

# Formulation of Dispersible Ayurvedic Kadha Tablet for the Management of Cold and Cough

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## ABSTRACT

The term "Ayurveda" combines the Sanskrit words *ayur* (life) and *veda* (science or knowledge). It is one of the traditional medicinal systems, with an established history of many centuries. Indian herbs, which are widely used in the preparation of Ayurvedic medicines in the form of Kadha to control various respiratory disorders such as, cough, cold and flu. In a traditional Kadha (decoction) preparation, the entire process is done manually Such as boiling, filtering and mixing of medicinal herbs and the aim of this research work was to skip all such manually process. The oral route of drug administration is most extensively used due to the obvious ease of administration. Dispersible tablets are a vital tool in keeping our children and elderly population healthy. Their ease of use and accurate dosing allow higher patient compliance and more reliable therapeutic effects. Medicinal plants and parts as like Tulsi (Rama-Tulsi) (*Ocimum Sanctum* Linn, family Lamiaceae), Ginger (*Zingiber officinale*, family Zingiberaceae), Clove (*Syzygium aromaticum*, family myrtaceae) and Turmeric (*Curcuma longa*, family Zingiberaceae) were used as a model drug. Phytochemicals present in these herbs, which have significant potential to heal cold and cough. The phytochemicals present in these herbs possess significant anti-inflammatory property. In order to determine the most effective type and optimal amount of superdisintegrants for dispersible tablets different formulation were evaluated. Wet granulation and direct compression methods were tried to develop dispersible tablet. Due to higher moisture in the granules the wet granulation method was not carried out further in the study and direct compress method was selected. Prepared tablets were tested for Appearance, Weight variation, Thickness, Friability (%), Hardness (kg/cm<sup>2</sup>), Disintegration time and IR spectroscopic analysis and finally for six months of stability studies at room temperature, 30°C/60% RH and at 45°C/75% RH. Sodium Starch Glycolate was superior to the other disintegrants and the non-fractionated granulation gave adequate dispersion. The ideal concentration was 1.33 % Sodium Starch Glycolate was used for the dispersible tablets.

## Keywords

Ayurveda, Dispersible tablet, Kadha, cold and cough.

## Introduction

The term Ayurveda literally means "knowledge of life". It encompasses the physical, psychological, spiritual, social and subtle dimensions of life, and the dynamic concepts of well-being, promotion of health, and prevention and management of diseases

[1,2]. In the beginning of the first millennium AD, there were mainly three principal medical systems: Ayurveda, Greek and Chinese medicine. The fundamental principle of the relationship between the man and nature was more or less same in all the medical systems, but their approach in therapy was different [3,4]. Of the three ancient medicinal systems, Ayurveda emerged as one of the world's classic systems of medicine, with renewed interest in the interaction between religion and spirituality, along with

health and medicine [5]. Ayurveda is one of the oldest systems of medicine in the world and medicine is as old as life itself.

### Disease as per Ayurveda

Disease (disease), is the disturbance of ease i.e. comfort, freedom from constraint, annoyance, awkwardness, pain or trouble both bodily and mental. Since time immemorial, man has tried to lead a disease-free life. For boosting the effects of herbal preparations, a large number of minerals, particularly mercury, with a miraculous power against microbes, became an integral part of Ayurvedic treatments. According to Ayurveda, the effect of environment, food, lifestyle alteration and stress can lead to disequilibrium of Dosha (Jataj Prakriti). When there is too much alteration of Dosha, pathology or Vikruti occur causing diseases [2].

### The Common Cold and cough

The term "common cold" refers to a mild viral illness of the upper respiratory tract. It is self-limiting, so it will go away without treatment. It is the most common acute illness throughout the world. It is a separate disease from the flu, throat infections, bronchitis, sinusitis, whooping cough, and allergic rhinitis. The average person catches cold two or three times a year [6]. Colds are caused by various viruses as like - rhinoviruses, adenoviruses, enteroviruses and recently corona virus, which cause similar symptoms. The same virus can cause another cold after a new exposure. However, the second illness is usually mild and lasts a short time. Seasonal patterns can be observed for some viruses.

### Allopathic Tablets for the Cough and Cold

Commonly available Over-the-counter cough and cold medications contain either singly or in combination a decongestant, cough suppressant, antihistamine, expectorant, and antipyretic, for example- Actifed (Pseudoephedrine HCl (30 mg) Triprolidine HCl (1.25 mg), Betafed Be-Tabs (Pseudoephedrine HCl (30 mg) Triprolidine HCl (1.25 mg) and Demazin NS (Pseudoephedrine sulphate (120 mg) Loratidine (5 mg). Oral tablet for the cold and cough should be used for the short-term only, because they may cause side effect [7-14] On other hand, kadha as a liquid will not have any side effect and easy to intake.

### Ayurvedic Kadha

Ayurveda Kadha is one of the many highly effective Ayurvedic supplements also known as – Kashayam, Kwath, Kadha, Herbal Decoctions. Kadha is basically the mixture of some herbs containing medicinal values, boiled with water till the herb's losses the values and the benefits of herbs mixed with water. Herbal medicines include herbs, herbal material, herbal preparations, herbal extracts or finished herbal products and are used as alternative or complementary medicines [15]. Kadha is also called as Swarasa (extracted juice) of herbs, which is used as a liquid dosage form of medicament predominately for internal administration, external application [16]. According to Ayurvedic studies, Kadha (decoction) is one of the permitted forms of medicine. A mixture of common herbs mixed in different proportions gives relief from many diseases. Some of these herbs are so common and ubiquitous that almost anyone doubts their healing abilities.

### Preparation of Ayurvedic Kadha

There are specific Ayurvedic methods to prepare the Kadha. In India, variants of standard Kadha are also prepared using different combinations of herbs depending on the severity of disease/ ailment and the availability of ingredients. The most common ingredients are Tulsi leaves, Ginger, Clove, Turmeric, Black pepper, Cardamom, Ashwagandha and Giloy [17]. Table 1 has indicated some common ingredients for the Kadha Preparation and their quantity. To make the Kadha, these herbs can be boiled in 200 ml water for 5–10 min, and jaggery or honey can be added to make it sweet. The preparation to be filtered and mixed with ¼ teaspoon of lemon juice. In case, if all ingredients are not available, it can be prepared using locally available ingredients.

**Table 1:** Most common ingredients for the Kadha Preparation [17].

S. No	Name of the Herb	Quantity
1	Tulsi leaves	10–15 leaves or ¼ teaspoon powder
2	Ginger	2–5 g rhizome or ¼ teaspoon powder
3	Clove	4–5 pieces
4	Black pepper	4–5 pieces
5	Cardamom	4–5 pieces
6	Ashwagandha	2–5 g raw or ¼ teaspoon powder
7	Giloy	2–5 g raw or ¼ teaspoon powder

### The Dispersible Tablet as a Dosage Form

Solid pharmaceutical dosage forms have been used since ancient times [18]. The original reference of a tablet dosage form can be found in Arabic medical literature, where the force exerted by a hammer compresses medicine particles among ebony rods. The pellet or tablets-making process was primary defined in 1843, when Thomas Brockendon was granted a patent for "manufacturing pills and medicinal lozenges by causing materials when in a state of granulation, dust or powder, to be made into form and solidified by pressure in dies.

### Material and Methodology

#### Material

**Tulsi** (Rama-Tulsi) (*Ocimum Sanctum* Linn, family *Lamiaceae*), **Ginger** (*Zingiber officinale*, family *Zingiberaceae*), **Clove** (*Syzygium aromaticum*, family *myrtaceae*) and **Turmeric** (*Curcuma longa*, family *Zingiberaceae*) were used as a model dose, poorly compressible materials (Table 2).

**Table 2:** Details of medicinal plants.

Sr. No	Name of the Material	Specification	Part Used	Supplier
1	Clove	Dried Clove Family -Myrtaceae Variety -Penang	Clove Bud	Nice Spices, Kerala
2	Turmeric	<i>Curcuma longa</i> (rhizomatous) Family- Zingiberaceae Variety -Madras	Rhizome powder	Nice Spices, Kerala
3	Ginger	<i>Zingiber officinale</i> family Zingiberaceae, Variety - Manures and Manuring	Rhizome powder	Farman Ginger Traders Karnataka
4	Tulsi	<i>Ocimum sanctum</i> Family -Lamiaceae Variety Rama Tulsi	Leaves	A.R. Herbs Neemuch MP

All The excipients used in the present investigation - Corn Starch Mannitol, Dextrose Monohydrate, Pregelatinized Starch, Colloidal Anhydrous Silica, Sodium Starch Glycolate, KBr., Lactose, Microcrystalline Cellulose, PVPK 30 Sucralose, Magnesium Stearate were food grade and purchased from reputed organization.

## Methodology

### Pre-Formulation Studies

Pre-formulation testing is an investigation of physical and chemical properties of drug substances alone and when combined with excipients. It is the first step in the rational development of dosage form. Selected Medicinal plant *Clove*, *Tulsi*, *Turmeric* and *Ginger* were grinded and sifted through #30 mesh to get uniform granules.

### Drug – Excipients compatibility studies

3.0 gm of each material *Clove*, *Tulsi*, *Turmeric* and *Ginger* was taken with each excipient that is Mannitol, Pregelatinized Starch, Sucralose, Croscarmellose Sodium, Crospovidone, Microcrystalline Cellulose, PVPK 30, Colloidal Anhydrous Silica, Magnesium Stearate and Sodium Starch Glycolate in 1:1 ratio in a glass vial and kept at various accelerated condition (30°C, 65% RH, 40°C, 75% RH and at room Temperature) in stability chamber. All samples were conducted three times each. It was carried out for 15 days in a closed glass vial. Samples were withdrawn at the intervals of 1, 2, 3, 6, 7, 14 and 15 days and evaluated for physical characteristics like colour-visualization, lumps and black particle.

### Drug – Drug compatibility studies

1.0 gm of each material *Clove*, *Tulsi*, *Turmeric* and *Ginger* was taken with Individual in 1:1 ratio in glass vials. Then glass vials were kept at various accelerated condition (30°C, 65%RH, 40°C, 75% RH and at room temperature) in stability chamber. It was carried out for 15 days in open and closed glass vials. Samples were withdrawn at the intervals of 1,2,3,6,7,14 and 15 days and evaluated for physical characteristics (lumps, black particle and flow). Finally, the mixtures with no colour change were selected for Formulation development.

### Infrared Spectroscopic Studies

IR spectra are acquired on a special instrument, called an IR spectrometer. IR is used for both, to gather the information about the structure of a compound and as an analytical tool to assess the purity of a compound. The IR region is divided into three regions: the near, mid, and far IR. In wavenumbers, the mid IR range is 4000–400  $\text{cm}^{-1}$ . An increase in wavenumber corresponds to an increase in energy.

IR Spectroscopy was performed using an FT-IR Spectrometer, Model Spectrum one, Sr No 69566 (Manufactured by Perkin Elmer Precisely Version 10.6.2) at 450-4000  $\text{cm}^{-1}$  for IR and 650 - 4000 $\text{cm}^{-1}$  for AT. IR Spectroscopy was performed for pure medicinal plant part and a mixture of all medicinal plant part and excipient selected for this project.

### KBr Pellet Method

50-100 mg of sample (*Clove*, *Tulsi*, *Ginger*, *Turmeric* individually) and 450 mg – 900 mg of Potassium Bromide [1:9 solid sample and KBr] were taken into the stone mortal and pastel and mixed well (total Four individual Samples).



Figure 1: Hydraulic Press machine to prepare KBr Pellet.

### Tablet manufacturing (Method of Preparation)

Tablets formulations was conducted by direct compression and wet granulation. In first experiment, wet granulation method was used to prepare granules for tablet [19,20].

During drying the granules (bind by starch paste) at high temperature (70-75°C for 4 hrs) the moisture level was 2.50- 3.0% but *Clove*, *Tulsi* and *Ginger* lost their flavour (became tasteless), when the temperature was reduced to 50-55°C for 4 hrs the moisture level was 12.5-13.5% which was not suitable for compression although *Clove*, *Tulsi* and *Ginger* lost their flavour (up to 50%), finally temperature was reduced at 45°C and dried for 3 hrs *Clove*, *Tulsi* and *Ginger* didn't lose their flavour but the moisture content was higher was not suitable for compression resulting the wet granulation method was not selected for further process. (Table 3 shows all 9 formulation's composition).

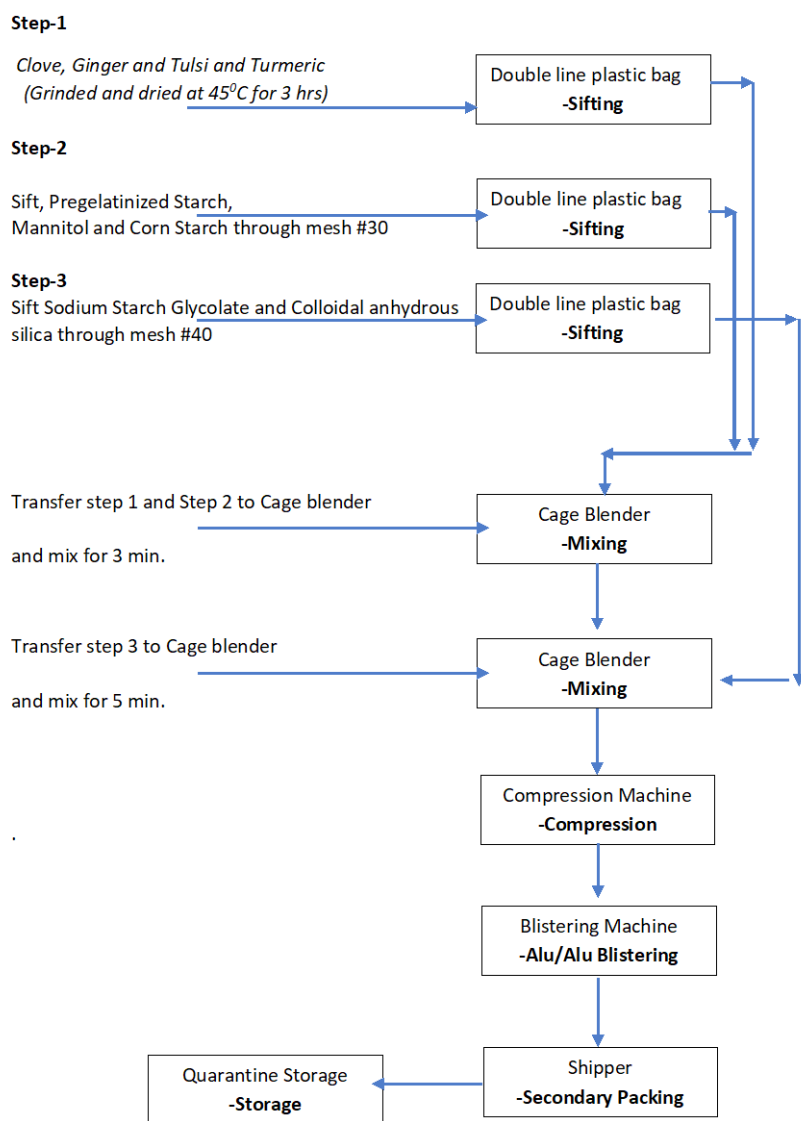
On second experiment direct compression method was chosen [21,22] figure 2 Process Flow of Tablet Manufacturing by direct compression Method.

## Results

### Evaluation of Lubricated Granules

#### Angle of repose

The angle of repose for the powder blends of all formulations exhibits good flow properties



**Figure 2:** Process Flow of Tablet Manufacturing by direct compression Method.

**Table 3:** Summary of all Formulas and materials tried during the research.

Sr. No.	Name of Ingredients	F01	F02	F03	F04	F05	F06	F07	F08	F09	Functional category
		mg/ tablet									
1	Clove	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	Active ingredient
2	Turmeric	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	Active ingredient
3	Ginger	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	Active ingredient
4	Tulsi	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	Active ingredient
5	Corn Starch	52.25	52.25	52.25	52.25	52.25	52.25	52.25	52.25	52.25	Diluent
6	Mannitol	237.40	236.90	236.40	139.40	139.40	139.40	139.40	235.15	224.15	Diluent
7	Pregelatinized Starch	-	-	-	97.50	96.85	-	46.85	4.25	4.25	Binder/ Disintegrant
8	Sucralose	-	-	-	-	-	-	-	-	5.00	Sweetener
9	Croscarmellose Sodium	-	-	-	-	8.00	-	-	-	-	Disintegrant
10	Crospovidone	-	-	-	-	-	8.00	8.00	-	-	Disintegrant
11	Microcrystalline Cellulose	-	-	-	-	-	96.85	50.00	-	-	Binder/ Disintegrant
12	PVPK 30	1.50	2.00	2.50	2.00	2.50	2.50	2.50	-	-	Binder/ Disintegrant
13	Colloidal Anhydrous Silica	0.35	0.35	0.35	0.35	0.50	0.50	0.50	0.35	0.35	Glidant
14	Magnesium Stearate	0.50	0.50	0.50	0.50	0.50	0.50	0.50	-	-	Lubricant
15	Sodium Starch Glycolate	8.00	8.00	8.00	8.00	-	-	-	8.00	8.00	Disintegrant
16	<b>Total</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	<b>600.00</b>	



### Bulk density

Bulk density is used as an index of the powder's ability to flow. The bulk density of all the formulation was in the range of 0.56 to 0.58 g/mL.

### Tapped density

The tapped density was used to access the free-flowing properties of the lubricated blend. The tapped density of the formulation was in the range of 0.64 to 0.65 g/mL.

## Evaluation and Optimization of Physicochemical Properties of Dispersible Tablet

### General appearance

The thickness and diameter of the formulation were used to determine the size and shape uniformity of the tablets. From the results, it was found that the tablet thickness was 5.3–5.7 mm (5.5 ± 0.2 mm) in all formulations and the tablet diameter was 11.0 mm in all formulations.

### Thickness and diameter

The hardness of the tablets of all the formulations was found to be in the range of 2.0-5.0 kg/cm<sup>2</sup>. The result indicated that all tablets had good mechanical strength.

### Weight variation test

The weight of all tablets from each formulation ranged from 579.20-623.0 mg. It was found that all tablets passed the weight variation test, as the percentage weight variation was within an acceptable range of ± 5%.

### Friability test

The results showed that the friability of first three formulation were had more than 1.0% (failed) while remaining formulation have friability lesser than 1% which indicated the tablets had a good mechanical resistance.

### Wetting Time

A piece of tissue paper folded twice was placed in a small Petri dish (internal diameter = 6.5cm) containing 6.0 ml of water. A tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. Two trials for each formulation were performed and results were recorded. The results of Wetting time and Water absorption ratio are presented in Table 5

### Water Absorption ratio

A piece of tissue paper folded twice was placed in a small Petri dish (internal diameter = 6.5 cm) containing 6.0 ml of water. A tablet was placed on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio (R) was determined using following Equation-

$$R = 100 \times \frac{Wa - Wb}{Wb}$$

Wa - weight of tablet after water absorption

Wb - weight of tablet before water absorption

The Wetting time ranges from 41 seconds to 252 seconds and water absorption ratio ranges from 23% to 58 %. Formulation F01, F02, F08 and 09 possess good wetting time and Formulation F03, F04, F09 and F08 shows water absorption ratio.

Table 4: Results of evaluation of lubricated granules.

Sr No	Characteristics of Powder	F01	F02	F03	F04	F05	F06	F07	F08	F09
1	Bulk density (gm/mL)	0.58	0.58	0.58	0.56	0.56	0.56	0.56	0.56	0.56
2	Tapped density(g/ml)	0.643	0.649	0.646	0.646	0.646	0.649	0.641	0.649	0.648
3	Hausner ratio	1.106	1.111	1.101	1.109	1.112	1.106	1.105	1.104	1.113
4	Carr's index (%)	9.79	10.63	10.21	13.31	13.31	13.71	12.63	10.63	13.58
5	Angle of repose $\theta$	31°	31°	33°	32°	33°	34°	31°	31°	32°
6	Loss on drying (%)	1.97	1.86	1.58	1.88	1.90	1.48	1.62	1.70	2.50

Table 5: Evaluation of compressed tablet from all trial formulations.

Sr No	Formulation No.	F01	F02	F03	F04	F05	F06	F07	F08	F09
1	Appearance	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet	Round, Yellow, Mottled Tablet
2	Weight variation	600 ± 3%	600 ± 2%	600 ± 5%	600 ± 3%	600 ± 2%	600 ± 2%	600 ± 2%	600 ± 2%	600 ± 2%
3	Thickness	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm	5.5 ± 0.2 mm
4	Friability (%)	Failed	Failed	Failed	0.8	0.85	0.84	0.9	0.7	0.8
5	Hardness (kg/Cm <sup>2</sup> )	3.0	4.0	3.5	4.5	4.0	5.0	3.5	4.5	4.5
6	Disintegration time	1 minute 40 seconds	1 minute 35 seconds	2 minutes 40 seconds	5 minutes 33 seconds	6 minutes 08 seconds	5 minutes 24 seconds	5 minutes 54 seconds	2 minutes 14 seconds	2 minutes 22 seconds
7	Uniformity of Dispersion	Pass	Pass	Pass	Failed	Failed	Failed	Failed	Pass	Pass
8	Wetting time	44 seconds	45 seconds	51 seconds	3 minutes 22 seconds	3 minutes 22 seconds	3 minutes 10 seconds	4 minutes 05 seconds	47 seconds	51 Seconds
9	Water absorption ratio (%)	41	43	47	55	41	45	23	47	48

### Uniformity of dispersion test-

Two tablets were placed in 100 ml of water and stirred gently until completely dispersed. A smooth dispersion was obtained which passes through a sieve screen with a nominal mesh aperture of 710µm (sieve number 22). Formulation F01, F02, F08 and F09 passed the 710µm remaining formulations were failed the test.

### Disintegration time

Formulations F01 to F09 showed the disintegration time was range from 1 minutes 35 seconds to 6 minutes 08 seconds. It was observed that Formulation F02 disintegrated rapidly in a short time (1 minutes 35 seconds) but this formulation was failed in the friability test. The results of disintegration of selected formulation were found to be lesser than 3 minutes. So, the formulation F01, F02, F08 and F09 satisfied the criteria of tablets.

### Stability study

Based on the results of tablet and granules best formulations F8 was selected for one-month stability studies at room temperature, 30°C/60% RH and at 45°C/75% RH. The stability studies were conducted according to the method described in ICH guidance. One months of stability studies revealed that; there was no any significant degradation of the drug.

### Comparative Study

Comparative study was conducted in two parts

- Comparison of prepared dispersible tablet with marketed tablet (Company A and Company B)
- Comparison of kadha, prepared from the dispersible tablet of formulation F08 and kadha prepared by traditional method at the home (kadha vs kadha).

### Comparison tablet vs tablet

#### i. Company A

- Content** - Holy basil, *Cinnamomum verum*, *Zingiber officinale*, *Syzygium aromaticum*.
- Application instruction** - disperse this tablet in hot water and consume it.
- Storage Condition** - Store at room temperature and keep it protected from moisture and direct sunlight.

#### ii. Company B

- Content** - 12 potent ayurvedic, organic and adaptogenic herbs & spices including *curcumin*, *holy basil*, *liquorice*, *Coriandrum sativum*, *Piper nigrum*, *Zingiber officinale*, *Convolvulus prostratus*, *Phyllanthus emblica*, *Ipomoea tricolor*, *Alpinia galanga*, *Andrographis paniculata* and *Justicia adhatoda*.
- Application instruction** - Just drop and dissolve an effervescent tablet in 250 mL hot water for 1-2 minutes kadha on the go.
- Storage Condition:** Store in a dry, ventilated place at a temperature below 25°C.

**Table 6:** Results of Comparative Study (Tablet vs Tablet).

Sr No	Parameters	Company A	Company B	Formulation F08
1	Thickness (mm)	5.24 ± 0.08	7.50 ± 0.15	5.49 ± 0.10
2	Diameter (mm)	9.05 ± 0.03	20.02 ± 0.01	11.01 ± 0.01
3	Hardness (kg/cm <sup>2</sup> )	3.62 ± 0.179	5.36 ± 0.770	4.92 ± 0.409

4	Weight Variation	148.2 ± 3.17	1011.5 ± 4.17	600.2 ± 1.33
5	Friability (%)	0.86	0.92	0.60
6	Disintegration time	1 minute 23 seconds ± 0.19	1 minute 09 seconds ± 0.32	1 minute 06 seconds ± 0.04

Overall, the results suggest that prepared tablet containing Clove, Tulsi, Turmeric and Ginger has successfully formulated and the present comparative study demonstrate that tablet from Formulation F08 is better than the marketed samples (Company A and company B).

### Comparison of kadha vs kadha

Kadha prepared from the dispersible tablet of formulation F08 and kadha prepared by traditional method at the home. Traditional Kadha was prepared at home with same ingredients and after filtration with in-house stainless-steel Tea strainer compare with kadha prepared from the dispersible tablet of formulation F08, Physical Description, IR Spectroscopy analysis and Taste were considered as Comparative evaluation Parameter.



**Figure 3:** Comparison on Kadha form formulation 8 and traditional kadha.

- The odour** of both Kadhas was Aromatic due to presence of Clove, ginger and Tulsi.
- Taste** – The taste of Traditional Kadha was Slightly Pungent however Kadha of formulation F08 was sweeter due to presence of Mannitol.

### Conclusion

The aim of this study has been to develop a novel technology for Ayurvedic kadha by formulation of dispersible tablets using direct compression method a dispersible tablet of Medicinal plants parts for ayurvedic kadha was successfully formulated. Clove 100 mg, Turmeric 50 mg, Ginger 50 mg and Tulsi 100 mg per tablet were selected as active substance as per traditional ayurvedic preparation. Mannitol 235.15 mg and corn 52.25 mg starch were selected as the diluent for 600 mg of tablet weight. Clove, Ginger mg and Tulsi are heating sensitive so wet granulation method was not selected for further process because drying of granules is an additional step.

Overall, the results suggest that prepared tablet containing Clove, Tulsi, Turmeric and Ginger has successfully formulated and the present comparative study demonstrate that tablet from Formulation F08 is better than the marketed samples (Company A and company B) and in comparison, traditional kadha, traditional

kadha was much clear solution, while kadha from formulation F08 was like suspension. In term of taste kadha from Formulation F08 was better than traditional kadha due to presence of Mannitol.

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