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Development And Evaluation Of Herbal Effervescent Granules Of *Trachyspermum Ammi* Seed Extract

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Abstract: The aim of this research was to formulate and evaluate effervescent granules of *Trachyspermum ammi* seed extract that would mask the peppery taste of herbal drugs and increase the dissolution, responsible for hastening the onset of action. Citric acid, tartaric acid, sodium bicarbonate, and other formulation ingredients were used to formulate effervescent granules using the wet granulation method. *Trachyspermum ammi* seed extract was prepared in five different formulations (F1–F5), and evaluation tests for flow properties, drug content, pH, effervescence time, and dissolution studies were carried out. The outcomes demonstrated the formulated granules have good flow characteristics. The effervescent time for all five formulas is under three minutes. According to the observations, formulation F4 was found to be optimized because it has the best drug release (98.89%) and effervescent time of about 80 sec.

Keywords: effervescent granules, *Trachyspermum ammi*, wet granulation, quicker onset of action.

I. INTRODUCTION

According to the World Health Organization, "conventional healthcare" refers to the use of knowledge, beliefs, and practices from a variety of cultures in order to maintain health. Symbiosis is a remarkable phenomenon that can be seen repeatedly in nature. The human body can respond favorably to natural substances found in plants, animals, and minerals (WHO, 2000). Many modern medications can be traced back to the diverse array of secondary metabolites found in medicinal plants, which have long been employed in traditional or herbal remedies. Leaves, fruits, seeds, stems, roots, barks, and even whole plants are used to treat or prevent a wide variety of illnesses in both humans and animals. There has been a rise in the number of people seeking herbal remedies. This is because of the widespread belief that herbal medicines provide fewer risks than standard medical care. They may be found easily and for a fair price. The traditional therapeutic value of many plant species has been confirmed by scientific testing. Plants provide a sustainable resource for the production of phytoconstituents that are useful in the treatment of ailments, and herbal treatments are increasingly being employed as an alternative to conventional pharmaceuticals (El-hassan *et al*., 2012)

Ajwain, or *Trachyspermum ammi* (L.), is an annual herbaceous plant of the family Apiaceae. Ajwain is being used here because of its antispasmodic, digestive stimulant, and antiulcer properties (Mayuri *et al*., 2017).

Figure 1: *Trachyspermum ammi* Plant

Figure 2: *Trachyspermum ammi* seeds

Sodium bicarbonate, citric acid, and tartaric acid are the usual ingredients for effervescent granules, which range in size from extremely coarse to coarse. They are a dry mixture containing the active therapeutic component. When a strong acid or base is added to water, carbon dioxide gas is released, causing the mixture to fizz (Divya *et al*., 2020). In most cases, the unpleasant taste of the medicine is masked by the carbonated beverage that results. The carbonation in these concoctions masks the medicinal flavour and increases the total amount of dissolved substances, making the medicine more palatable. Effervescent granules can be made using wet granulation, dry granulation, or direct mixing. An effervescent vehicle, which has the property of swiftly dissolving granules in solution, could be added to the granule formulation to enhance the herbal decoction product's flavour and palatability (Lieberman *et al*., 1993; Ansel *et al*., 1999). Effervescent granules have excellent solubility, high stability, rapid dissolution, and a convenient dosing form. When compared to liquid dose forms, effervescent granules excel in all of these areas: taste, stability, and ease of administration. Additionally, they get to work quickly, stimulate stomach secretions, and act as a carminative (Shet *et al*., 2014; Palanisamy *et al*., 2011; Aslani and Jahangiri, 2013).

Effervescent granules, powders, and tablets are among the many forms of granules sold commercially.

The reaction between acid and Bicarbonate, which results in liberation of carbon dioxide (Vergeire, 2016) shown as follows:

$$\text{A-COOH} + \text{B-HCO}_3 \longrightarrow \text{CO}_2 + \text{H}_2\text{O} + \text{B-A-COO}^-$$

(Acid) (Bicarbonate) (Acidic Salt of Base)

II. MATERIAL AND METHOD:

The citric acid, tartaric acid, and sodium bicarbonate were acquired from the local market, Central drug house (P) Ltd supplied the sodium bicarbonate, and Finar supplied the sucrose, Hydroxypropyl methylcellulose (HPMC E5), and sodium starch glycolate.

Preparation of extract

Ten gram of coarsely powdered drug was soaked in approximately 200 ml of hydro-alcoholic (70:30) solvent, on an electrical shaker for three hours at room temperature and then left to stand overnight. The extract was then filtered using Whatmann filter paper No. 1. Filtrate was then concentrated on a rotary evaporator at 40°C. The extract was stored in a refrigerator for further use (Shubham, 2016).

Determination of λ max

Sample solution was taken in the cuvette and mixed it well. Measured the absorbance or transmittance at different wavelengths. The minimum transmittance at a particular wavelength will correspond to maximum absorbance which will give λmax.

Standard graph

The Ajwain extract was used prepared and dissolved in phosphate buffer which is also used as a blank solution. Four standard dilutions were prepared by dilution of concentrated stock (1000mg/ml) using the concentration range of 0.2µg/ml-1.0µg/ml with the following formula and absorbance was determined by using UV-Vis Spectroscopy. Calibration Curve of Ajwain (*Trachyspermum ammi*) in Phosphate Buffer of pH 6.8 is given in Table 4 and Figure 4.

Method of Preparation

The effervescent granules of herbal medicine were prepared using the wet granulation method (Amidon *et al*., 1995). Table 1 lists the ingredients and their respective amounts. All of the formulation's ingredients will be thoroughly mixed using geometrical dilution to ensure uniform distribution of the drug, and the powder will be passed through sieve no. 20 after a suitable amount of binding agent has been added to create a wet mass. The wet mass was then pressed through a No. 20 filter to separate out the grains. These granules spent the previous night drying in a hot air oven at 40 degrees Celsius (Al-Mousawy *et al*., 2019). Various compositions of effervescent granules are given in Table 1.

Table 1: Composition of effervescent granules of *Trachyspermum ammi* seed extract

Ingredients (mg)	F1	F2	F3	F4	F5
Carom extract (drug)	200	200	200	200	200
Citric acid	50	150	250	350	450
Tartaric acid	450	350	250	150	50
Sodium bicarbonate	600	600	600	600	600
Sucrose	200	200	200	200	200
HPMC in alcohol 2%	2.5	2.5	2.5	2.5	2.5
Sodium starch glycolate	10	10	10	10	10

Evaluation of effervescent granules:

Flow properties:

Bulk density and tapped density- The original volume of the granules was measured after they were weighed and spooned into a 100 ml measuring cylinder. The volume of the cylinder was then checked every two seconds until no longer affected by tapping at a height of 2.5 centimetres (Patel and Patel, 2009). Both bulk density and tapped density can be determined using the following equation.

$$BD = \frac{\text{weight of granules}}{\text{packing volume}}$$

$$TD = \frac{\text{weight of granules}}{\text{tapped volume of the packing}}$$

Where BD is the bulk density and TD is the tapped density

Carr's Index (%): The tendency of a powder to be compressed is quantified using the Compressibility index (Carr's index). It is calculated by comparing the bulk density to the tapped density. More fluidity is associated with lower compressibility. Bulk and tapped densities will be closer to one another in a freely moving powder since such interactions are typically less important there. The difference between the bulk and tapped densities will be larger for poorer flowing materials due to the increased inter-particle interactions (Senthil *et al*., 2010; Wells, 2004).

Compressibility index = [(Tapped density- Bulk density) / Tapped density] ×100

The standard chart carr's index is given in the Table 2.

Table 2: Carr's index values

Flow properties	Carr's index
Excellent	1-10
Good	11-15
Fair	16-20
Passable	21-25
Poor	26-31
Very Poor	32-37
Extremely Poor	>38

Angle of Repose: By measuring the angle of repose, we were able to get a sense of how well the designed effervescent granules flowed. The angle of repose was calculated with a fixed funnel. This technique involved taping the top of a funnel to a horizontal surface at a specific height (h), above a sheet of graph paper. The mixture was slowly poured down the funnel until the tip of the conical pile reached the very end of the device (Kaerger *et al*., 2004). The conical pile's base radius was calculated used is

$\tan \theta = h/r$

Where, θ = Angle of repose, h = Height of the pile, r = Radius of the pile.

The standard chart of Angle of repose is given in the Table 3.

Table 3: Values of angle of repose

Flow properties	Angle of repose
Excellent	<20
Good	20-30
Passable	30-40
Very poor	>40

Flow properties of all formulations are given in Table 5 and Figure 5.

Determination of effervescent solution pH

Prescribed dose of drug was dissolved in 200 ml of distilled water at 20 1 °C, the pH of the solution is measured using a pH metre. Each experiment was conducted three times (Jassim et al., 2018). The pH of all formulations is given in Table 6.

% Drug content- After measuring out 100 ml of phosphate buffer solution (pH 6.8), 100 mg of effervescent granules were weighed and added to the mixture. After that, a UV-visible spectrophotometer was used to analyse the filtered solution (Lachmann *et al*., 1991). The findings regarding the percentage of drug content is given in Table 7 and Figure 6.

Effervescence time- One dose of granules was added to a glass containing 250 ml of water, and the effervescent time was recorded when a clear solution was created. Table 8 displays the results of the effervescence time (Sandhya *et al*., 2012; Bhattacharyya, 2014).

Figure 3: Granules showing effervescence

Dissolution study- Effervescent granule dissolution was studied in a phosphate buffer at 37 0.5 C and 50 rpm. The buffer had a pH of 6.8. At 1-minute intervals, a 5-milliliter (ml) sample will be taken, followed by a 5-ml addition to keep the volume stable. The sample was subsequently filtered, and its absorbance was determined at 260 nm (Chandira *et al*., 2012; Saudagar, 2015; Parz and Pramod Kumar, 2014) . Dissolution profile of effervescent granules is given in Table 9 and figure 7.

III. RESULTS AND DISCUSSION

Determination of λmax and preparation of standard graph

Determination of λmax Maximum absorbance was determined in order to find out the maximum wavelength using UV Spectrophotometer. The absorbencies were noted at wavelength ranging from 200 to 400nm, and the maximum wavelength has been declared as 219nm for ajwain extract.

Table 4: Calibration Curve of Ajwain (*Trachyspermum ammi*) in Phosphate Buffer of pH 6.8

S.No	Concentartion(ug/ml)	Absorbance (λ max)
1	10	0.013
2	20	0.026
3	30	0.04
4	40	0.053
5	50	0.064
6	60	0.079

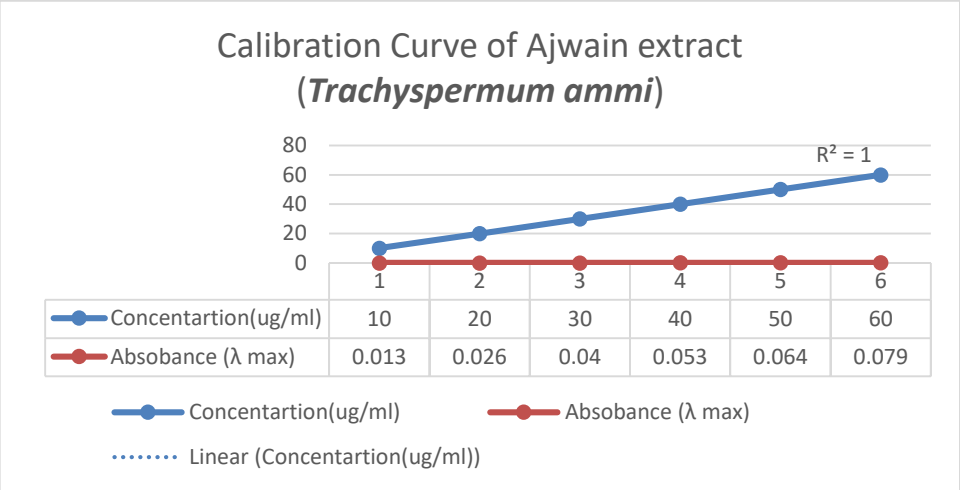


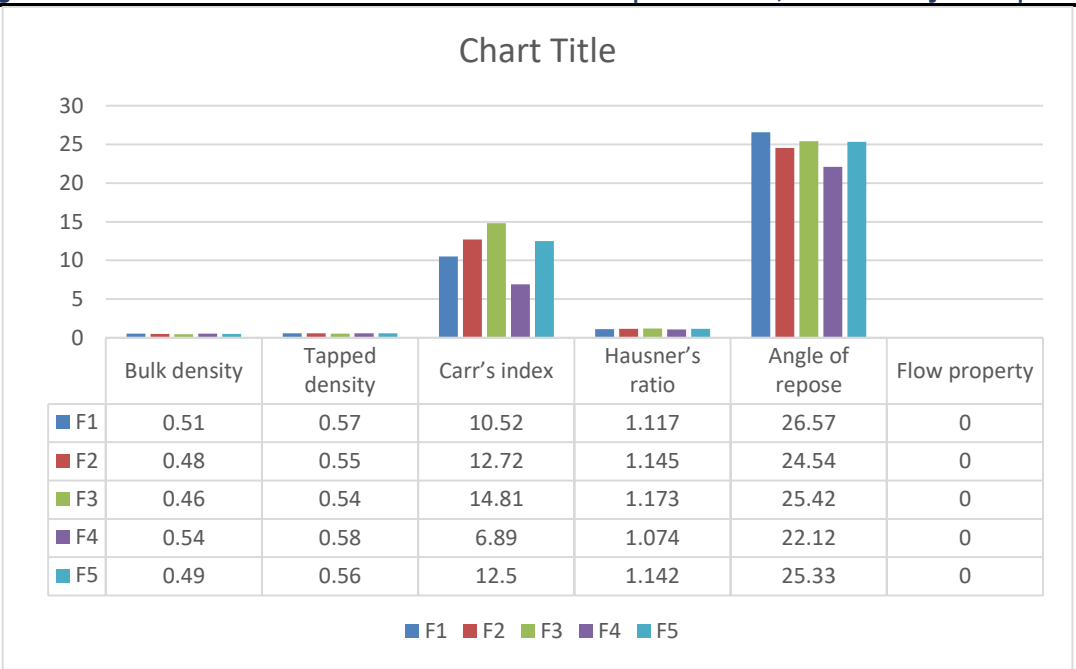
Figure 4: Calibration Curve of Ajwain (*Trachyspermum ammi*) in Phosphate Buffer of pH 6.8

Evaluation of effervescent granules

Flow properties: Flow properties of all formulations were determined by Carr's index, Hausner's ratio and Angle of repose. Flow behavior of all formulations were found to be good.

Table 5: Flow properties of effervescent granules

Formulation no.	Bulk density	Tapped density	Carr's index	Hausner's ratio	Angle of repose	Flow property
F1	0.51	0.57	10.52	1.117	26.57	Good
F2	0.48	0.55	12.72	1.145	24.54	Good
F3	0.46	0.54	14.81	1.173	25.42	Good
F4	0.54	0.58	6.89	1.074	22.12	Good
F5	0.49	0.56	12.5	1.142	25.33	Good



	Bulk density	Tapped density	Carr's index	Hausner's ratio	Angle of repose	Flow property
F1	0.51	0.57	10.52	1.117	26.57	0
F2	0.48	0.55	12.72	1.145	24.54	0
F3	0.46	0.54	14.81	1.173	25.42	0
F4	0.54	0.58	6.89	1.074	22.12	0
F5	0.49	0.56	12.5	1.142	25.33	0

Figure 5: Graphical representation of values of bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose

Determination of effervescent solution pH- pH of the formulations was in the range of 3.2 to 5.5. Acidic pH of the formulations may be due to free or unreacted citric acid.

Table 6: Effervescent solution pH of all formulations

Formulation	pH of the formulation
F1	3.2
F2	3.7
F3	4.6
F4	4.2
F5	5.3

Determination of % drug content -. The values for the percentage of drug content ranged from 93.43 to 96.84%. All five of the formulations met the requirements of the intellectual property standard for the assay of ibuprofen granules, which stipulated that the percentage should be between 90% and 110%.

Table 7: Drug release of all formulations (F1 - F5)

Formulation	% Drug content
F1	93.43
F2	95.67
F3	94.72
F4	96.84
F5	94.35

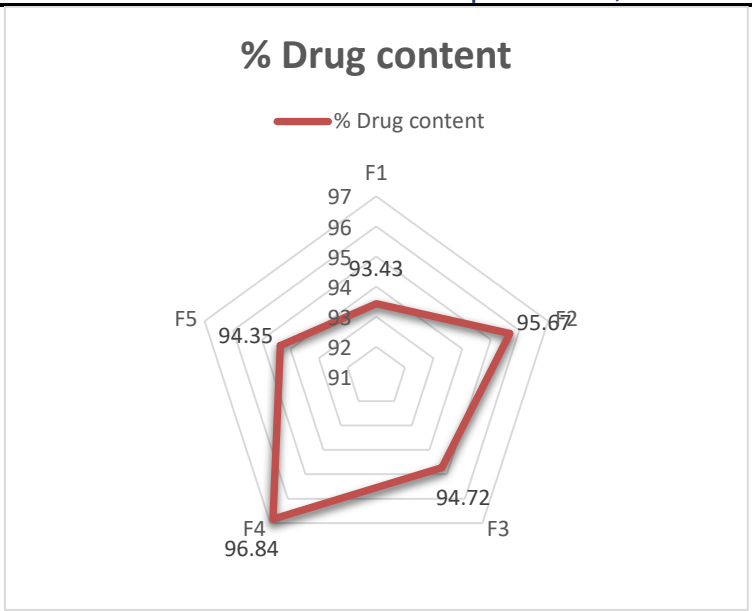


Figure 6: % Drug content of all formulations

Effervescence time- The effervescence time of all formulations ware in the range of 82 and 105 seconds. According to USP, the effervescence time of the results, which was less than 3 minutes, was acceptable for this study.

Table 8: Effervescence time of all formulations (F1 - F5)

Formulation	Effervescence time (sec)
F1	**105**
F2	**98**
F3	**96**
F4	**82**
F5	**101**

Dissolution study - Table 5 displays the percent of medication released after 5 minutes for each of the five ibuprofen effervescent granules formulations. The data demonstrates that after 5 minutes, all five formulations exhibited an optimal release profile. The effervescence created by the shattering of the granules into minute particles improves the solubility of the herbal medication. The fastest drug clearance was seen in F4, at 98.89% within 5 minutes. Citric acid, tartaric acid, and sodium bicarbonate were mixed in just the right proportions to create F4's favourable release profile.

Table 9: Drug release of all formulations (F1 - F5)

Formulation	% Drug release
F1	90.52
F2	94.63
F3	95.82
F4	98.89
F5	91.38

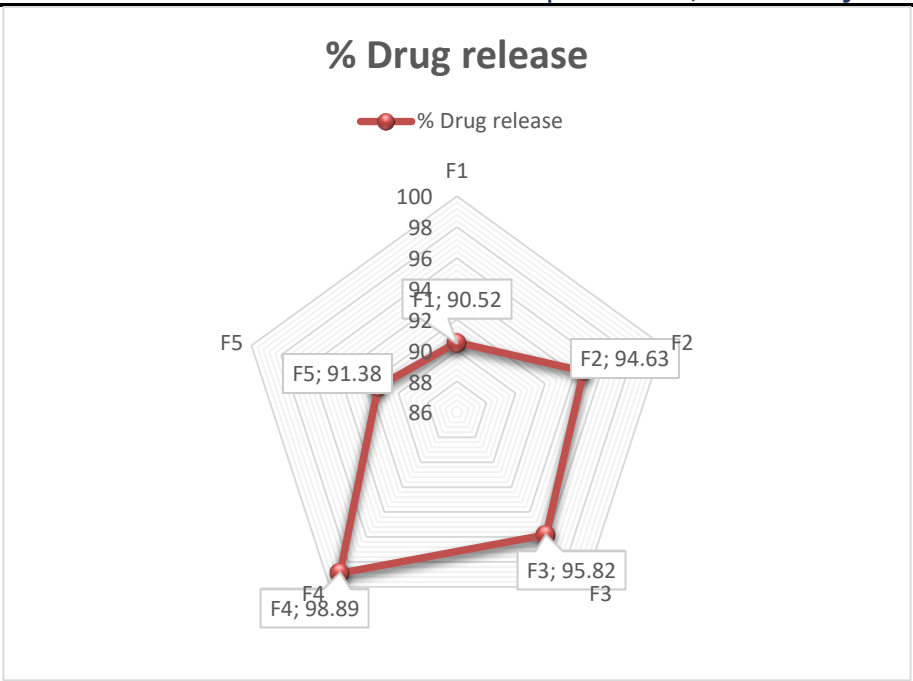


Figure 7: % Drug release of all formulations

IV. Conclusion

Trachyspermum ammi is having many potent phytoconstituents responsible for carminative property, antispasmodic, flatulence, abdominal pain and lack of apetite but due to it's pungent and peppery taste it is difficult to consume as is also and thus to taste mask and fast effective dosage form, in this study effervescent granules of Trachyspermum ammi has been prepared and evaluated. For this five different formulations of Trachyspermum ammi were formulate using citric acid, tartaric acid and Sodium bicarbonate. And further various studies like flow property, compatibility, % drug content, effervescent time and dissolution study it has been found that F4 formulation found to be the best formulation and can be used further for its in-vivo studies.

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