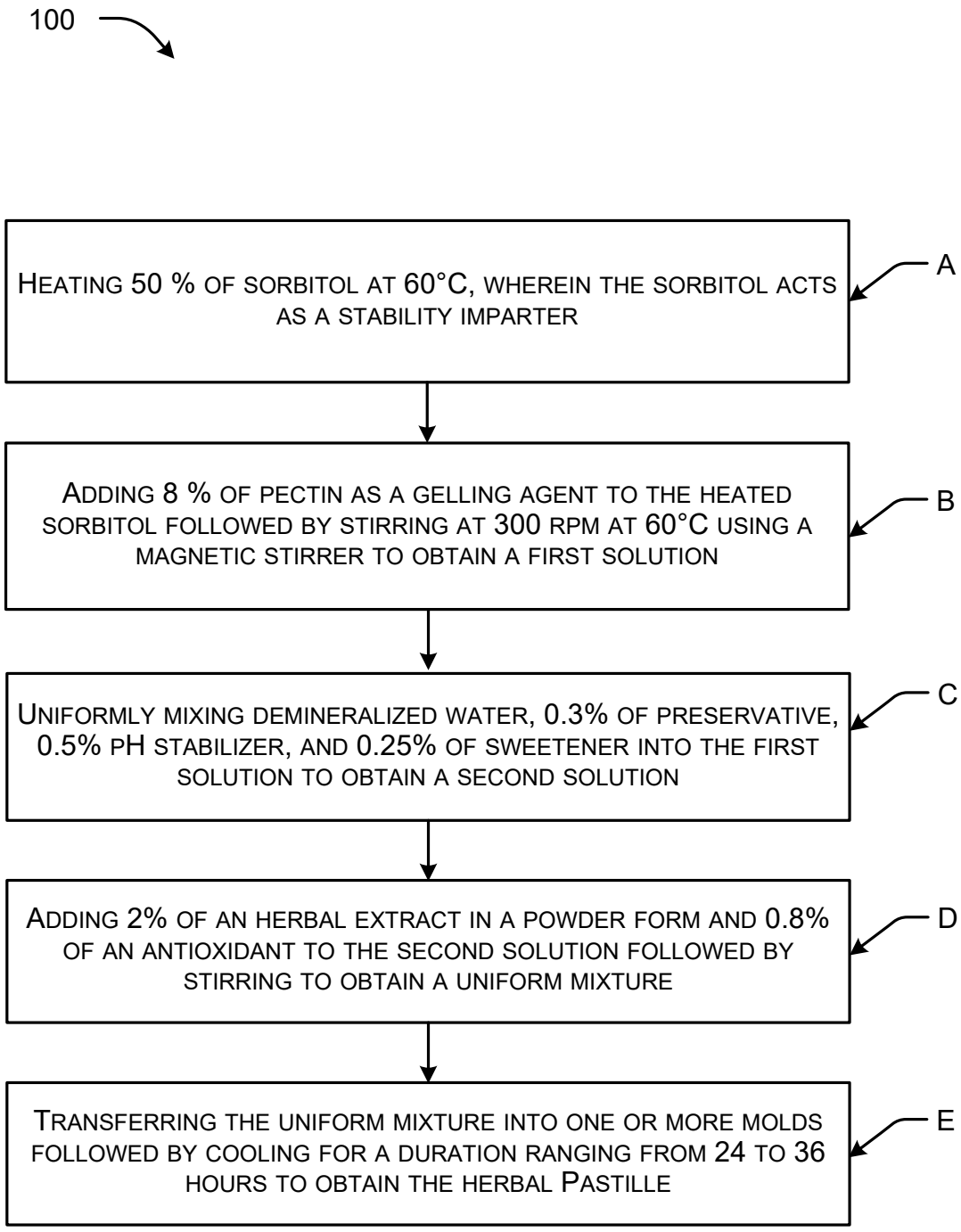



FIG. 1

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200



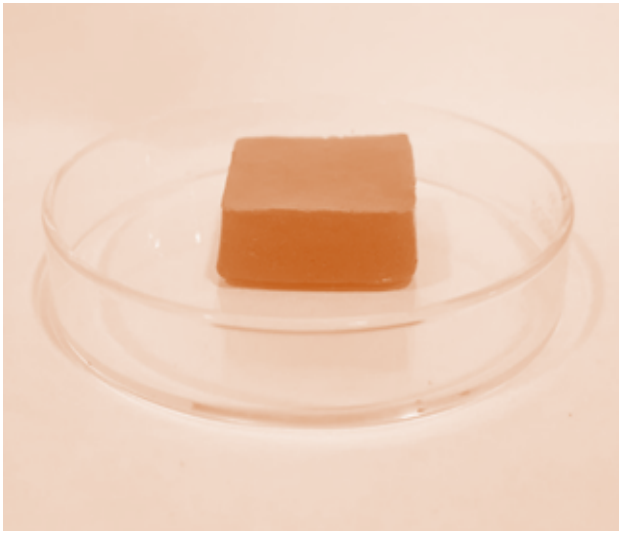

A



B



C



D

FIG. 2

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300

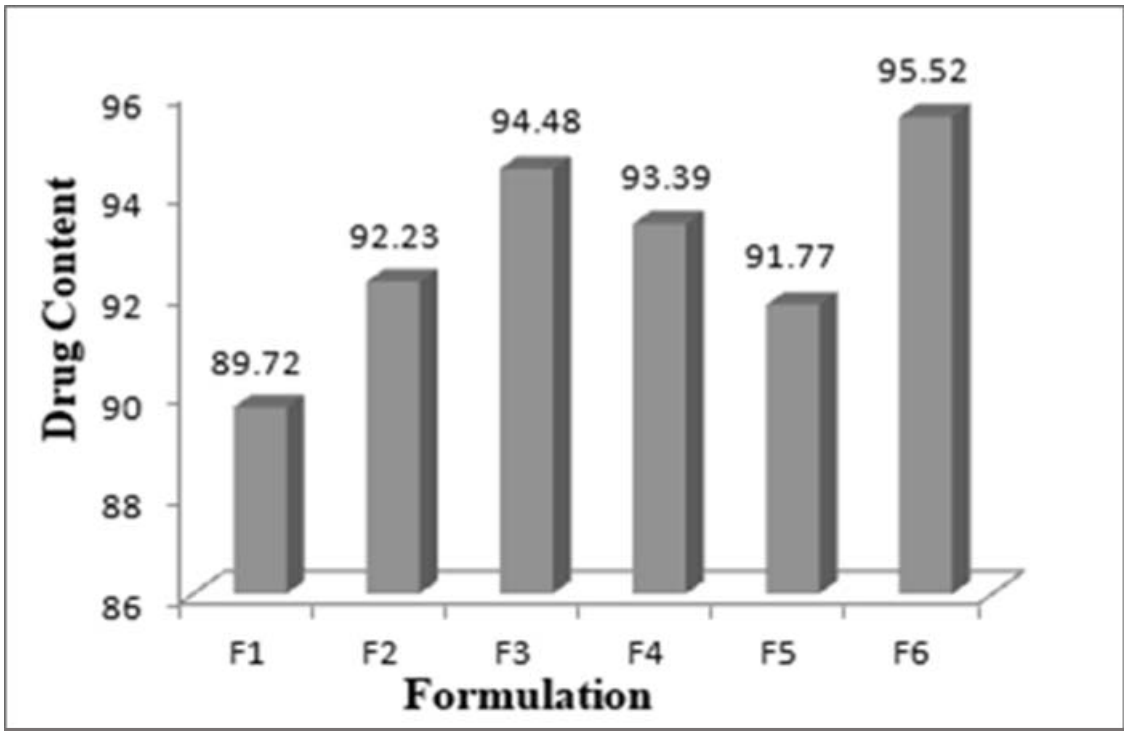



FIG. 3

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400

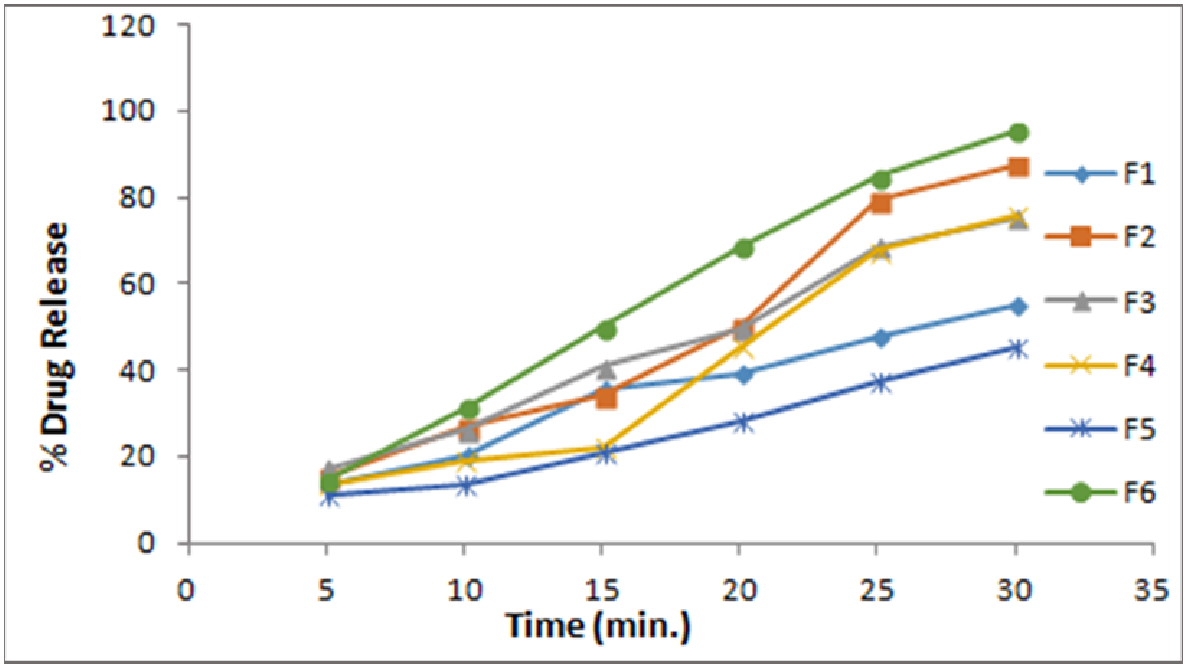



FIG. 4

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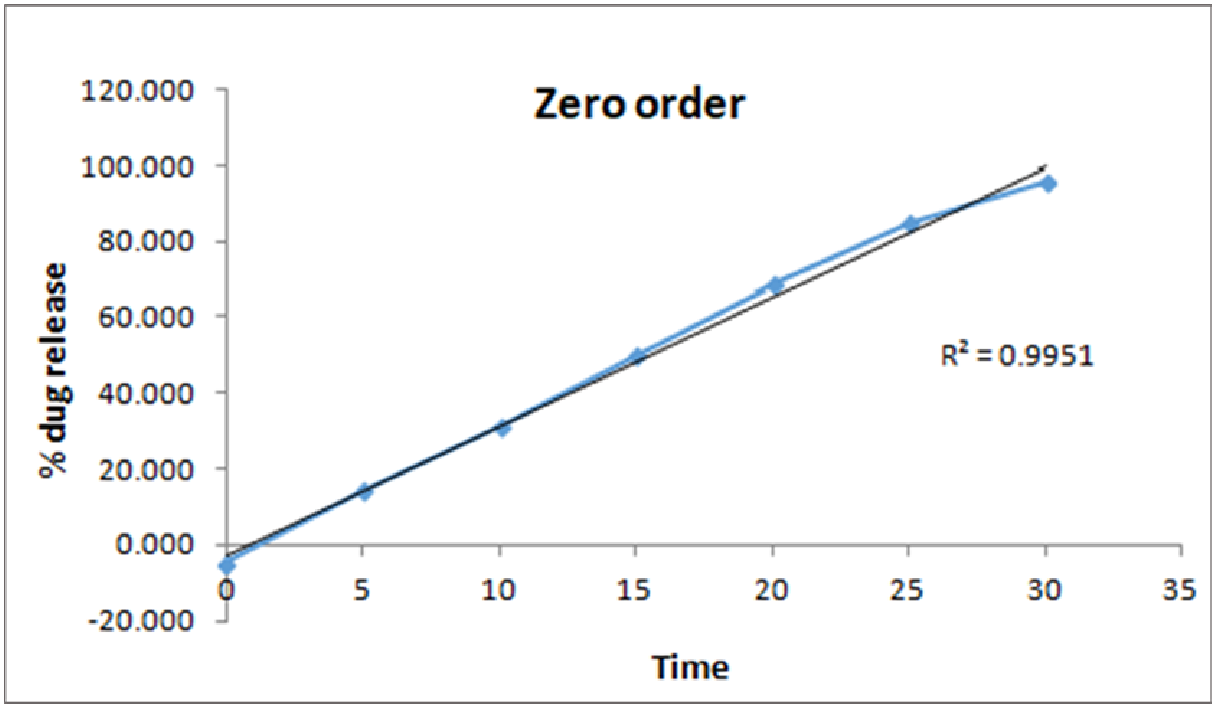



FIG. 5

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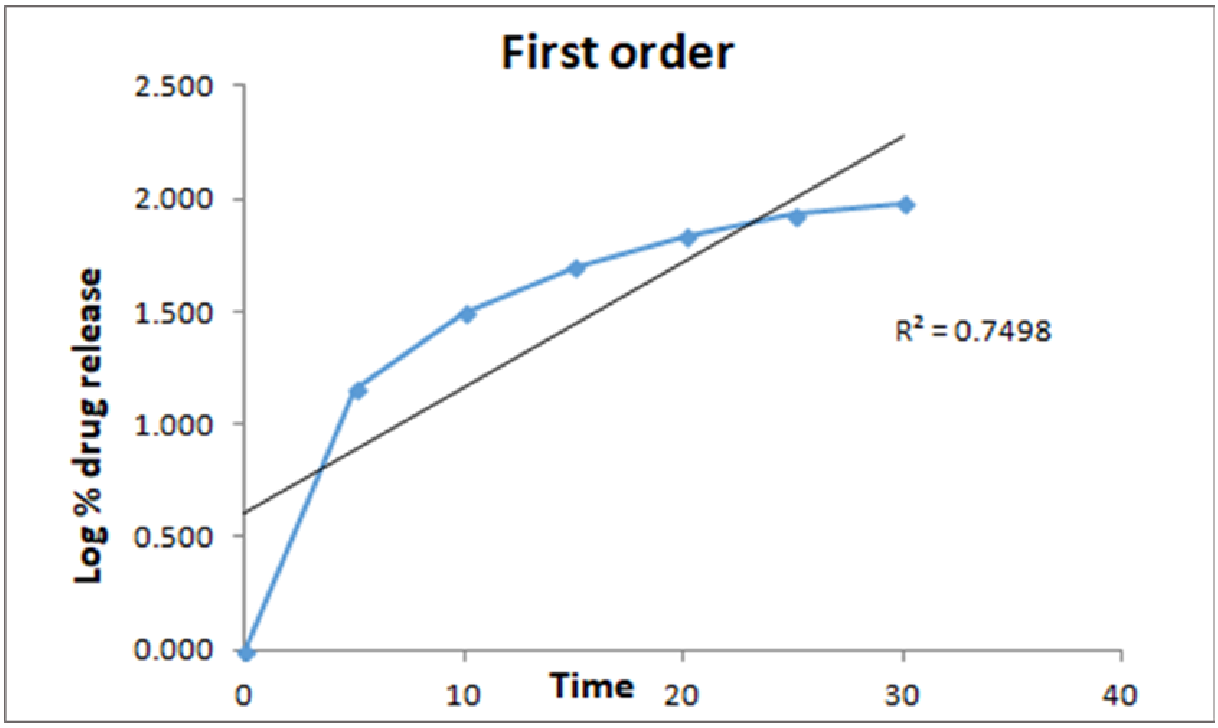



FIG. 6

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700

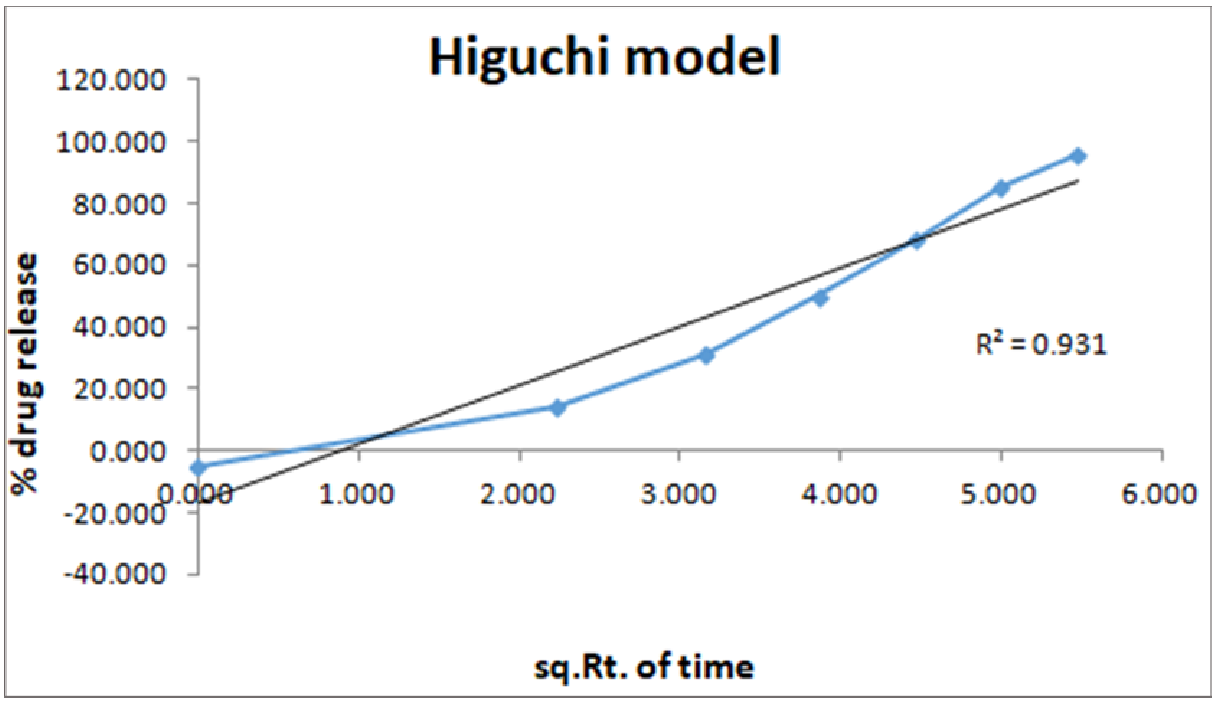



FIG. 7

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800

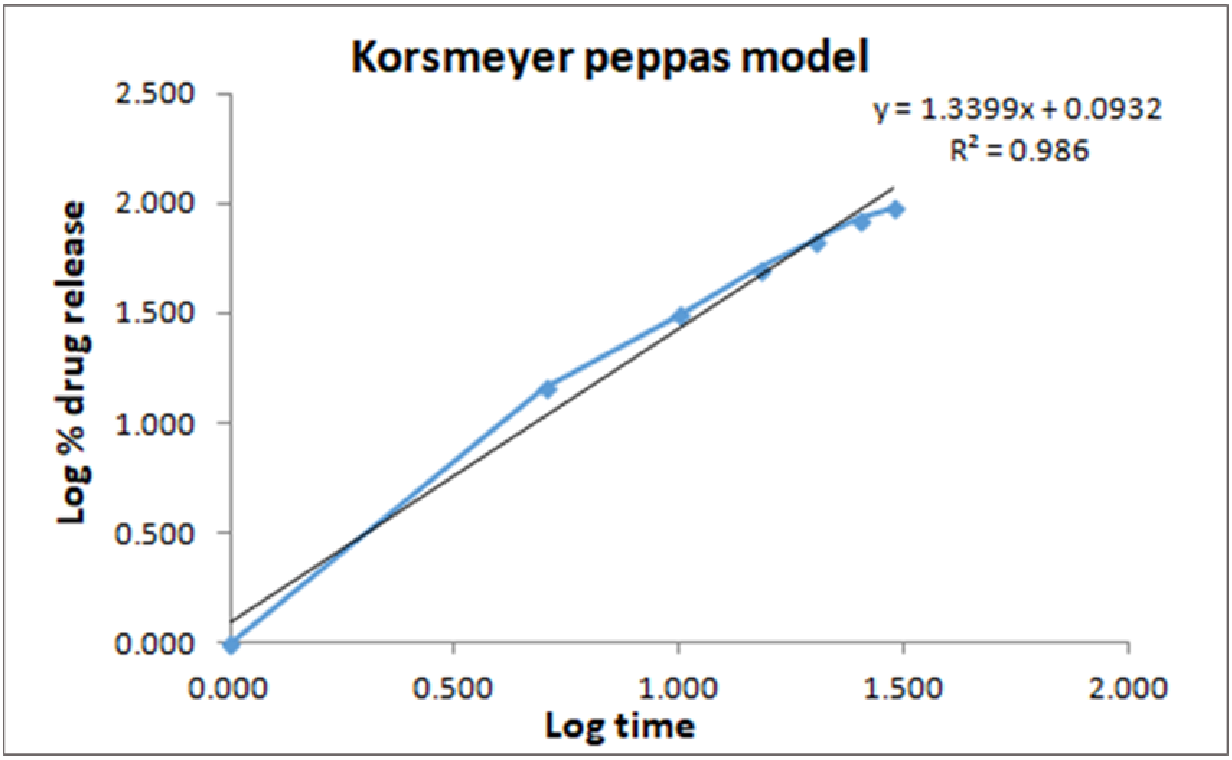



FIG. 8

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Dated: 23rd January, 2024

**FORM 2**

THE PATENTS ACT, 1970

(39 of 1970)

&

The Patent Rules, 2003

**COMPLETE SPECIFICATION**

(See sections 10 & rule 13)

**1. TITLE OF THE INVENTION**

**COMPOSITION AND METHOD FOR PREPARING AN HERBAL PASTILLE**

**2. APPLICANT (S)**

| NAME | NATIONALITY | ADDRESS |
|---|---|---|
| Sharda University | IN | Plot No. 32-34, Knowledge Park-III, Greater Noida - 201310, Uttar Pradesh, India. |

**3. PREAMBLE TO THE DESCRIPTION**

**COMPLETE SPECIFICATION**

The following specification particularly describes the invention and the manner in which it is to be performed.

## FIELD OF INVENTION

**[0001]** The present disclosure relates generally to a field of pharmaceutical formulation and drug delivery. In particular, the present disclosure pertains to a composition and a method for preparing an herbal Pastille.

## BACKGROUND

**[0002]** Hyperlipidemia, characterized by elevated levels of lipids in the blood, is a significant risk factor for the development of coronary and extra-coronary atherosclerosis, as well as other cardiovascular disorders. Hyperlipidemia is a prevalent condition globally, affecting millions of people. High levels of cholesterol and triglycerides in the blood can lead to the formation of plaque in the arteries, restricting blood flow and increasing the risk of heart attacks and strokes.

**[0003]** The management of hyperlipidemia typically involves lifestyle modifications and pharmacological interventions. Oral medications, such as statins, are commonly prescribed to lower lipid levels and reduce the risk of cardiovascular events. However, adherence to oral medication regimens can be challenging for various patient populations.

**[0004]** One particular challenge is faced by patients with dysphagia, a condition that impairs swallowing. Dysphagia can be caused by various factors, including neurological disorders, structural abnormalities, and age-related changes. Patients with dysphagia often struggle to swallow solid dosage forms, such as tablets or capsules, making it difficult to take their prescribed medications. This can result in poor treatment outcomes and increased healthcare costs.

**[0005]** Another population that faces difficulties with oral medication administration is pediatrics. Children often have difficulty swallowing tablets or capsules due to their size or taste. This can lead to medication non-compliance and inadequate treatment of hyperlipidemia. Similarly, elderly individuals may have difficulty swallowing due to age-related changes in the swallowing mechanism or the presence of other medical conditions. This can pose a significant challenge in managing their hyperlipidemia effectively.

**[0006]** To address these challenges, there is a need for alternative methods of drug delivery that are more accessible, less complicated, and more likely to be taken as prescribed by patients. Developing a formulation that can bypass the inconvenience of administering therapeutic drugs to patients with dysphagia, pediatrics, and geriatrics is crucial. Such a formulation would ensure that these patients receive the necessary medication in a form that is easier to swallow and more readily accepted.

**[0007]** In recent years, there has been growing interest in the use of herbal remedies for various health conditions, including hyperlipidemia. Herbal medicines are perceived as natural and potentially safer alternatives to conventional pharmaceuticals. They often contain bioactive compounds that can help lower lipid levels and improve cardiovascular health. However, the efficacy of herbal remedies can vary, and their formulation and standardization pose unique challenges.

**[0008]** Therefore, there is a need for a composition for an herbal Pastille that is easy to administer, effective, and standardized which not only improve patient compliance but also enhance the therapeutic outcomes for individuals with hyperlipidemia.

## OBJECTS OF THE PRESENT DISCLOSURE

**[0009]** Some of the objects of the present disclosure, which at least one embodiment herein satisfies are as listed herein below.

**[0010]** An object of the present disclosure is to develop an herbal pastille formulation or composition for the treatment of hyperlipidemia that is easy to swallow and suitable for patients with dysphagia, pediatrics, and geriatrics.

**[0011]** An object of the present disclosure is to standardize the composition and ensure consistency in the content and quality of the herbal pastille.

**[0012]** An object of the present disclosure is to evaluate the physicochemical properties of the herbal pastille, including its appearance, texture, and taste.

**[0013]** An object of the present disclosure is to assess the drug release profile of the herbal pastille and optimize its release kinetics for maximum therapeutic efficacy.

**[0014]** An object of the present disclosure is to provide a cost-effective and accessible alternative method of drug delivery for the management of hyperlipidemia, potentially reducing healthcare costs and improving patient outcomes.

## SUMMARY

**[0015]** In accordance with an aspect of the present disclosure, a composition for a herbal Pastille is provided. The composition comprises 0.5 to 1 % of an antioxidant, wherein the antioxidant is Coenzyme $Q_{10}$; and 1 to 3 % of an herbal extract, wherein the herbal extract is an extract of *Curcuma longa*.

**[0016]** In various embodiments, the extract of *Curcuma longa* may utilized in combination of one or more extracts selected from Ginger (*Zingiber officinale*), Boswellia (*Boswellia serrata*), Black Pepper (*Piper nigrum*), Ashwagandha (*Withania somnifera*), Green Tea (*Camellia sinensis*), Holy Basil (*Ocimum sanctum*), Milk Thistle (*Silybum marianum*), Cinnamon (*Cinnamomum verum*), Ginkgo Biloba (*Ginkgo biloba*), and Licorice (*Glycyrrhiza glabra*).

**[0017]** In various embodiments, the composition preferably comprises 0.8% of the antioxidant.

**[0018]** In certain embodiments, the composition preferably comprises 2% of the herbal extract.

**[0019]** In accordance with another aspect of the present disclosure, a method for preparing an herbal Pastille is provided. The method including the step of:

a) heating 50 % of sorbitol at 60°C, wherein the sorbitol acts as a stability imparter;
b) adding 8 % of pectin as a gelling agent to the heated sorbitol followed by stirring at 300 rpm at 60°C using a magnetic stirrer to obtain a first solution;
c) uniformly mixing demineralized water, 0.3% of preservative, 0.5% pH stabilizer, and 0.25% of sweetener into the first solution to obtain a second solution;

d) adding 2% of an herbal extract in a powder form and 0.8% of an antioxidant to the second solution followed by stirring to obtain a uniform mixture; and

e) transferring the uniform mixture into one or more molds followed by cooling for a duration ranging from 24 to 3 hours to obtain the herbal Pastille.

**[0020]** In certain embodiments, the preservative comprises Sodium Benzoate; wherein the pH stabilizer comprises Citric acid; wherein the sweetener comprises Sucralose.

**[0021]** In various embodiments, the herbal extract preferably comprises extract of *Curcuma longa*.

**[0022]** In certain embodiments, the antioxidant is Coenzyme $Q_{10}$.

**[0023]** In various embodiments, the herbal Pastille comprises a thickness of 2±0.05 cm.

**[0024]** In certain embodiments, the herbal Pastille exhibit a maximum drug release of 95.30% in a duration of 30 minutes, resulting in fast *in-vitro* release.

**[0025]** Various objects, features, aspects, and advantages of the inventive subject matter will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures in which like numerals represent like components.

## BRIEF DESCRIPTION OF DRAWINGS

**[0026]** The accompanying drawings are included to provide a further understanding of the present disclosure and are incorporated in and constitute a part of this specification. The drawings illustrate exemplary embodiments of the present disclosure and, together with the description, serve to explain the principles of the present disclosure.

**[0027]** **FIG. 1** illustrates an exemplary method for preparing an herbal Pastille, in accordance with an embodiment of the present disclosure.

**[0028]** **FIG. 2** illustrates a) a uniform mixture of the composition, b) transferring the uniform mixture into one or more molds, c) cooling the uniform

mixture for a duration ranging from 24 to 36 hours, and d) prepared herbal Pastille of *Curcuma longa* and Coenzyme $Q_{10}$, in accordance with an embodiment of the present disclosure.

**[0029]** **FIG. 3** illustrates drug content (%) of different compositions (F1 to F6) studied in the present invention, in accordance with an embodiment of the present disclosure.

**[0030]** **FIG. 4** illustrates release study of the compositions F1 to F6, in accordance with an embodiment of the present disclosure.

**[0031]** **FIG. 5** illustrates Zero order kinetic model of the composition F6, in accordance with an embodiment of the present disclosure.

**[0032]** **FIG. 6** illustrates First order kinetic model of the composition F6, in accordance with an embodiment of the present disclosure.

**[0033]** **FIG. 7** illustrates Higuchi kinetic model of the composition F6, in accordance with an embodiment of the present disclosure.

**[0034]** **FIG. 8** illustrates Korsmeyer peppas kinetic model of the composition F6, in accordance with an embodiment of the present disclosure.

## DETAILED DESCRIPTION

**[0035]** The following is a detailed description of embodiments of the present invention. The embodiments are in such detail as to clearly communicate the invention. However, the amount of detail offered is not intended to limit the anticipated variations of embodiments; on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

**[0036]** Unless the context requires otherwise, throughout the specification which follow, the word “comprise” and variations thereof, such as, “comprises” and “comprising” are to be construed in an open, inclusive sense that is as “including, but not limited to.”

**[0037]** Reference throughout this specification to “one embodiment” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment. Thus,

the appearances of the phrases “in one embodiment” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

**[0038]** As used in the description herein and throughout the claims that follow, the meaning of “a,” “an,” and “the” includes plural reference unless the context clearly dictates otherwise. Also, as used in the description herein, the meaning of “in” includes “in” and “on” unless the context clearly dictates otherwise.

**[0039]** In some embodiments, the numbers expressing quantities of ingredients, properties such as concentration, process conditions, and so forth, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term “about.” Accordingly, in some embodiments, the numerical parameters set forth in the written description are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable.

**[0040]** The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein.

**[0041]** All methods described herein can be performed in suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. “such as”) provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No

language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

**[0042]** The headings and abstract of the invention provided herein are for convenience only and do not interpret the scope or meaning of the embodiments.

**[0043]** Various terms are used herein. To the extent a term used in a claim is not defined below, it should be given the broadest definition persons in the pertinent art have given that term as reflected in printed publications and issued patents at the time of filing.

**[0044]** The present disclosure discloses a composition for an herbal Pastille and method to prepare the herbal Pastille. The herbal Pastille discloses by the present invention is easy to administer, effective, and standardized which not only improve patient compliance but also enhance the therapeutic outcomes for individuals with hyperlipidemia.

**[0045]** Accordingly, in one aspect the present disclosure provides the composition for an herbal Pastille. The composition includes 0.5 to 1 % of an antioxidant, wherein the antioxidant is Coenzyme $Q_{10}$; and 1 to 3 % of an herbal extract, wherein the herbal extract is an extract of *Curcuma longa*.

**[0046]** In an embodiment, the Coenzyme $Q_{10}$ ($CoQ_{10}$) is a naturally occurring antioxidant that plays a crucial role in cellular energy production and acts as a potent free radical scavenger. $CoQ_{10}$ acts as a coenzyme in the electron transport chain, facilitating the production of adenosine triphosphate (ATP) in mitochondria, which is essential for cellular energy metabolism. The objective of incorporating $CoQ_{10}$ in the herbal pastille formulation is to enhance its therapeutic efficacy in reducing lipid levels and improving cardiovascular health. $CoQ_{10}$ has been extensively studied for its potential benefits in managing hyperlipidemia, as it has shown promising results in reducing oxidative stress, inflammation, and lipid peroxidation. By including $CoQ_{10}$ as the antioxidant in the composition, the invention aims to harness its antioxidant properties to protect against lipid peroxidation and oxidative damage caused by elevated lipid levels. Furthermore, $CoQ_{10}$ has been shown to have additional cardiovascular benefits, such as improving endothelial function, reducing blood pressure, and enhancing the bioavailability of nitric oxide, which

helps in maintaining vascular health. The inclusion of $CoQ_{10}$ in the herbal pastille enhances the overall therapeutic potential of the herbal Pastille.

**[0047]** In various embodiments, the herbal extract preferably comprises extract of *Curcuma longa*. *Curcuma longa* is a perennial plant native to South Asia and is well-known for its medicinal properties. The active compound responsible for its therapeutic effects is curcumin, a polyphenol with potent antioxidant and anti-inflammatory properties. By incorporating *Curcuma longa* extract in the herbal pastille, the invention aims to harness the potential health benefits associated with curcumin. Curcumin has been extensively studied for its various pharmacological activities, including its ability to reduce oxidative stress, inflammation, and lipid peroxidation. Curcumin has shown promising results in managing hyperlipidemia by modulating lipid metabolism, reducing cholesterol levels, and improving lipid profile. Curcumin has also been reported to enhance the activity of antioxidant enzymes, thereby counteracting the detrimental effects of free radicals and oxidative damage. In addition to its lipid-lowering effects, curcumin has been associated with numerous other health benefits, such as improving cardiovascular health, boosting immune function, and exhibiting anticancer properties.

**[0048]** In various embodiments, the extract of *Curcuma longa* may utilized in combination of one or more extracts selected from Ginger (*Zingiber officinale*), Boswellia (*Boswellia serrata*), Black Pepper (*Piper nigrum*), Ashwagandha (*Withania somnifera*), Green Tea (*Camellia sinensis*), Holy Basil (*Ocimum sanctum*), Milk Thistle (*Silybum marianum*), Cinnamon (*Cinnamomum verum*), Ginkgo Biloba (*Ginkgo biloba*), and Licorice (*Glycyrrhiza glabra*). *Curcuma longa* (turmeric) is often combined with other herbal extracts to enhance its therapeutic effects. Different herbal combinations are used for various purposes, such as joint health, inflammation reduction, and overall well-being. Ginger (*Zingiber officinale*) is often combined with turmeric for its anti-inflammatory properties. The combination of ginger and turmeric is popular for joint health and may help reduce inflammation. Boswellia (*Boswellia serrata*) also known as Indian frankincense, Boswellia is used alongside turmeric for its anti-inflammatory effects. The combination may be beneficial for conditions involving joint pain and

inflammation. Black Pepper (*Piper nigrum*) while not an herbal extract, black pepper is often added to formulations containing turmeric. Piperine, the active compound in black pepper, enhances the bioavailability of curcumin, the active compound in turmeric. Ashwagandha (*Withania somnifera*) is an adaptogenic herb that is sometimes combined with turmeric for its potential stress-reducing and immune-modulating properties. Green Tea (*Camellia sinensis*) extract is rich in antioxidants, and when combined with turmeric, it may contribute to overall antioxidant support and well-being. Holy Basil (*Ocimum sanctum*) also known as Tulsi, is revered in Ayurvedic medicine. Combining it with turmeric may enhance the adaptogenic and anti-inflammatory effects. Milk Thistle (*Silybum marianum*) is often used for liver support, and when combined with turmeric, it may provide comprehensive antioxidant and anti-inflammatory benefits. Cinnamon (*Cinnamomum verum*) is sometimes included in formulations with turmeric for its potential anti-inflammatory and antioxidant effects. Ginkgo Biloba (*Ginkgo biloba*) extract is known for its cognitive benefits. Combining it with turmeric may offer synergistic effects for brain health. Licorice (*Glycyrrhiza glabra*) is occasionally used in combination with turmeric for its anti-inflammatory properties, and it may contribute to gastrointestinal health.

**[0049]** In certain embodiments, the composition preferably comprises 0.8% of the antioxidant.

**[0050]** In various embodiments, the composition preferably comprises 2% of the herbal extract.

**[0051]** In another aspect, the invention provides a method for preparing the herbal Pastille using the composition.

**[0052]** **FIG. 1** illustrates a schematic flow diagram for the method for preparing the herbal Pastille, including the steps of:

a) heating 50 % of sorbitol at 60°C, wherein the sorbitol acts as a stability imparter;

b) adding 8 % of pectin as a gelling agent to the heated sorbitol followed by stirring at 300 rpm at 60°C using a magnetic stirrer to obtain a first solution;

c) uniformly mixing demineralized water, 0.3% of preservative, 0.5% pH stabilizer, and 0.25% of sweetener into the first solution to obtain a second solution;

d) adding 2% of an herbal extract in a powder form and 0.8% of an antioxidant to the second solution followed by stirring to obtain a uniform mixture; and

e) transferring the uniform mixture into one or more molds followed by cooling for a duration ranging from 24 to 36 hours to obtain the herbal Pastille.

**[0053]** In various embodiments, the preservative comprises Sodium Benzoate; wherein the pH stabilizer comprises Citric acid; wherein the sweetener comprises Sucralose.

**[0054]** In certain embodiments, the herbal extract preferably comprises extract of *Curcuma longa*.

**[0055]** In various embodiments, the antioxidant is Coenzyme $Q_{10}$.

**[0056]** In certain embodiments, the herbal Pastille comprises a thickness of 2±0.05 cm.

**[0057]** In certain embodiments, the herbal Pastille exhibit a maximum drug release of 95.30% in a duration of 30 minutes, resulting in fast *in-vitro* release.

**[0058]** While the foregoing description discloses various embodiments of the invention, other and further embodiments of the invention may be devised without departing from the basic scope of the disclosure. The invention is not limited to the described embodiments, versions or examples, which are included to enable a person having ordinary skill in the art to make and use the invention when combined with information and knowledge available to the person having ordinary skill in the art.

**EXAMPLES**

**[0059]** The present invention is further explained in the form of following examples. However, it is to be understood that the foregoing examples are merely illustrative and are not to be taken as limitations upon the scope of the invention. Various changes and modifications to the disclosed embodiments will be apparent

to those skilled in the art. Such changes and modifications may be made without departing from the scope of the invention.

**Example 1**

**Method for formulation of Curcuma longa and Coenzyme-Q10 herbal pastille:**

**[0060]** A freshly weighed amount of sorbitol was taken in a beaker, and then placed on magnetic stirrer at 60°C. Upon heating of sorbitol, add pectin and start stirring at 300rpm at 60°C until it is fully solubilized. After complete dissolution of pectin, add demineralized water (DM Water), preservative, pH stabilizer and sweetener and mix thoroughly and uniformly. Now, curcuma longa powdered extract and co-enzyme Q10 were added to the solution and kept for stirring until uniform texture (FIG. 2a). After complete mixing, the solution was transferred into molds of and allowed to cool for up to 24 hours to 36 hours and let it settle undisturbed by properly covering the molds to avoid exposure to the outer environment (FIGs. 2b and 2c). Kept formulated Pastilles in a closed container to protect from environmental effects (FIG. 2d). The method includes Pectin as a gelling agent and thickening agent, Sorbitol as stability imparter, Sodium Benzoate as preservative, Citric acid as pH stabilizer, Curcuma longa extract and Co-enzyme Q10 as API's and Sucralose as a sweetener used in the formulation.

**Example 1**

**Development of different batches of herbal pastille**

**[0061]** The herbal pastille was prepared into multiple batches (F1 to F6) which were then taken for further development and the herbal pastille with desired properties was selected. The compositions of all batches are given in table 1. In the table 1, the formula is given for 100gms of composition in total, where after pouring into the mold it divides into 4 parts consisting pastille of 25gm each.

**Table 1: Different batches of herbal pastille**

| **Materials** | **Formulation (quantity in gm)** | | | | | |
|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** |
| **Pectin** | 5.5 | 6 | 6.5 | 7 | 7.5 | 8 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Citric acid** | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| **Sorbitol** | 75 | 70 | 65 | 60 | 55 | 50 |
| **Sodium Benzoate** | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| **Sucralose** | 0.1 | 0.2 | 0.25 | 0.2 | 0.2 | 0.25 |
| ***Curcuma longa* extract** | 2 | 2 | 2 | 2 | 2 | 2 |
| **Coenzyme Q10** | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 |
| **D. M. water** | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. |

**Example 2**

**Evaluation of herbal pastille composition**

**[0062]** The mentioned evaluation parameters were performed on the herbal pastille and selected the best one on the basis of desired properties as mentioned in table 2.

**Table 2: Evaluation parameters**

| **Physical Appearance** | **Formulation** | | | | | |
|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** |
| **Transparent** | + | - | - | + | - | + |
| **Smooth texture** | + | - | + | - | - | + |
| **Stickiness** | + | + | - | - | + | - |
| **Grittiness** | - | - | + | + | - | + |
| **Syneresis** | + | + | - | - | + | - |

**[0063]** As it is shown in Table 2, F6 showed the most desired physical attributes required for the herbal pastille such as F6 was found to be transparent. F6 had the

smooth texture. F6 was non sticky and showed no sign of water loss for a given period. Thus, F6 was selected as best formulation and implied for further evaluation:

- **Weight variation-** the weight was found to be 25.0±0.05 (gm).
- **Thickness-** the thickness was found to be 2±0.05 (cm)
- **pH-** A pH of 7.12 was reported in a 1mg/ml concentration of herbal Pastille with a 7.4 pH phosphate buffer.

**[0064]** As mentioned in table 3 and FIG. 3, the formulation F6 was found to have greatest drug content(%) of 95.52±0.27 among all the compositions.

**Table 3: Drug Content of formulations**

| S. no. | Formulation | Drug content (%) |
|---|---|---|
| 1 | F1 | 89.72±0.62 |
| 2 | F2 | 92.23±0.61 |
| 3 | F3 | 94.48±0.75 |
| 4 | F4 | 93.39±0.88 |
| 5 | F5 | 91.77±0.20 |
| 6 | F6 | 95.52±0.27 |

**Example 3**

**In-Vitro Release Study**

**[0065]** As given in table 4, the dissolving experiment lasted 30 minutes at pH 6.8. All formulations were compared to pure herbal extract in *in-vitro* dissolving experiments. Table 5 shows the findings of *in-vitro* drug release tests from the herbal Pastilles. When compared to the pure herbal extract, the *in-vitro* release profile of all formulations is substantially higher (FIG. 4).

**Table 4: Description of dissolution apparatus**

| | |
|---|---|
| **Temperature** | 37 ± 0.5˚ C |
| **Volume of Dissolution fluid** | 900 ml |
| **Dissolution Medium** | Phosphate buffer (pH 6.8) |
| **Sample withdrawal at time interval** | 10 ml |
| **Speed** | 60 Rotation per min |

**Table 5: In-vitro release profile of Herbal Pastilles [F1-F6]**

| **Formulation** | **Herbal extract release (%)** | | | | | |
|---|---|---|---|---|---|---|
| | **5 min** | **10 min** | **15 min** | **20 min** | **25 min** | **30 min** |
| F1 | 13.66 | 20.42 | 35.55 | 39.26 | 47.83 | 54.97 |
| F2 | 15.04 | 26.67 | 33.96 | 50.13 | 79.40 | 87.39 |
| F3 | 17.08 | 26.03 | 40.66 | 49.51 | 68.37 | 75.01 |
| F4 | 13.39 | 18.74 | 22.05 | 45.51 | 67.51 | 75.59 |
| F5 | 10.96 | 13.49 | 20.59 | 28.19 | 37.24 | 45.03 |
| F6 | 14.44 | 31.37 | 50.11 | 68.55 | 84.87 | 95.30 |

**Example 4**

**Release Kinetic Model of best composition**

**[0066]** As per the results of evaluation parameters, Formulation F6 was the best among all formulations. F6 shows good texture with no stickiness. F6 also passes the weight variation test with 25.0±0.05 (gm) of formulation. Its pH was 7.4 and Syneresis test shows no separation of water from the formulation. Drug Release profile of the F6 was found to be 95.30% under 30 minutes resulting in fast release of the herbal content present in the formulation (table 6).

**Table 6: Drug release profile of F6 composition**

| Drug Release Profile | | | | | | |
|---|---|---|---|---|---|---|
| **Time (min)** | **Absorbance ($cm^{-1}$)** | **Conc. in DF(mg)** | **% Drug Release** | **Log % Drug Release** | **Sq. rt. of time** | **Log Time** |
| 5 | 0 | -4.564 | -4.855 | -4.987 | 1.000 | 0.000 |
| 10 | 0.358 | 11.709 | 12.456 | 1.095 | 1.414 | 0.301 |
| 15 | 0.721 | 28.209 | 30.010 | 1.477 | 1.732 | 0.477 |
| 20 | 1.087 | 44.845 | 47.708 | 1.679 | 2.000 | 0.602 |
| 25 | 1.446 | 61.164 | 65.068 | 1.813 | 2.236 | 0.699 |
| 30 | 2.148 | 93.073 | 95.30 | 1.996 | 2.646 | 0.845 |

**[0067]** For kinetic study of formulated pastilles, the plots were made for Zero order kinetic model (% drug release vs time) (FIG. 5), First order kinetic model (log of % drug release vs time) (FIG. 6), Higuchi model (% drug release vs square root of time) (FIG. 7) and Korsmeyer Peppas model (log % drug release vs log time) (FIG. 8). Plots of above mentioned models are shown in FIGs. (5-8) and results are summarized in Table 7. In the table 7, $R^2$ is correlation value, k is rate constant and n is release exponent.

**Table 7: Interpretation of $R^2$ values of release kinetics of pastilles**

| **Kinetic Model** | **Correlation value ($R^{2)}$** |
|---|---|
| Zero order model | 0.9951 |
| First order model | 0.7498 |
| Higuchi model | 0.931 |
| Korsmeyer – Peppas model | 0.986 |

**[0068]** Based on the above values of ($R^2$), the best fit kinetic model with the highest correlation value is the Zero-order model. It is concluded that the optimized formulated herbal pastille follow Zero-order model kinetics.

**[0069]** In the Korsmeyer-Peppas model, the release exponent value "n" is 1.3399. The magnitude is more than the range ($0.45 < n < 0.89$) indicates the release mechanism is super case II transport meaning the release of drug is happening at higher rate.

**Example 5**

**Stability studies**

**[0070]** The formulated herbal pastille F6 was evaluated for the accelerated stability studies in order to assess the formulation stability studies it is done according to the International Conference on Harmonization (ICH) guidelines. As per ICH guidelines the herbal pastille was packed in clean closed container and different replicates were held in humidity chamber at 25± 2℃ and 60±5% RH.

**[0071]** The evaluation was carried out in between 0-6 months for the stability analysis in order to check change in the pH, drug content and % release hence from the overall analysis the good stability is seen in every terms (table 8).

**Table 8: Stability study**

| **Parameters** | **Months** | | | | |
|---|---|---|---|---|---|
| | **0** | **1** | **2** | **3** | **6** |
| Drug content (gm) | 89.63 | 89.61 | 89.59 | 89.55 | 89.51 |
| pH | 7.12 | 7.11 | 7.09 | 7.08 | 7.08 |
| (%) Drug release | 95.30 | 95.26 | 95.19 | 95.15 | 95.11 |
| Physical appearance | Brown colour | Brown colour | Brown colour | Brown colour | Brown colour |

**[0072]** Therefore, among various batches *in-vitro* release profile of the developed herbal pastille (F6) showed the greatest drug release (%) of 95.30% in 30 minutes resulting in fast release. Among the drug release kinetic models, the

formulation followed the Zero order kinetic model with correlation value ($R^2$) of 0.9951. In Korsemeyer peppas model the value of release exponent (n) was 1.339, indicating the release mechanism is super case II transport. In addition to that, accelerated stability investigations were carried out over the course of a period of six months.

**[0073]** In the present invention, it is investigated that the combination of Coenzyme $Q_{10}$ ($CoQ_{10}$) and *Curcuma longa* extract is believed to exhibit a synergistic effect, offering potential health benefits greater than what each component may provide individually. The composition exhibit:

1. Enhanced Antioxidant Activity: both $CoQ_{10}$ and curcumin are known for their antioxidant properties. Together, they neutralize free radicals, reducing oxidative stress and supporting cellular health.
2. Neuroprotective Effects: the composition have potential neuroprotective effects, guarding against oxidative stress and inflammation in the brain. This could be relevant for cognitive health and may contribute to the prevention of neurodegenerative diseases.
3. Potential Anti-Aging Effects: as antioxidants, $CoQ_{10}$ and curcumin may collectively contribute to reducing the effects of aging by protecting cells from damage caused by free radicals.
4. Optimized Bioavailability: Curcumin, on its own, has poor bioavailability, meaning it is not easily absorbed by the body. Some formulations include black pepper extract (piperine) or other enhancers to improve curcumin absorption, potentially maximizing its effectiveness when combined with $CoQ_{10}$.

**ADVANTAGES OF THE INVENTION:**

**[0074]** The herbal Pastille ensures fast release of the active ingredients, allowing for quicker absorption and potential therapeutic effects.

**[0075]** The herbal Pastille is specifically formulated to have antihyperlipidemic effects, helping to reduce high lipid levels and promote cardiovascular health.

**[0076]** The herbal Pastille may also have antidiabetic properties, potentially aiding in the management of diabetes.

**[0077]** The inclusion of antioxidant ($CoQ_{10}$) ingredients in the formulation may contribute to anti-aging effects, protecting against oxidative stress and promoting overall well-being.

**[0078]** The herbal Pastille contains antioxidants that help neutralize harmful free radicals in the body, contributing to overall health and well-being.

**[0079]** The herbal Pastille may possess anti-cancer properties, potentially providing additional health benefits.

**[0080]** The herbal Pastille offers an economical option for managing hyperlipidemia, potentially reducing healthcare costs for patients.

**[0081]** By providing an alternative method of drug delivery, the herbal Pastille may help reduce the overall cost of treatment for hyperlipidemia.

**[0082]** The herbal Pastille form allows for easy administration, especially for individuals who may have difficulty swallowing conventional tablets or capsules.

**[0083]** The herbal Pastille may contribute to weight loss, as the *Curcuma longa* have been associated with metabolic benefits and appetite regulation.

**[0084]** The herbal Pastille can potentially benefit a wider population, including individuals with dysphagia, pediatrics, and geriatric patients who may have difficulty swallowing traditional medications.

**We Claim:**

1. A composition for an herbal Pastille, comprising:
   0.5 to 1 % of an antioxidant, wherein the antioxidant is Coenzyme $Q_{10}$; and
   1 to 3 % of an herbal extract, wherein the herbal extract is an extract of *Curcuma longa*.
2. The composition as claimed in claim 1, wherein the extract of *Curcuma longa* may utilized in combination of one or more extracts selected from Ginger (*Zingiber officinale*), Boswellia (*Boswellia serrata*), Black Pepper (*Piper nigrum*), Ashwagandha (*Withania somnifera*), Green Tea (*Camellia sinensis*), Holy Basil (*Ocimum sanctum*), Milk Thistle (*Silybum marianum*), Cinnamon (*Cinnamomum verum*), Ginkgo Biloba (*Ginkgo biloba*), and Licorice (*Glycyrrhiza glabra*).
3. The composition as claimed in claim 1, wherein the composition preferably comprises 0.8% of the antioxidant.
4. The composition as claimed in claim 1, wherein the composition preferably comprises 2% of the herbal extract.
5. A method for preparing an herbal Pastille using the composition of claim 1, comprising:
   f) heating 50 % of sorbitol at 60°C, wherein the sorbitol acts as a stability imparter;
   g) adding 8 % of pectin as a gelling agent to the heated sorbitol followed by stirring at 300 rpm at 60°C using a magnetic stirrer to obtain a first solution;
   h) uniformly mixing demineralized water, 0.3% of preservative, 0.5% pH stabilizer, and 0.25% of sweetener into the first solution to obtain a second solution;
   i) adding 2% of an herbal extract in a powder form and 0.8% of an antioxidant to the second solution followed by stirring to obtain a uniform mixture; and

j) transferring the uniform mixture into one or more molds followed by cooling for a duration ranging from 24 to 36 hours to obtain the herbal Pastille.

6. The method as claimed in claim 5, wherein the preservative comprises Sodium Benzoate; wherein the pH stabilizer comprises Citric acid; wherein the sweetener comprises Sucralose.

7. The method as claimed in claim 5, wherein the herbal extract preferably comprises an extract of *Curcuma longa*.

8. The method as claimed in claim 5, wherein the antioxidant is Coenzyme $Q_{10}$.

9. The method as claimed in claim 5, wherein the herbal Pastille comprises a thickness of 2±0.05 cm.

10. The method as claimed in claim 5, wherein the herbal Pastille exhibit a maximum drug release of 95.30% in a duration of 30 minutes, resulting in fast *in-vitro* release.

**For Sharda University**



**Tarun Khurana**
**Regd. Patent Agent [INPA-1325]**
**Dated: 23rd January, 2024**

## ABSTRACT

**COMPOSITION AND METHOD FOR PREPARING AN HERBAL PASTILLE**

A composition and method for preparing an herbal pastille is provided. The composition involves an antioxidant Coenzyme $Q_{10}$ and an herbal extract having extract of *Curcuma longa*. The herbal Pastille exhibit a maximum drug release of 95.30% in a duration of 30 minutes, resulting in fast *in-vitro* release. The herbal Pastille is specifically formulated to have antihyperlipidemic effects, helping to reduce high lipid levels and promote cardiovascular health. The herbal Pastille may also have antidiabetic properties and anti-cancer properties, potentially providing additional health benefits. The herbal Pastille offers an economical option for managing hyperlipidemia, potentially reducing healthcare costs for patients. The herbal Pastille can potentially benefit a wider population, including individuals with dysphagia, pediatrics, and geriatric patients who may have difficulty swallowing traditional medications.

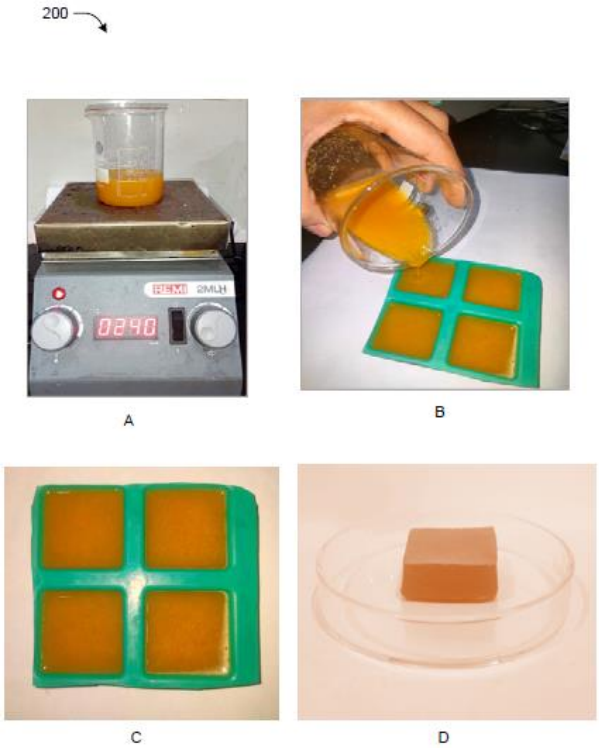




**FIG. 2**