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EXPLORATION OF *AMORPHOPHALLUS PAEONIIFOLIUS* STARCH AS NATURAL BINDER

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ABSTRACT: The aim of the present work was to characterize the starchy components of *Amorphophallus paeoniifolius* tuber and evaluate its potential as a binder. The tuber starch was extracted and characterized in terms of Phyto-chemical and physicochemical properties. Cyproheptadine was selected as model drug, and drug excipient compatibility studies were carried. Granules containing 5%, 7.5%, 10%, and 12.5% of isolated starch were prepared by wet granulation and evaluated for pre and post-compression parameters. The isolated sample was white in color and free from contaminant with moderate flow properties. The drug was found to be compatible with excipients, as revealed in the FTIR study. Prepared granules were found to have good flow property and compressibility as evident from the angle of repose and Carr's compressibility index. The tablets were also evaluated for hardness, friability, disintegration time and *in-vitro* dissolution and all the result were found to be in the standard limit as per I.P. Results shows that *Amorphophallus paeoniifolius* starch can be used as a tablet binder and could be effectively utilized as a multi-functional natural excipient.

INTRODUCTION: Tablet is the most popular formulation found till date due to ease of administration, transportation and low processing cost as compare to other dosage form. These can be prepared by either wet or dry granulation. Dry granulation is applied only for directly compressible excipients. Hence, wet granulation is the most widely used. Various synthetic, as well as natural binding agents have been used for the production of wet granules, among which starch is found to be most popular due to its abundant availability. Chemically it is a polysaccharide composed of anhydroglucose units linked by α-D (1, 4) glycosidic bonds.

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It consists of one linear and one branched polymer, mainly amylose (15-30%) and amylopectin (85-70%) [1]. For many decades, starch is used as the diluent, disintegrant, and binder in pharmaceutical formulations. 5-20% of the freshly prepared starch paste is commonly used as a binder, and 5-15% of starch is applicable as disintegrant [2-3].

It is also used in novel applications such as periodontal, film-based, and nasal delivery [4-6]. Although it is a well-established excipient, diversified applications have been made to explore new sources of starch and find its applicability as an alternative pharmaceutical excipient. *Amorpho-phallus paeoniifolius* (commonly known as elephant foot yam) tuber crop of tropical and subtropical countries. It is a dark brown corm, a perennial, terrestrial underground hemispherical depressed approximately 20-25 cm in diameter which bears flowers and fruits in the month of April – May [7-9]. It bears leaves which are 30-90 cm, solitary broad. Inflorescence consists of a foliar

organ, the spathe, which usually envelops a stalk-like organ, the spadix. The flowers are tiny, monoecious, and strongly reduced and are found at the base of the spadix. In India, it is cultivated in Maharashtra, Gujarat, Uttar Pradesh, Andhra Pradesh, West Bengal, Kerala, Tamil Nadu, and Jharkhand. The tubers are rich in starch (11-28 %) and other nutrients; it is much popular as a vegetable in various delicious cuisines.

It possesses blood purifier properties and has been used traditionally for the treatment of asthma, abdominal disorders, piles, tumors, enlargement of the spleen, and rheumatism [10-11]. Recent medicinal uses of *Amorphophallus Paeoniifolius* was summarised by Anuradha Singh and Neeraj Wadhwa [12].

For the formulation of tablets, Cyproheptadine HCl is used as a model drug. It is a serotonin antagonist, histamine H1 blocker, and potent antihistaminic drug used as antiallergic. Cyproheptadine HCl has a half-life of about 16 h, well absorbed after oral administration. In the present study, an attempt has been made to prepare and evaluate the tablets by using novel starch isolated from *Amorphophallus paeoniifolius* as a binder.

MATERIALS AND METHODS: *Amorphophallus paeoniifolius* tuber was procured from the local market of Pune, Cyproheptadine HCl was received as a gift sample from Shalini Labs, Pune, Microcrystalline cellulose, Magnesium stearate, Avicel 101, and Talc were purchased from Loba chem. All excipients used were of analytical grade.

Extraction of Starch: Starch was isolated from *Amorphophallus paeoniifolius* tubers by little modification in the method adopted by Sukhija *et al.* (2016). The fresh tubers were washed thoroughly with distilled water, and all bruises were pitted out. Washed tubers were peeled and subsequently reduced to small sizes before pulverizing. The pulverized mass was then passed through a sieve of diameter 150 µm, and the slurry allowed to sediment for 12 h in an aq. solution of (0.075%) of sodium metabisulphite. The supernatant water was then decanted while the sediment (starch) was treated with 0.1N NaOH in order to precipitate the protein content of the starch. The starch was then washed two to three times with distilled water to remove excess sodium hydroxide. The resulting starch extracted was dried in an oven for 50 ºC for 2 h. Dried mass was pulverized into a fine powder and weighed [13].

Phytochemical Test for Isolated Starch: Phyto-chemical screening was performed with respect to the presence of carbohydrates, polysaccharides, alkaloids, glycosides, flavonoids, steroids, saponins, organic acids, proteins, loss on drying, ash value, as per the reported method [14].

Physicochemical Properties of Starch:

Flow Properties:

Angle of Repose: The angle of repose of starch powder and Cyproheptadine granules were determined using a glass funnel clamped on a retort stand which was 2.5 cm away from the flat surface of the bench. 50 g of each sample starch powder or Cyproheptadine granules were placed into the funnel and allowed to flow freely, forming a conical heap. The angle of repose was calculated from the heap of each sample using the equation;

$$\text{Angle of repose, } \tan\theta = h/r$$

Where h = height and r = radius of the circular heap.

Bulk Density: It was carried out by measuring the volume occupied by a 50 g weight of starch powder or Cyproheptadine granules in a dry measuring cylinder. The bulk density was calculated using the formula;

$$\text{Bulk density} = \text{Weight of sample} / \text{Volume of sample}$$

Tapped Density: The measuring cylinder was subjected to a tap density test apparatus, tapped 100 times, and the tapped volume was recorded. The tapped density was calculated as;

$$\text{Tapped density} = \text{Weight of sample} / \text{Tapped volume of sample}$$

Determination of Carr's Index: Carr's index was calculated from the results obtained from bulk and tapped densities above using the relation;

$$\text{Carr' index (\%)} = \text{Tapped density- Bulk density} / \text{Tapped density} \times 100$$

Determination of Hausner's Ratio: Hausner's ratio was determined using the results obtained from both bulk and tapped density. It was calculated using the formula [15]:

Hausner's ratio = Tapped density / Bulk density

Gelation Temperature: 1 g of the starch sample was transferred to a 20 ml beaker, and 10 ml of distilled water was added. The suspension was heated on a hot plate with stirring. The temperature at which suspended starch began to gel was noted as gelation temperature [16].

pH Determination: The pH values of 1% starch suspensions were measured using a digital pH meter.

Swelling Capacity: Swelling power was determined by using method described by Adewmi *et al.,* (2018) with slight modification [17] , 0.1 g of starch sample was heated in 10 ml distilled water in a water bath at 60 °C for 30 min with continuous and vigorous shaking. The gel was centrifuged at 1600 rpm for 15 min. Supernatant was decanted and weight of sediment was taken. Swelling power was calculated by following formula:

Swelling Power = Weight of starch (g) / Weight of sample on dry basis (g)

Paste Clarity: The clarity (transmittance % at 650 nm) of isolated starch paste was measured using the procedure performed by Ritika *et al.* (2018). 1% aqueous suspension of starch near-neutral pH was heated in a boiling water bath for 30 min with intermittent shaking. Suspension was cooled for 1 h. at room temperature and the light transmittance at 650 nm was read against water as a blank [18].

Moisture Content: 2 g weight (W1) of starch was dried for 24 h. at 105 ºC in hot air oven and weight (W2). Then the moisture content was calculated as

$$\text{Moisture content (\%)} = W_1 - W_2 / W_1 \times 100$$

W_1 = Weight of wet sample (gm.) and W_2 = Weight of dry sample gm [19]

Pre-formulation Studies for Drug and Excipients: FT-IR spectroscopy was carried out to check the compatibility between the drug and the polymer. FTIR spectra were recorded using Fourier transform Infrared Spectrophotometer (Shimadzu, Japan) within the operating range of 4000 to 400 cm^{-1} [20].

Preparation of Tablet: Granules were prepared by wet granulation method; calculation made for 50 tablets in each batch. Accurately weighed 4 mg/tablet Cyproheptadine HCl and a predetermined quantity of Avicel PH102. The starch paste was prepared by varying 5%, 7.5%, 10%, and 12.5% of isolated starch and wet massed with drug and Avicel PH102. This mass was kneaded thoroughly, passed through no 16 sieves, and dried in a hot air oven at 50 ºC for 15 min. Dried mass was then passed through no 22 sieves to get the final product. Obtained granules were evaluated for pre-compression parameters such as flow properties as discussed in the evaluation of isolated starch powder. Various batches of granules were mixed with 5% of isolated dry starch, to this 1% magnesium stearate was added and mixed for 5 min, later 1% talc was added and mixed for 2 min. The mixture equivalent to 100 mg was compressed into tablets with 6 mm tablet punches on a single station compression machine (CIP, India). Obtained tablets were further evaluated for post-compression parameters as per I.P. standards [21].

Weight Variation: Twenty tablets were randomly selected from each batch and weighed individually. The mean weight of the tablets was then calculated, and the standard deviation was determined.

Hardness: The Monsanto hardness tester was used in measuring the hardness of the tablets. Six tablets were randomly selected from each batch and placed individually between the anvil and the spindle of the Monsanto hardness tester and subjected to increasing pressure by turning the knurled knob until the tablet was crushed. The mean of the six determinations was taken for each batch.

Friability Test: Pre-weighed tablet samples were placed in the friability test apparatus, which was then operated for 25 revolutions/min for 4 min, dropping the tablets a distance of 6 inches with each revolution. The percentage of friability was calculated using the formula.

F = Initial weight-Final weight / Initial weight × 100

Disintegration Test: Six tablets were randomly selected from each batch and placed individually in the six tubes of the disintegration test apparatus. It was subjected to up and down movement in 0.1 N HCl contained in a glass jar suspended in a water bath whose temperature was thermostatically maintained at 37 °C ± 1 °C the time taken for the last

tablet or its fragment to pass through the 2 mm mesh into the disintegrating medium was recorded for each batch.

***In-vitro* Dissolution Test:** It was carried out by IP I dissolution test apparatus; briefly, 900 of 0.1 N HCl was added in a dissolution vessel, and the temperature of the medium was set at 37 ± 0.5 ºC. Tablet was placed in each dissolution vessel and rotational speed of paddle was set at 50 rpm. The 5 ml of sample was withdrawn at predetermined interval and same volume of fresh medium was replaced. The samples were analysed for drug content against 0.1 N HCl as blank at λ_{max} of 221 nm using double beam UV visible spectrophotometer. Percentage cumulative drug release was calculated [22].

RESULTS AND DISCUSSION: The isolation procedure for starch was relatively easy and does not involve the use of and toxic chemicals for the extraction process. Starch particles settled easily and other contaminants remained suspended in supernatant liquid and these could be decanted off. Organoleptic properties indicated white colored powder, odorless with bland taste and smooth texture. Phytochemical studies showed that the sample was free from other phytoconstituents apart from protein and fat. Igniting the starch sample and analysis of the residue indicates contamination of the starch. Lower ash values indicate less contamination. Isolated starch was subjected to flow properties, and the result showed that it had moderate flow characteristics. Hence, it was the utmost need of formulation to prepare granules by wet granulation method. It meets the specific requirement of pH. To be utilized as an excipient, swelling power was of crucial importance; it indicates association forces in the particles as well as hydration power of the starch. The crystallinity and molecular order inside the starch molecule were broken down upon heating in the presence of water, referred to as gelation [23]. Starch is a water-insoluble component; hence could be hydrated by increasing temperature. High hydration increases swelling power and gelation ability of the starch granules as a result of the breaking of hydrogen bonds and replacement with water molecules. Gelation temperature was recorded and found to be 65-70 ºC. Moisture absorption of starch was due to the interaction between water molecules and the hydroxyl groups of the hexose moiety. Water molecules had a tendency to form a hydrogen bond with amylose and amylopectin; amylopectin tends to physically trap the water molecules [24]. The result of the evaluation was shown in **Table 1**.

TABLE 1: EVALUATION OF ISOLATED STARCH

S. no.	Parameter	Results
1	Angle of repose(^{0})	33 ±0.23
2	Bulk density (g/ml)	0.46 ± 0.57
3	Tapped density (g/ml)	0.67 ± 0.74
4	Carr's compressibility index (%)	31.34 ± 0.56
5	Hausner's ratio	1.46 ± 0.45
6	Gelation temperature (^{0}C)	65-70 ± 0.96
7	pH	6.8 ± 0.34
8	Swelling index (%)	0.96 ± 0.24
9	Paste clarity (%)	13.5 ± 0.87
10	Ash value (% w/w)	0.10 ± 0.93
11	Moisture content (%)	3.56 ± 0.54

*All the reading were taken in triplicate

While designing the formulation, drug and excipients must be compatible; this would affect the final stability of the product. FTIR study was a common tool to study the compatibility between drug and excipient.

FT-IR Spectra of Isolated Starch:

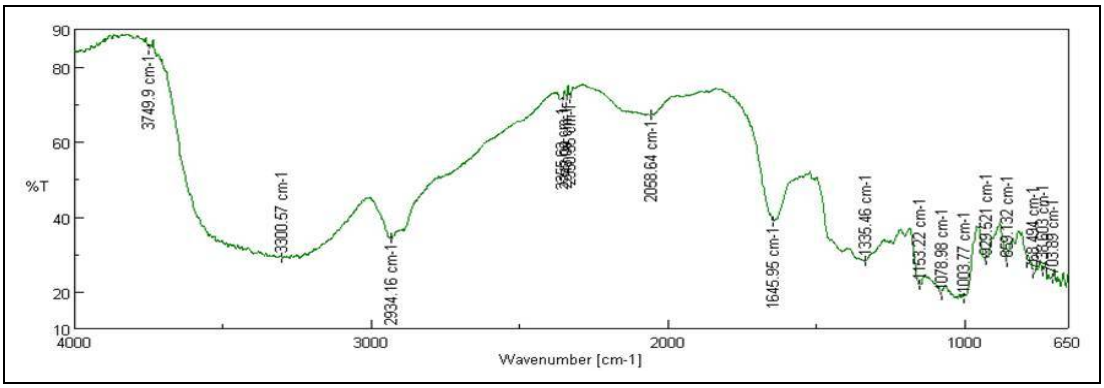

FIG. 1: FT-IR SPECTRA OF ISOLATED STARCH

FTIR spectra of isolated starch showed the vibration of C-O-C ring at 768.49 cm^{-1}. C-O, C-C and C-O-H stretching and C-O-H bending of anhydrous glucose ring seen at 929.52, 1003.44-1153.22 cm^{-1}, vibrations at 3300.57 cm^{-1} showed glucopyranose ring O-H stretching. C-H stretching vibration of the aliphatic group observed at 2934.16 cm^{-1}, vibration corresponds to moisture absorption observed at 1645.95 cm^{-1}.

C-C and C-O stretching observed at 1153.22 cm^{-1}, 1078.98 cm^{-1}. Characteristic functional groups were observed, which represents the polysaccharide groups **Fig. 1** [25-27].

FT-IR Spectra of Cyproheptadine Pure Drug:

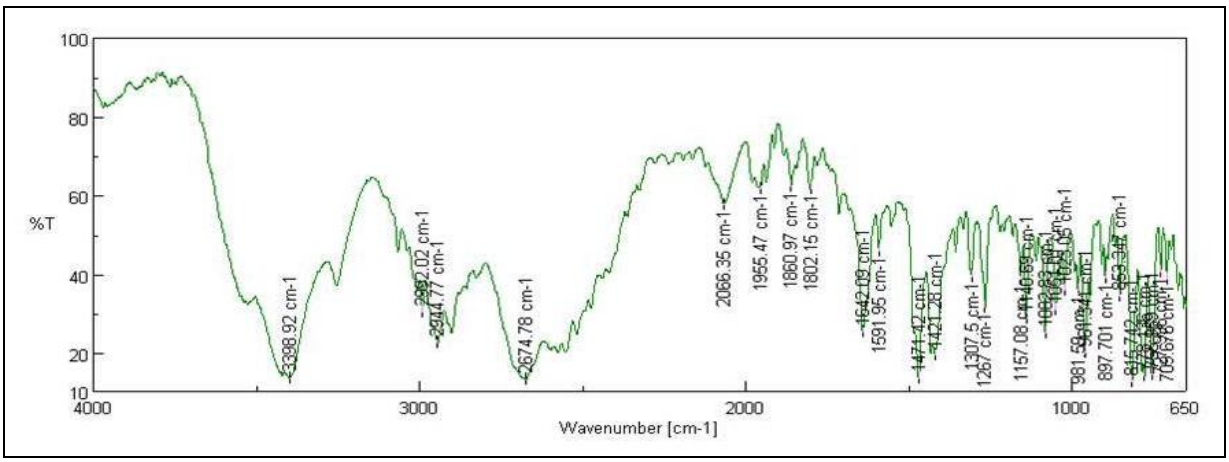

FIG. 2: FT-IR SPECTRA OF CYPROHEPTADINE PURE DRUG

FT-IR spectra **Fig. 2** of the pure drug showed characteristic absorption peaks at 3398.92 cm^{-1} indicated N-CH_3 stretching, aromatic phenyl stretching was observed at 1591.5 cm^{-1}, C=C at C10-C11 seen at 1642.09 cm^{-1} C-N stretches observed at 1267 cm^{-1}, aromatic C-H stretch observed at 1082.83 cm^{-1} [28].

FT-IR Spectra of Cyproheptadine Pure Drug and Excipients:

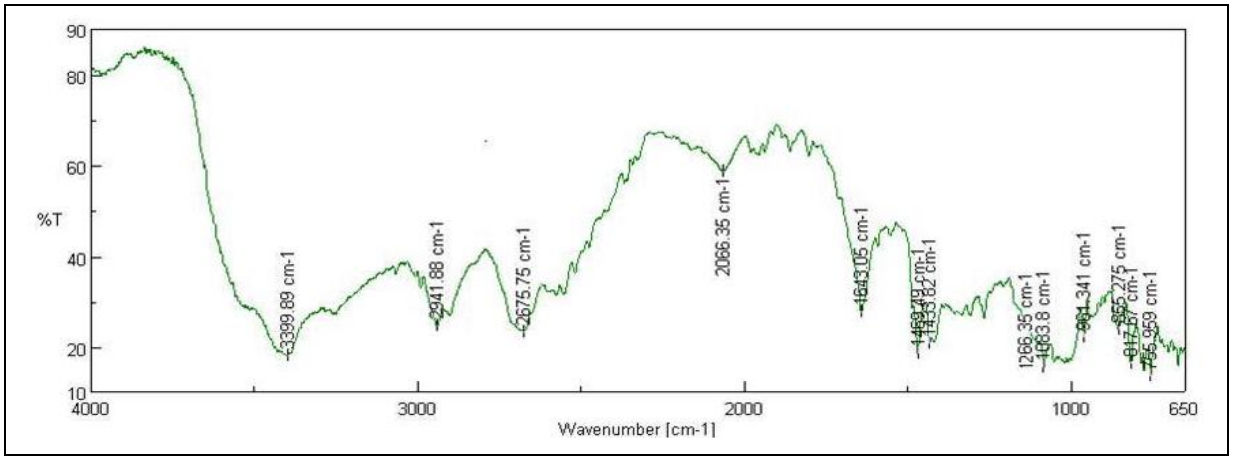

FIG. 3: FT-IR SPECTRA OF CYPROHEPTADINE PURE DRUG AND EXCIPIENTS

FT-IR spectra of drug and excipients were studied to check the drug-excipient and excipient-excipient compatibility **Fig. 3**. As compared to FT-IR spectra of pure drug, physical mixture showed characteristic absorption peaks at 3399.89 cm^{-1}, 1643.05 cm^{-1} 1267 cm^{-1}, aromatic C-H stretch observed at 1083.8 cm^{-1}. No significant variations were observed apart from a slight change in intensity of peaks. These findings revealed the compatibility between drug and excipient.

Evaluation of Pre-compression Parameters: Various pre-compression parameters were evaluated as per specifications given in I.P.

Data obtained after evaluation of pre-compression parameters was summarised in **Table 2**. Low values of bulk and tapped density indicative of nonporous and free-flowing nature of the granules. Further flowability of the granules was confirmed by compressibility index value, ranged between 10.16-13.23%, indicated that the prepared granules exhibited the required flow property of compression. The values were found to be in the range from 270-300, and Hausner's ratio was less than 1.25. This indicated good flow property of the granules with increasing concentration of binder.

TABLE 2: PRE-COMPRESSION STUDY OF GRANULES

Formulation	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Compressibility index (%)	Hausner's ratio	Angle of Repose (θ)
CF1	0.49 ± 0.27	0.55 ± 0.54	10.91 ± 0.25	1.12 ± 0.25	28^0 ± 0.78
CF2	0.53 ± 0.36	0.59 ± 0.46	10.17 ± 0.37	1.11 ± 0.32	27^0 ± 0.98
CF3	0.55 ± 0.22	0.62 ± 0.49	11.29 ± 0.54	1.13 ± 0.41	29^0 ± 0.77
CF4	0.59 ± 0.43	0.68 ± 0.53	13.24 ± 0.47	1.15 ± 0.36	30^0 ± 0.68

*All the reading were taken in triplicate (n=3)

Evaluation of Post-compression Parameters: Tablet hardness in an indicator of mechanical strength, tablet must have sufficient mechanical strength to withstand integrity during packaging and transportation. Hardness was found in the range of 4.1–4.7 kg/cm^2 and increased with increased binder concentration. Friability for all the concentration was within 1%. The ratio of hardness and friability (HFR) and hardness and disinter-gration (HDR) were parameter for measuring tablet strength [29-30]. Higher the HFR value more will be the tablet strength. HFR values were increased with increasing concentration of binder, and HDR decreased with increasing concentration of binder. Results showed that formulated tablets gave acceptable uniformity of weight; no tablet deviates more than 5% in weight. The weight of the tablet ranges from 99.8 mg-100.2 mg slight difference in weight might be attributed to segregation of larger granules from fines or non-uniform flow rate. Disintegration time increased with increasing starch concentration. It has been reported by Tsinge and Alexander; 1993 that starch mucilage used as binder forms a thin film around the granules with thickness increasing as the quantity of mucilage increases, and this retards disintegration [31]. All the post-compression parameters discussed were complying with specification as per I. P. standards.

TABLE 3: EVALUATION PARAMETERS FOR TABLET

Formulation	Hardness kg/cm^2	Friability (%)	Hardness Friability Ratio	Disintegration time (min)	Hardness Disintegration Ratio	Weight variation (mg)
CF1	4.1 ± 0.87	0.51 ± 0.37	8.04 ± 0.65	5.23 ± 0.43	0.78 ± 0.61	99.8 ± 0.52
CF2	4.3 ± 0.63	0.42 ± 0.56	10.24 ± 0.35	6.71 ± 0.86	0.64 ± 0.45	100.2 ± 0.76
CF3	4.4 ± 0.91	0.35 ± 0.67	12.57 ± 0.72	7.54 ± 0.94	0.58 ± 0.39	100 ± 0.33
CF4	4.7 ± 0.55	0.27 ± 0.41	17.41 ± 0.48	8.57 ± 0.74	0.55 ± 0.47	100 ± 0.57

*All the reading were taken in triplicate (n=3)

FT-IR Spectra of Cyproheptadine Tablet:

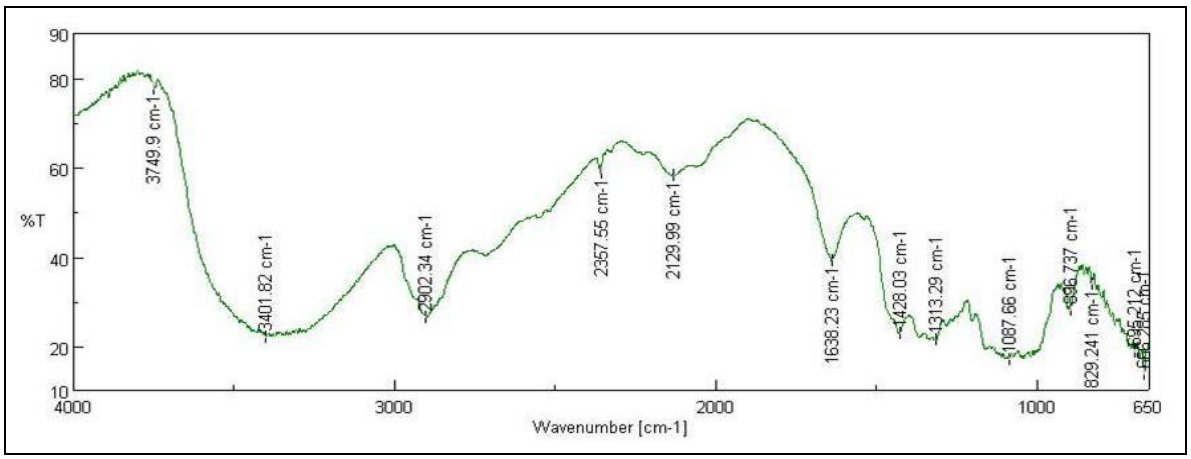

FIG. 4: FT-IR SPECTRA OF CYPROHEPTADINE TABLET

FT-IR spectra show characteristic absorption peaks at 3401.82 cm^{-1} indicated N-CH_3 stretching, C=C at C_{10}-C_{11} seen at 1638.23 cm^{-1}, C-N stretch observed at 1131.29 cm^{-1}, aromatic C-H stretch observed at 1087.66 cm^{-1}. All these peaks were indicative of the stability of the drug within the formulation.

A dissolution test was carried out to check the release of the drug. Cumulative % drug release for 5% binder concentration was completed within less time as compared to 12.5%, which restrict the drug release even at the end of 90 min. These studies indicated that drug release decreased with increasing concentration of binder. The dissolution profile was shown in **Fig. 5**.

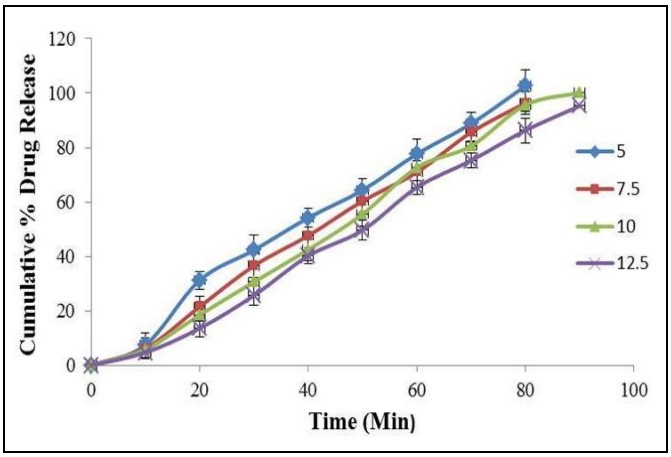

FIG. 5: DISSOLUTION GRAPH OF VARIOUS FORMULATIONS

CONCLUSION: The aim of the current study was to evaluate the efficiency of *Amorphophallus paeoniifolius* tuber starch as binder in tablet formulation. Concentration of starch was varied from 5%, 7.5%, 10% and 12.5% in different formulation. Results showed that isolated starch is free from significant contamination and suitable for use as a binder. FT-IR study indicated compatibility between drug and excipients.

Prepared granules exhibited good flow and compression characteristics. The entire prepared tablet complied specification as per I.P. standards. It was found that with increasing concentration of binder hardness, disintegration and dissolution time was increased, friability was decreased. From the above results it could be concluded that *Amorphophallus paeoniifolius* tuber starch could be effective as a binder in tablet formulation and further developed as an excipient for commercial use.

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CONFLICTS OF INTEREST: Authors declare that they have no conflict of interest.

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