RESEARCH ARTICLE

An Innovative Formulation and Evaluation of Super Disintegrating Tea Tablet

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Received: 21 Jan 2026 Revised: 20 Feb 2026 Accepted: 10 Mar 2026

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ABSTRACT

Super disintegrating tea tablets can disintegrate rapidly in hot water and/or milk within a few seconds and can manage tea-making within a short period. On the contrary, this particular formulation has been formulated by the direct compression. This formulation provides optimum quantity of tea in a tea tablet which can manage making of tea appropriately and to overcome the unnecessary wastage of tea, proper dispersion of tea leaves to make tea liquor, and overcomes the consumer's complications with conventional tea consumption. During the evaluation tests, it was found that the tablet which contains small amount of tea can manage concocting tea with two times more liquor release compared to the conventional tea leaves (results obtained from UV spectrogram that the absorbance at 272 nm of formulated tea was 1.025 whereas the absorbance of commercially procured tea was 0.513), longer shelf life (results obtained from FTIR spectrogram that no microbial contamination or degradation observed), and more caffeine content (results obtained from HPLC chromatogram that the Rf value of caffeine in the formulated tea tablet was 3.580 whereas, standard Rf value of caffeine in tea is 3.569). Interestingly, this formulation can reduce the wastage of money compared to the conventional tea drawing up.

Keywords: Super disintegrating agent, Tea powder, Tea tablet, Caffeine release, Oligomerization, Noyes-Whitney equation

INTRODUCTION

Tea (*Camellia sinensis*) which is one of the most substantially consumed liquid refreshments in the world was derived from Southeast China. Then slowly expanded to India, Sri Lanka and further into many tropical and sub-tropical regions of the world, respectively. There are fundamentally two varieties of tea. *Camellia sinensis* var. sinensis (known as China tea) which is grown vividly in China, Japan, and Taiwan, while *C. assamica* var. assamica (Assam tea) found in south and south East Asia, and nowadays in Australia [1]. Starting from the 19th century more than forty types of inorganic compound have been found in tea [2]. Tea predominantly contains polyphenols of thirty types among which the content of polyphenols is large uttermostly in green tea [3]. Tea also includes catechin, epicatechin, epicatechin gallate, and epigalocatechin gallate which have various therapeutic properties for different diseases [4, 5, and 6]. Green tea comprised of numerous flavonoids among which myricetin glycosides, quercetin glycosides, and behenyl glycosides are significantly remarkable [7, 8]. Anthocianin which is soluble in water is a flavonoid found in tea. Even though the content of anthocyanins is not in huge amount in tea but is responsible for the bitter taste [9, 10]. Gallic acid, Chlorogenic acid, Caffeic acid, p-Coumaric acid, Ellagic acid, Quinic acid, and tea gallate are the phenolic acids respectively are non-identical acids or acidic compounds which can be found in tea [13]. Among the discrete alkaloids the caffeine content is found to be more in tea. Apart from that a small amount of theophylline and theobromine can also be found [14]. The alkaloids are responsible for the revitalizing effect of tea [15]. Tea comprises of 1% to 4% of amino acids. So far, 26 amino acids have been found in tea, including 20 essential amino acids and 6 non-essential amino acids. The highest content is theanine, glutamic acid, arginine, serine, and aspartic acid [16]. Theanine and Aminobutyric acid are two significant active amino acids identified in tea. They have exceptional protective effects on the human nervous system [17, 18]. Most carbohydrates found in tea are polysaccharides in nature, such as cellulose, starch, and pectin, which are insoluble in water and are also responsible for a bit of sweetness in tea [4]. Among the chemical constituents of green tea, the aromatic components are not found much quantity. However, 0.005% to 0.020% has been found which is responsible for the impression of tea [20]. As of now more than 40 organic acids have been isolated and got identified from tea, including unbound organic acids and more than 30 have been found in aromatic components [21, 22, and 23]. The striking mineral elements are Phosphorus and Potassium, including Calcium, Magnesium, Iron, Manganese, Aluminum, Sulpher, Silicon, and also some trace elements such as Zinc, and Copper [24, 25, and 26] have been found in tea. Green tea also comprised of certain number of vitamins, such as vitamin B, vitamin C, and vitamin E, enzymes such as glucosidases and lipoxidases, and also chlorophyll, which is recognized as a safe natural edible pigment [27, 28, 29] have been detected and identified.

Disintegrants or disintegrating agents are those substances or combinations of ingredients added to different medicinal and/or nutraceutical formulations to enhance the disemination or foundering of tablets and capsule contents into very small fragments or minute particles resulting faster dissolving. When they encounter with watery substance in the GI tract or perhaps outside of GI tract of the human body they may work by gulping water into the tablet, causing it to expand and break into minute diminutive fragments. The most common disintegrating agents are starch USP, numerous starch derivatives, and many natural disintegrants. Numerous pre gelatinized starches are also employed as disintegrants during different formulations, with 5 % concentration [30, 31, 32, 33, and 34]. The API powders with compressibility of 12% to 16% are considered as good flowing powders. In contrast to other superdisintegrants, crospovidone are remarkabely compressible and established [35, 36, and 37].

MATERIALS AND METHODS

Materials and Chemicals: Tea Powder: Tea Powder is a powdered form of tea leaves prepared in the experimental laboratory from the tea leaves (TATA Tea Gold, FSSAI Lic No: 10014031001025) obtained from the local market in Barasat, West Bengal, India.

Compressible Agent (Microcrystalline cellulose): Microcrystalline cellulose $(C_6H_{10}O_5)_n$ is meliorated pulp made up of wood. It's white, free flowing greasepaint. Chemically, it's an inert substance. It was supplied from Sigma-Aldrich, CAS No: 9004-34-6.

Diluent (Lactose): Lactose is a disaccharide type sugar which gets synthesized by galactose and glucose subunits with the molecular formula $C_{12}H_{22}O_{11}$. Lactose was purchased from Sigma-Aldrich, CAS No: 63-42-3.

Lubricant (Talc): Talc is a naturally being mineral that's generally used in a wide range of diligence, as well as a lubricant; including the pharmaceutical assiduity. Talc used in this formulation was from Loba Chemie, CAS No: 14807-96-6.

Super Disintegrant (Sodium Starch Glycolate): A disintegrant is a cumulative that promotes decomposition, which is the breakage of a tablet into small fractions when in contact with a liquid medium. It was collected from Sigma-Aldrich, CAS No: 9063-38-1. .

Glidants (Magnesium Stearate): Glidants are blended with the expression to enhance the tablet- core mix- material inflow property. In this formulation it was collected from Loba Chemie, CAS No: 557-04-0.

Equipment: - Weighing balance (Danwer High Precision Weighing Scale 220 g, DWAI-223**),**

HPLC (Waters, Quaternary or Binary gradient pump with manual injector, PDA Detector, Model 2489 UV/Visible [UV/Vis] Detector),

IR spectrophotometer (Bruker, Alpha ii Compact FTIR Spectrometer),

UV spectrophotometer (Shimadzu, UV-1900 UV-VIS Spectrophotometer)

Method: -The present invention relates to a process for making a Biconvex Shaped Super Disintegrating Tea Tablet with the composition comprising of Tea Powder: Microcrystalline Cellulose: Talc: Magnesium Stearate: Sodium Starch Glycolate = 25: 2: 2: 2: 6; whereas to get faster disintegration the ratio should be 25: 2: 2: 2: 9 by which better result can be obtained.

Commercially procured tea powder in granular form (50 gms). This was taken in a mortar and subjected for drying at 50 to 60 ℃ in hot air oven (Remi). It should be considered that temperature in between 40 to 45 ℃ is enough to remove moisture from the tea leaves. Time should be approximately two to five minutes. It is highly recommended to do dry heating in a closed system in order to keep the tea flavour intact. As there was the usage of large particle tea of CTC (Crush Tear Curl), the temperature was adjusted up to 60 ℃. It is highly recommended to keep the temperature between 40 to 45 ℃ in order to get better result (flavour and infusion).

The dried tea powder was crushed with the help of a pestle and finely powdered. Here in this case crushing of dried tea leaves by using machine is recommended. The obtained tea powder was passed through sieve no 85 (As sieve 120 was not available during the experiment) to get uniform size particles (up to sieve no 120 can be used to get more fine particles) with which remaining ingredients, such as, microcrystalline cellulose (5%), "Sigma –Aldrich", sodium starch glycolate, "Sigma –Aldrich" (5%, 10%, and 15%) was added and mixed uniformly. Lactose was added in required quantity. Talc, "Loba Chemie", and magnesium stearate, "Loba Chemie" was incorporated in required quantity and mixed uniformly.

The obtained mixture was subjected to tablet compression using 8 stationed (Kambert Tablet Press) tablet compression machine. Tablets of 400 mg were prepared which was evaluated for various parameters like solubility, disintegration time, hardness etc. Now, it should be considered that tea is a naturally occurring substance. Therefore, according to the quality of tea leaves the flavour and taste will differ but the basic pattern to prepare tea tablet is same in every case. Here according to the requirement and/or choice different colour and different flavour can also be added in order to gain its different appearance and flavours. It is highly recommended that there should be pure form of dried tea powder. Additions of less adulterant or no adulterants can enhance the quality of tea tablet.

Therefore, it can easily be considered that small particles of tea tablet/tablets can easily disperse into the boiled water and/or boiled milk in order to release flavour very quickly. Here the comparatively small particles of tea leaves dust are highly recommended.

As it is described earlier that Lactose is not required to prepare the whole formulation but here in this case during the experiment Lactose was added to fill up the total quantity. Instead of not using Lactose here the similar amount of dried tea powder or ginger powder, elichi powder, tulsi powder etc. can be added to get some unique flavor. Similarly other flavoring agents can also be added like peppermint oil rose oil, jasmine oil etc. According to the requirement FDC (Food, Drugs, and Cosmetics) approved colour can also be added to get colour and texture. On the other hand, for different tea formulations the main ingredient will change whereas, the rest of the elements i.e. compressible agent, lubricant, glidant, and super disintegrating agent will remain same.

In this present invention the amount of tea powder required will be less 200 to 250 mg of tea powder for making 100 ml of tea. Fine powder (Sieve 120 can be used which can produce 0.125 mm of particle size) can be obtained. Therefore, after disintegration, the effective surface area will be more resulting in the rapid solubilization of the active ingredient. Extraction of tea liquor will be obtained instantly. In this present formulation the amount of tea powder required will be less. 200 mg to 250 mg of tea powder is required for making 100 ml of tea. Fine powder (Sieve 120 can be used which can produce 0.125 mm of particle size) can be obtained. Therefore, after disintegration, the effective surface area will be more resulting in the rapid solubilization of the active ingredient. Extraction of tea liquor will be obtained instantly. Caffeine in tea dissolves in hot water because it has significant intermolecular forces, specifically hydrogen bonds and dipole-dipole interactions. Caffeine is polar in nature molecule with more than one hydrogen bond, which allows it to interact with polar water molecules. In hot water, the kinetic energy of the water molecule increases, which helps break the intermolecular forces between the caffeine molecules and allows more dissolution in the hot water.

As the tea granules were crushed in a powder form therefore, the effective surface area becomes greater. The less amount of particle size can give more effective surface area by which the tablet can release its colour and flavour rapidly. It is highly recommended to keep the particle size lesser as far as possible. During the research work initially Sieve 85 was used where the particle size was 0.177 mm approximately. Then Sieve 120 was used where the particle size was 0.125 mm approximately which was responsible for more effective surface area. It is recommended to use Sieve 170 or more in order to gain better outcome i.e. less than 0.100 mm of particle size to get highly effective result. (Ref: Noyes and Whitney Equation). The tea tablet also reflected a disintegration time of 38 sec, while maintaining the water temperature of 60-65 degree Celsius. Later on the temperature was raised up to 70 degree Celsius or more by which it showed the time of disintegration of 28 sec. This indicates the disintegration time is dependent on temperature of the medium which may be suitably maintained above 70 degree Celsius. Therefore, considering the conventional tea powder or tea bag, the tea tablet would be a better choice as it can disintegrate very fast (less than half minute) and consume lesser time.

RESULTS

Fig 1: Flowchart describes the processing steps of biconvex shaped super disintegrating tea tablet
Fig 2: Shows the mixture of the required ingredients to formulate biconvex shaped super disintegrating tea tablet
Fig 3: Shows the formulated biconvex shaped super disintegrating tea tablet
Fig 4/a: Shows the insertion of biconvex shaped using super disintegrating tea tablet in hot water
Fig 4/b: Shows the starting of disintegration of biconvex shaped using super disintegrating tea tablet in hot water
Fig 4/c: Shows the initial stage of liquor release of biconvex shaped using super disintegrating tea tablet in hot water
Fig 4/d: Shows the final stage of liquor release of biconvex shaped using super disintegrating tea tablet in hot water
Fig 4/e: Shows the end product (tea liquor) after complete disintegration of biconvex shaped using super disintegrating tea tablet in hot water

Fig 5: Comparative data of UV Spectrogram of commercially procured tea granules and formulated tea tablet
Fig 6: Shows the comparative study of caffeine release from commercially procured tea and the biconvex shaped super disintegrating tablet respectively
Fig 7: Shows a comparative study of FTIR Spectrogram of biconvex shaped super disintegrating tea tablet before and after accelerated stability study respectively
Fig 7A: Shows the overlapping data of caffeine release from the formulated tea tablet (CTC granules) [Pink line], conventional tea leaves [Green line] and, the formulated tea tablet (tea leaves) [Blue line] respectively
Fig 7B: Shows the FTIR spectrogram of pure caffeine along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.
Fig 7C: Shows the FTIR spectrogram of caffeine from the formulated tea tablet (CTC) along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.
Fig 7D: Shows the FTIR spectrogram of caffeine from the conventional tea leaves along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.
Fig7E: Shows the FTIR spectrogram of caffeine from the formulated tea tablet (tea leaves) along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.
Fig 8: HPLC chromatogram of the formulated biconvex shaped super disintegrating tea tablet
Fig 9: Comparative HPLC chromatogram of (a) standard caffeine release, (b) black tea caffeine release, and (c) commercially procured green tea caffeine release respectively

DISCUSSION

The release of soluble active ingredients was studied by taking tea tablets containing 250 mg finely divided tea powder and the same amount of marketed tea granules. 100 ml distilled water was heated around 65 degree Celsius in which one tea tablet was placed and occasionally stirred with a glass rod providing gentle agitation. After 60 seconds, the resultant solution was filtered. In fig: 5 and fig: 6 respectively the filtrate was taken after 10 times dilution using distilled water and the obtained samples were analyzed using UV Visible Spectrophotometer. The absorbance was found at 1.025 at 272 nm. Similar procedure was followed for marketed tea granules which reflected an absorbance of 0.513 at 272 nm. Caffeine in tea dissolves in hot water because it has significant intermolecular forces, between the hydrogen bonds and dipole interactions. Caffeine molecule is polar in nature with more than one hydrogen bond, which allows it to interact with polar water molecules. In hot water, the kinetic energy of the water molecule increases, which helps break the intermolecular forces between the caffeine molecules and allows more dissolution in the hot water.

Initially, the tea granules were roasted at 45 to 50 degree Celsius and crushed into fine particles to get a better taste and smoky flavour. Therefore, during the making of the infusion, it produced fully induced flavour. It is applicable to any type of tea. On the other hand, dry roasting of tea leaves results an oligomerization in tea catechins which is responsible for the reduction of the astringency of tea and never effect on sleep. In fig: 7, the stability was determined by using FTIR Spectroscopy whether any biochemical changes were occurring or not. Initially the spectrogram was taken for the tea tablet which was prepared approximately six months earlier and the data was recorded. Then after having kept them in stability chamber the spectrogram was taken. The results of accelerated stability proved that there is no significant changes have been found, also there is no decay or degradation of the tea tablet for last six months and no any microbial contamination found. Therefore, it can be concluded that the shelf life of the tea tablet is approximately 24 months. In Fig 7A to Fig 7E, Caffeine shows its efficacy due to the presence of the Carbon-Nitrogen bond, Carbon-Hydrogen bond, and amide carboxyl group. In the spectrogram, FTIR (Fourier Transform Infrared Spectroscopy) was determined. In pure caffeine the Carbon-Hydrogen bond vibration showed the peak at 1357.02 cm^{-1}, the Carbon-Nitrogen bond vibration showed the peak at 1546.50 cm^{-1}, and the amide carboxyl group vibration showed the peak at 1645.96 cm^{-1}, respectively. On the other hand, in caffeine obtained from conventional tea leaves the Carbon-Hydrogen bond vibration showed the peak at 1320.06 cm^{-1}, the Carbon-Nitrogen bond vibration showed the peak at 1549.19 cm^{-1}, and the amide carboxyl group vibration showed the peak at 1690.56 cm^{-1}.

On the contrary, in the case of the formulated tea tablet (CTC), the caffeine has shown the Carbon-Hydrogen bond vibration with the peak at 1326.16 cm^{-1}, the Carbon-Nitrogen bond vibration has shown the peak at 1540.21 cm^{-1}, and the amide carboxyl group vibration has shown the peak at 1632.90 cm^{-1}. Similarly, in the case of the formulated tea tablet (tea leaves), the caffeine has shown the Carbon-Hydrogen bond vibration with a peak at 1327.80 cm^{-1}, the Carbon-Nitrogen bond vibration has shown a peak at 1539.27 cm^{-1}, and the amide carboxyl group vibration has shown the peak at 1634.87 cm^{-1} , respectively.

Now, from the obtained results it can clearly be stated that despite treatment with some other excipients the end product (tea tablet prepared from CTC tea granules and/or tea leaves) is showing similar or almost similar caffeine content as the conventional tea leaves and CTC tea granules have. On the contrary, the amount of tea is less in the tea tablet compared to the conventional usage of tea that is it can manage to make one cup of tea with only one tablet consisting of 200 mg to 250 mg of tea. It can also be concluded that the other chemical constituents present in the tea tablet will remain the same or almost the same as compared to conventional tea leaves and CTC tea granules.

In case of the formulated tea tablet the release of caffeine is higher than the conventional tea leaves whether it may be caffeine release from black tea or green tea. The given chromatogram data clearly proves that the standard caffeine release which is denoted as Rf value is 3.569. Whereas, in black tea leaves the caffeine release is 3.551 and in green tea leaves the caffeine release is 3.544. That is also observed in the representation of the chromatogram. Now, in the formulated and developed tea tablet the release of caffeine is more superior that is 3.580. Therefore, it can be clearly concluded that the release of flavonoids, theine, and other chemical constituents will be higher compared to the conventional tea leaves. On the other hand, in order to gain similar amount of active ingredient release from the tea leaves there is a requirement of more amount of tea leaves. Whereas, the caffeine/active ingredient release is almost two times in tea tablet in spite of using less amount of tea powder. The UV-Vis spectrogram already denoted that earlier.

CONCLUSION

In conclusion it can be clearly stated that no requirement to isolate the active ingredient separately. The formulated biconvex super disintegrating tea tablet itself can release the active ingredient (caffeine) very fast while putting into hot water and/or milk. There is no requirement of any type of chemical treatment. There is no requirement of any type of granulation. Fine tea powder can show its efficacy in a better way. There is no requirement of freeze drying, spray drying and/or any lyophilization. Similarly, there is no requirement to produce effervescence as during effervescence in case of the preparation of milk-tea it can produce casein or curd due to the presence of citric or tartaric acid. There is no requirement of any diluents or fillers (completely optional).There is no requirement of any type of adulterants as adulterants can reduce the quality of tea. Whereas particular in that case it can be confirmed that the tea tablet can be the most preferable option for the consumers and the tea makers compared to conventional tea leaves. Definitely it is possible to prepare four to five cups of tea by using same amount of tea leaves conventionally used to prepare only one cup of tea. There is no requirement of any combinational drug/drugs. There is no requirement of centrifugation to separate the fine particles as at the initial stage during the formulation already fine particles were obtained. There is no requirement of any purification and concentration of the end product. Already all the ingredients used in this formulation was in pure form. During the quality control tests it showed greater hardness (4 kg approx and it can be adjusted according to the requirement). Finally the prepared tea can be consumed directly. On the other hand, the unique ratio of the chemical compositions makes it exceptional compared to other ways of conventional tea consumption. The amount of tea powder will be less by which only a few amount of tea powder can prepare more number of super disintegrating tea tablets. Fine powder can be obtained. Therefore, after disintegration, the effective surface area will be more resulting in the rapid solubilization of the active ingredient which is already found in the experiment. Extraction of tea liquor will be obtained instantly by which the prepared tea can be consumed instantly. Total time of disintegration will be less (max 30 seconds) which clearly denotes the pioneering in this formulation. The number of ingredients will be lesser (no requirement of any kind of

diluents). It has less astringency by which those who are suffering from insomnia or any other ambiguities regarding sleeping can use the tea tablet undoubtedly. Better shelf life (experimentally proved) can prevent any further degradation and/or any microbial contamination.

Patent: We acknowledge to Mr. Gaurav Singhal and Mrs. Sanchita Singhal of Singhwal Techlaw OPC Private Limited, No.33/1, 4th Floor, Krishna Complex, Near Mahatma Gandhi Statue, Horamavu Main Rd, Horamavu, Bengaluru, Karnataka 560043, India for going further to file the patent application regarding this formulation vide Patent Application Number: 202341074315; Reference Number: TEMP/E-1/87416/2023-CHE.

Approval: We acknowledge to the honorable member secretary, Dr. B. Balaji (IFS) of National Biodiversity Authority, Government of India (NBA), 5th Floor, TICEL Biopark, CSIR Road, Taramani, Chennai-600113, Tamil Nadu, India, for issuing the Form-8 approval vide Application Number: NBA/IPR Appl/INBA/8202500920/26/25-26/2879.

SUPPLEMENTARY MATERIALS

Authors' contribution: "Conceptualization, Debasish Bhattacharya and Baisnabdas Pathak; methodology, Baisnabdas Pathak; software, Baisnabdas Pathak; validation, Baisnabdas Pathak and Tirthankar Choudhury; formal analysis, Debasish Bhattacharya and Tirthankar Choudhury; investigation, Baisnabdas Pathak; resources, Debasish Bhattacharya, Tirthankar Chudhury, and Baisnabdas Pathak; data curation, Baisnabdas Pathak; writing—original draft preparation, Debasish Bhattacharya; writing—review and editing, Debasish Bhattacharya; visualization, Debasish Bhattacharya; supervision, Baisnabdas Pathak and Tirthankar Choudhury; project administration, Baisnabdas Pathak, and Tirthankar Choudhury; funding acquisition, Debasish Bhattacharya, Baisnabdas Pathak, and Tirthankar Choudhury. All authors have read and agreed to the published version of the manuscript."

Funding
"This research received no external funding".

Data availability statement: Apart from the given data in the manuscript neither new data were created nor separate data are available.

ACKNOWLEDGEMENTS

We acknowledge to Mr. Gaurav Singhal and Mrs. Sanchita Singhal of Singhwal Techlaw OPC Private Limited, No.33/1, 4th Floor, Krishna Complex, Near Mahatma Gandhi Statue, Horamavu Main Rd, Horamavu, Bengaluru, Karnataka 560043, India for going further to file the patent application regarding this formulation, The Central Instrumentation Laboratory of Brainware University, 398 Ramkrishnapur Road, Barasat, Kolkata: 700125, West Bengal, India for the tests and evaluations, and Dr. B. Balaji (IFS) of National Biodiversity Authority, Government of India (NBA), 5th Floor, TICEL Biopark, CSIR Road, Taramani, Chennai-600113, Tamil Nadu, India, for issuing the Form-8 approval.

Conflicts of interest
"The authors declare no conflicts of interest."

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Table 1: Ingredients used during the formulation of biconconvex shaped super disintegrating tea tablet.

Formulation batch	Main Ingredient (Tea Powder) mg	Compressible Agent (Microcrystalline Cellulose) mg	Lubricant (Talc) mg	Glidant (Magnesium Stearate) mg	Super Disintegrating Agent (Sodium Starch Glycolate) mg
1	250	20	20	20	20
2	250	20	20	20	40
3	250	20	20	20	60

Table 2: Comparison of conventional tea granules and super disintegrating tea tablet

Parameter	Conventional Tea Granules	Super Disintegrating Tea Tablet
Particle Size	Larger (CTC granules)	Fine powder (<0.125 mm)
Surface Area	Lower	Significantly higher
Disintegration	Time consuming	Very fast (<30 s)

Extraction Efficiency	Moderate	Nearly 2× (UV data)
Dose Uniformity	Variable	Standardized
Shelf Stability	Moisture-sensitive	Improved stability
Processing	Simple drying	Direct compression

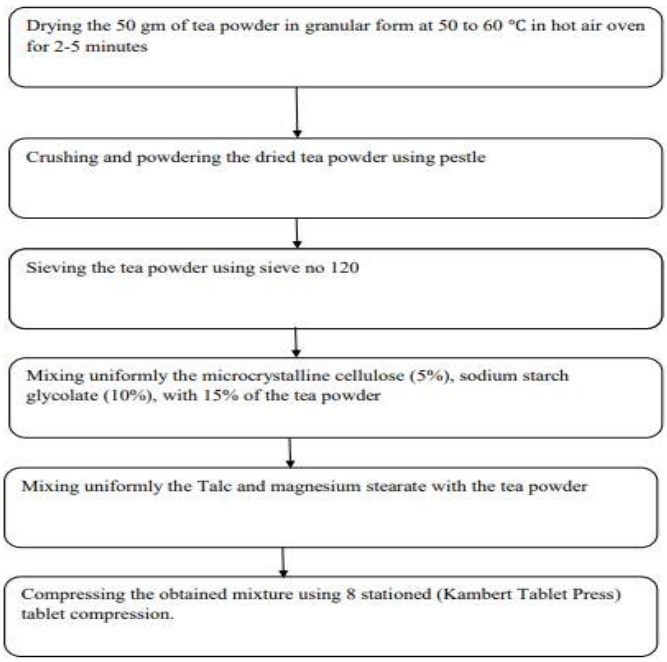


Fig 1: Flowchart describes the processing steps of biconvex shaped super disintegrating tea tablet



Fig 2: Shows the mixture of the required ingredients to formulate biconvex shaped super disintegrating tea tablet



Fig 3: Shows the formulated biconvex shaped super disintegrating tea tablet



Fig 4/a: Shows the insertion of biconvex shaped using super disintegrating tea tablet in hot water



Fig 4/b: Shows the starting of disintegration of biconvex shaped using super disintegrating tea tablet in hot water



Fig 4/c: Shows the initial stage of liquor release of biconvex shaped using super disintegrating tea tablet in hot water



Fig 4/d: Shows the final stage of liquor release of biconvex shaped using super disintegrating tea tablet in hot water



Fig 4/e: Shows the end product (tea liquor) after complete disintegration of biconvex shaped using super disintegrating tea tablet in hot water

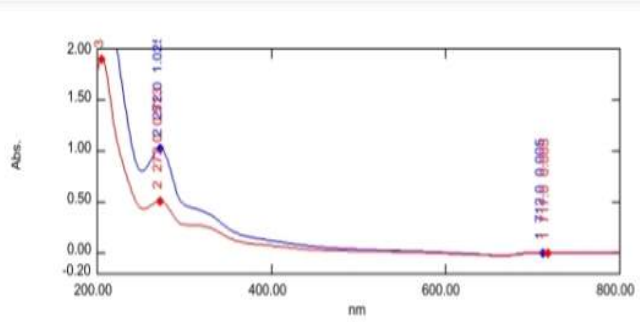


Fig 5: Comparative data of UV Spectrogram of commercially procured tea granules and formulated tea tablet

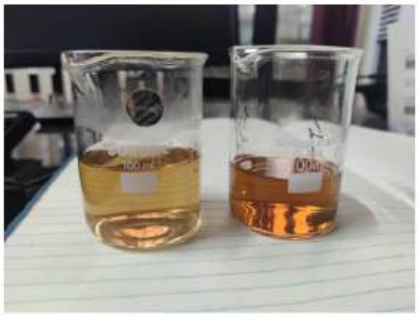


Fig 6: Shows the comparative study of caffeine release from commercially procured tea and the biconvex shaped super disintegrating tablet respectively

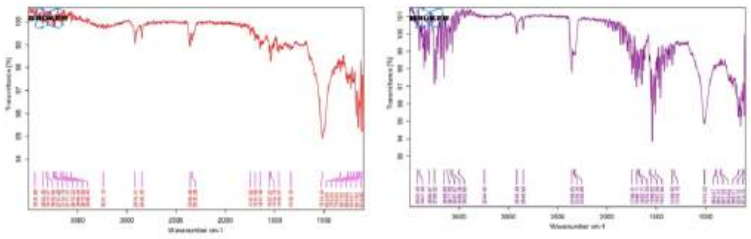


Fig 7: Shows a comparative study of FTIR Spectrogram of biconvex shaped super disintegrating tea tablet before and after accelerated stability study respectively

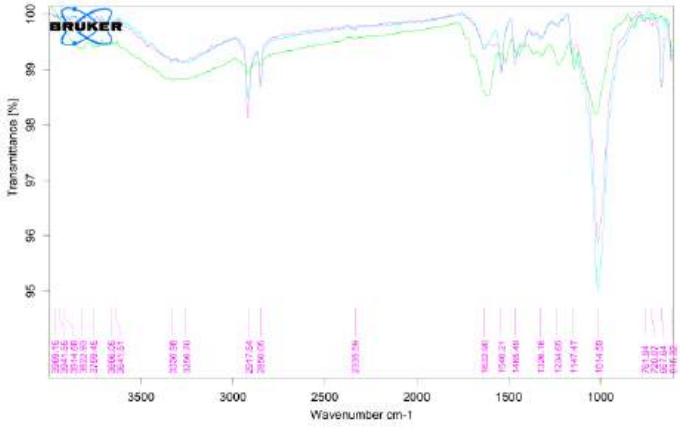


Fig 7A: Shows the overlapping data of caffeine release from the formulated tea tablet (CTC granules) [Pink line], conventional tea leaves [Green line] and, the formulated tea tablet (tea leaves) [Blue line] respectively

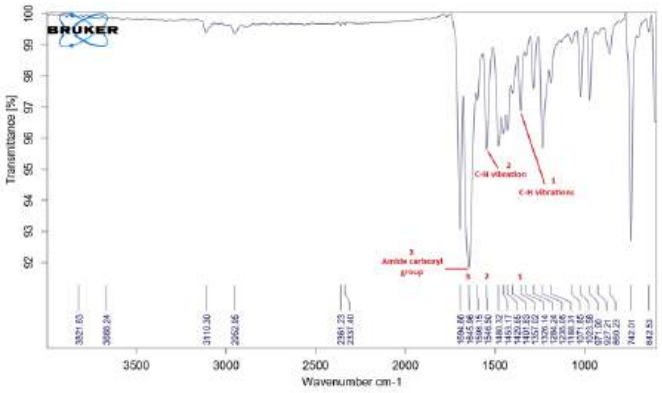


Fig 7B: Shows the FTIR spectrogram of pure caffeine along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.

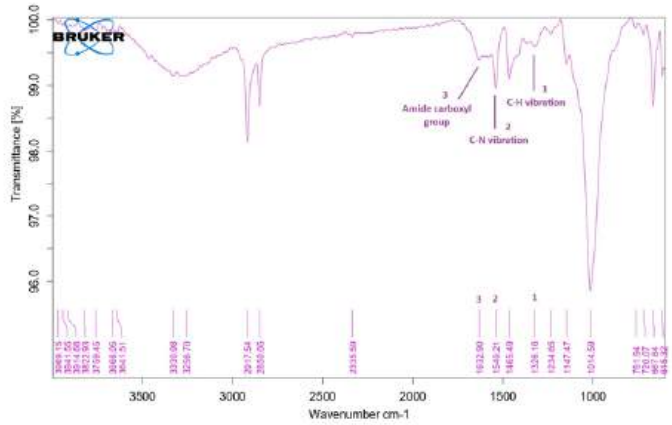


Fig 7C: Shows the FTIR spectrogram of caffeine from the formulated tea tablet (CTC) along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.

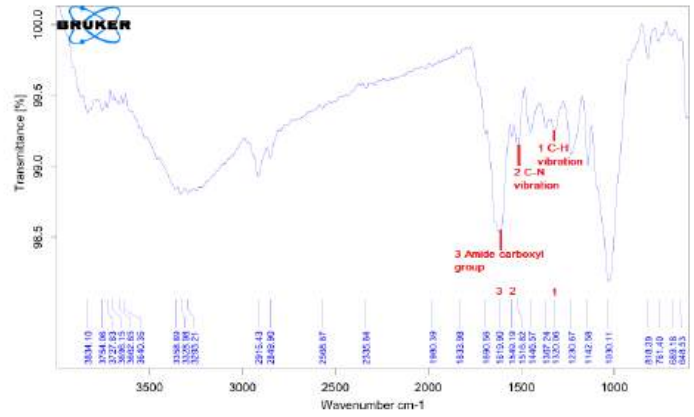


Fig 7D: Shows the FTIR spectrogram of caffeine from the conventional tea leaves along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.

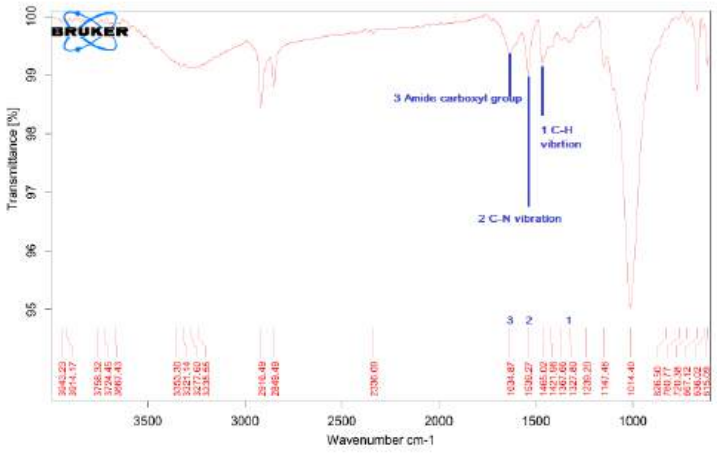


Fig7E: Shows the FTIR spectrogram of caffeine from the formulated tea tablet (tea leaves) along with the marked peaks of C-H vibration, C-N vibration and, Amide carboxyl group respectively.

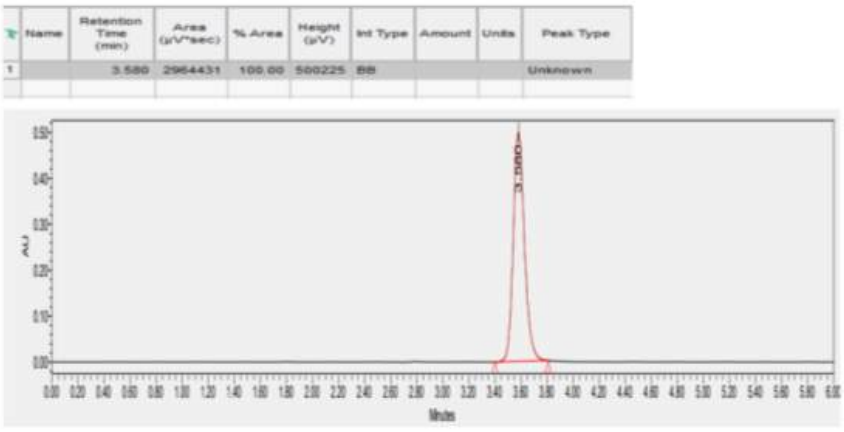


Fig 8: HPLC chromatogram of the formulated biconvex shaped super disintegrating tea tablet

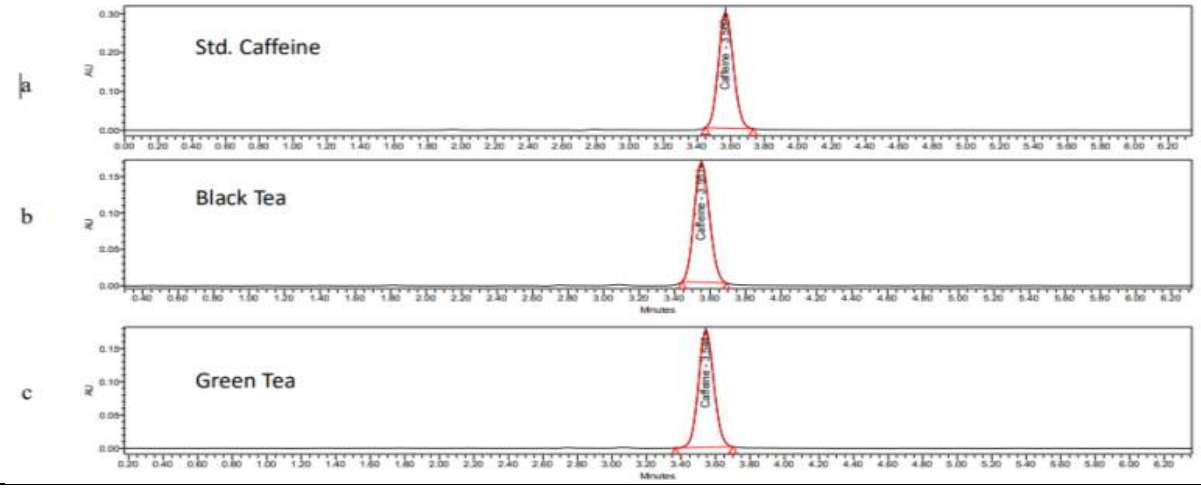


Fig 9: Comparative HPLC chromatogram of (a) standard caffeine release, (b) black tea caffeine release, and (c) commercially procured green tea caffeine release respectively

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