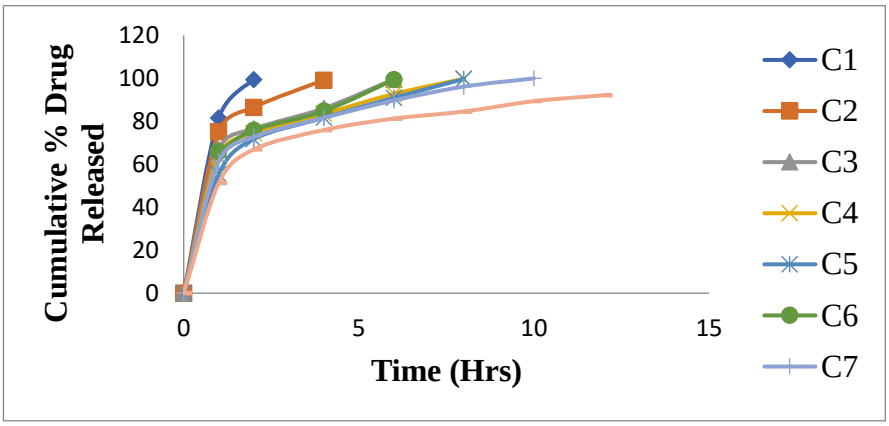
Ingredients (mg)	C1	C2	C3	C4	C5	C6	C7	C8
Hydroalcoholic extract of CO	300	300	300	300	300	300	300	300
Xanthum gum	10	20	30	40	-	-	-	-
Gum karaya	-	-	-	-	10	20	30	40
Microcrystaline cellulose pH 102	180	170	160	150	180	170	160	150
Magnesium streate	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5

Flow Properties of Prepared Controlled Release Herbal tablets

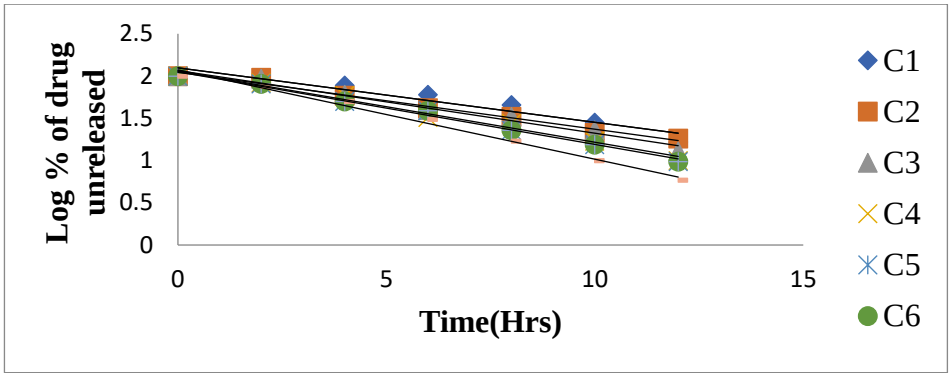
S. No.	Formulation	Angle of repose (θ)	Compressibility Index (%)	Hausner's ratio	Drug content (%)
1	C1	23.14±0.02	11.25±0.051	1.222±0.05	98
2	C2	21.94±0.05	12.40±0.024	1.142±0.07	93
3	C3	24.69±0.02	14.10±0.022	1.143±0.04	92
4	C4	23.42±0.05	12.29±0.009	1.322±0.05	95
5	C5	22.85±0.01	13.17±0.017	1.152±0.04	93
6	C6	23.01±0.03	14.08±0.014	1.114±0.02	94
7	C7	25.76±0.05	15.35±0.024	1.178±0.01	93
8	C8	25.42±0.05	14.89±0.009	1.192±0.03	96

Table 5: Drug Release Profiles of Controlled Release Herbal tablets

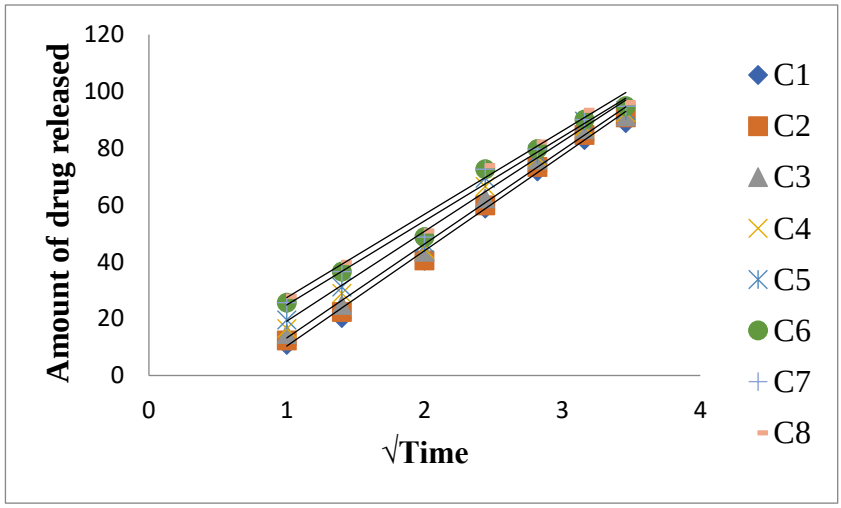
S.No	Time (hrs)	Cumulative % Drug Released							
		C1	C2	C3	C4	C5	C6	C7	C8
1	1	81.44	75.11	66.87	63.77	55.41	65.89	61.32	51.22
2	2	99.36	86.47	76.41	74.52	71.69	75.86	72.69	66.87
3	4	-	99.12	85.99	83.41	81.59	84.74	81.58	75.91
4	6	-	-	99.56	92.68	90.88	99.36	89.66	81.23
5	8	-	-	-	99.74	99.67	-	96.11	84.52
6	10	-	-	-	-	-	-	99.91	89.32
7	12	-	-	-	-	-	-	-	92.11



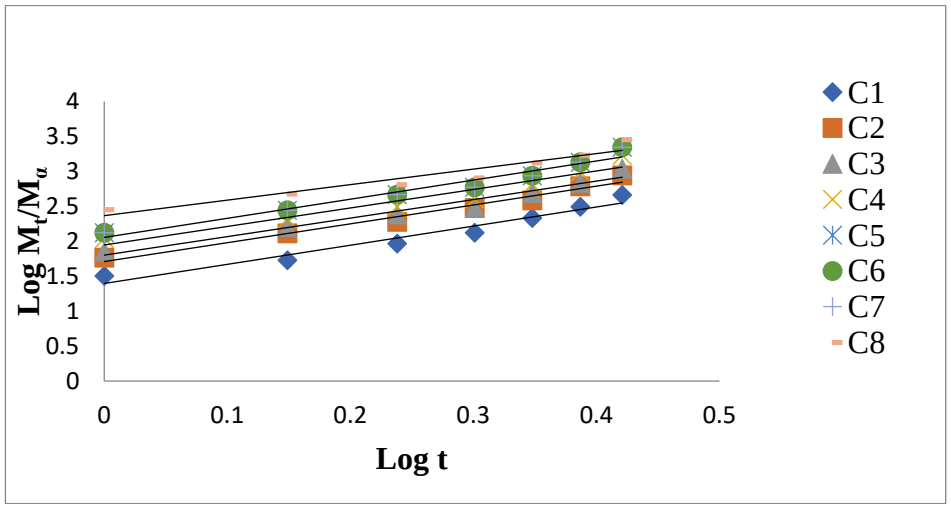
Graph no1: Drug Release Profiles of Controlled Release Herbal tablets



First order plots for Controlled Release Herbal tablets



Higuchi plots for Controlled Release Herbal tablets

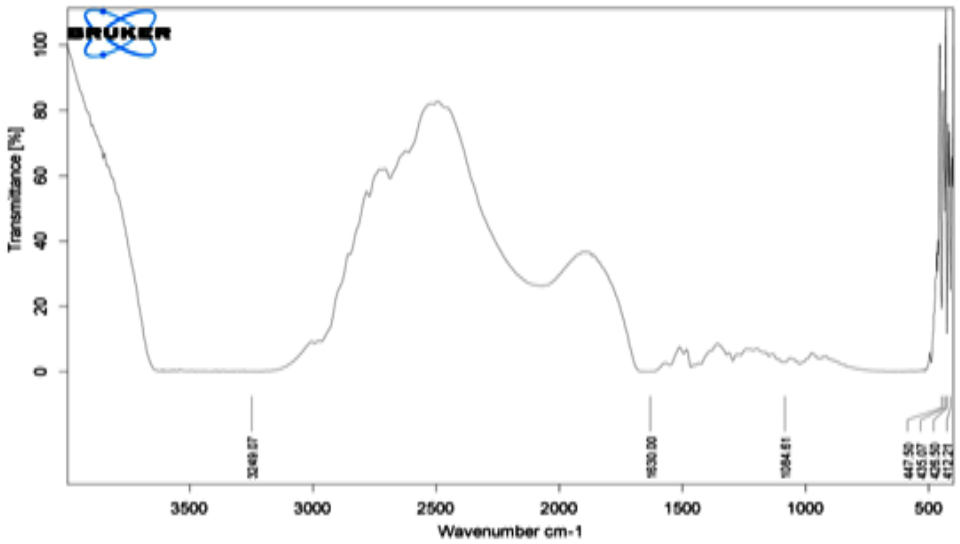


Peppas plots for Controlled Release Herbal tablets

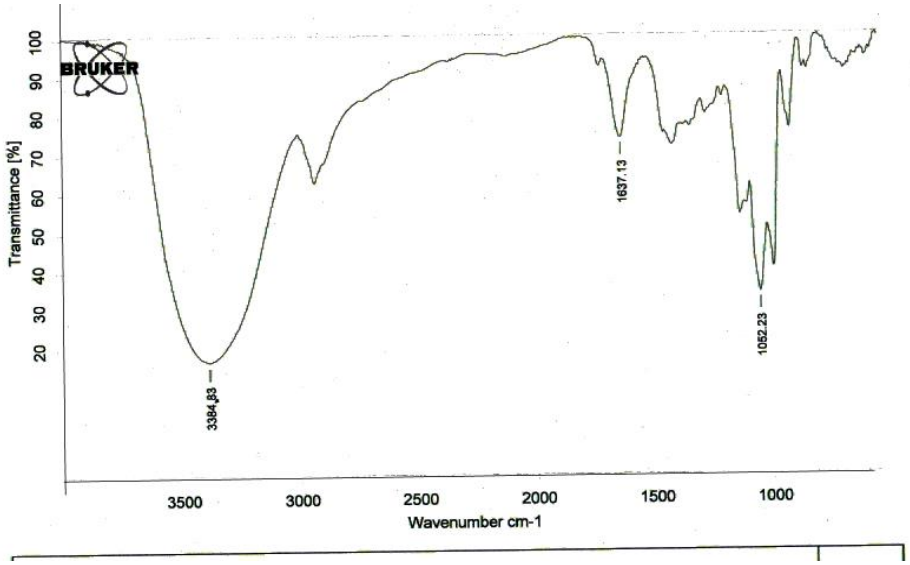
Table 8: Dissolution Parameters of Controlled Release Herbal tablets

Formulation	First Order		Higuchi		Peppas	
	K_1 (h^{-1})	R^2	K_H ($mg/h^{1/2}$)	R^2	n	R^2
C1	0.274	0.932	38.186	0.942	0.734	0.984
C2	0.303	0.954	38.588	0.966	0.518	0.970
C3	0.204	0.926	33.634	0.998	0.597	0.943
C4	0.325	0.932	32.574	0.911	0.625	0.947
C5	0.347	0.956	37.017	0.971	0.784	0.981
C6	0.455	0.919	27.888	0.955	0.650	0.987
C7	0.455	0.939	26.888	0.945	0.730	0.967
C8	0.232	0.986	22.889	0.998	0.877	0.978

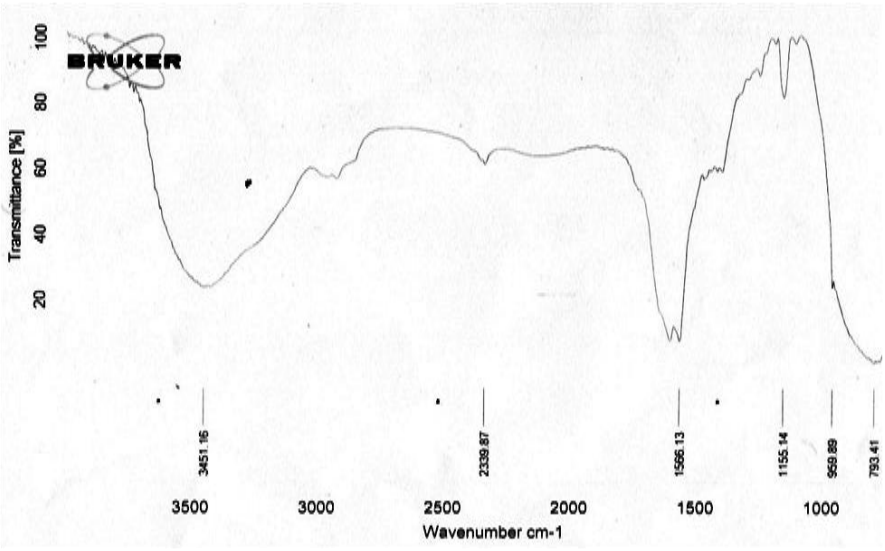
FTIR SPECTRUMS



FTIR Spectra for CO Extract



FTIR Spectra for Xanthum gum



FTIR Spectra for Gum karaya

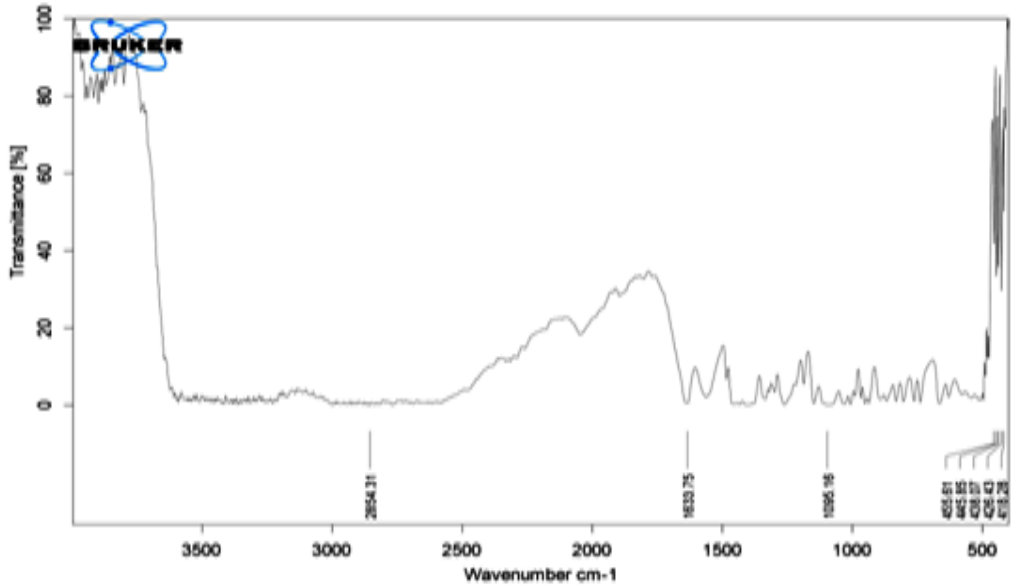
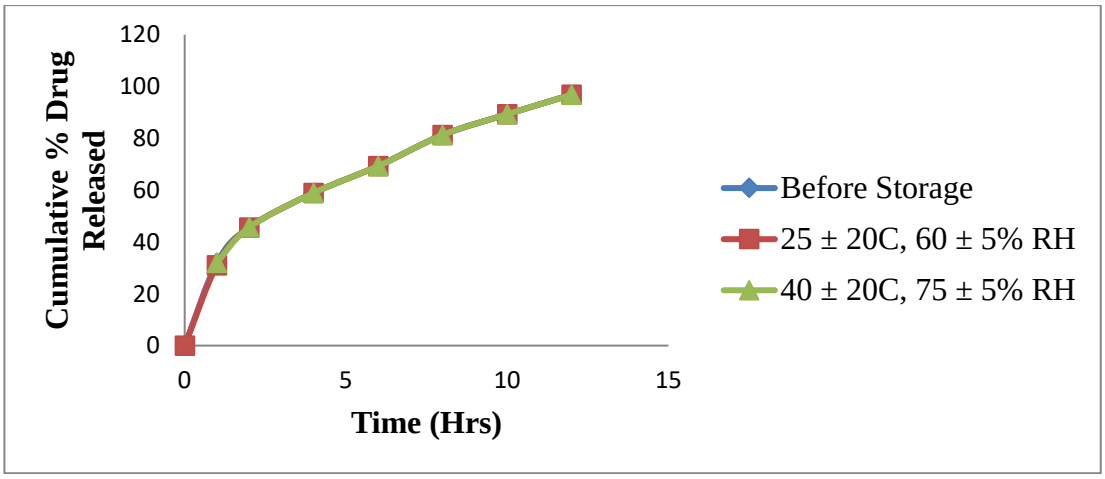


Figure 15: FTIR Spectra for optimized formulation (C8)

Drug Release profiles of Controlled Release Herbal tablets before and after Storage at Different Conditions

Time (hrs)	Before Storage	25 ± 2^{0}C, 60 ± 5% RH	40 ± 2^{0}C, 75 ± 5% RH
1	51.22	51.21	51.20
2	66.87	66.86	66.85
4	75.91	75.90	75.89
6	81.23	81.22	81.20
8	84.52	84.51	84.50
10	89.32	89.31	89.30
12	92.11	92.10	92.09



Drug Release profiles of Controlled Release Herbal tablets before and after Storage at Different Conditions

CONCLUSION:

According to the aforementioned study, the direct compression method was used to create the nutraceutical tablets, and the results were satisfactory and acceptable. Due to direct tablet compression, conventional nutraceutical tablets exhibit regulated drug release. According to the results of the aforementioned research, herbal nutraceutical tablets should be made in a way that minimises patient compliance while simultaneously suppressing adverse effects and promoting beneficial effects on the body.

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