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The Patent Act 1970
(39 of 1970)

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The Patents Rules, 2003

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Complete Specification

Title: A medicated nano sponge based finger sling device and a method of preparation thereof

Name of the Applicant:

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

Technical field

The present disclosure relates to a device for maintaining oral hygiene. More particularly, the present disclosure provides a medicated nanosponge based finger sling device for cleaning oral cavity of a subject in need thereof and a method of preparation/ fabrication thereof.

Background

Generally speaking, oral hygiene is nothing but a practice of keeping one's mouth, teeth, gums and tongue clean, healthy and free of diseases. Improper and poor maintenance of oral hygiene is the root cause of various diseases. Simply put, oral health is nothing but a gateway to an individual's overall health. Traditionally, oral cavity is kept clean by brushing the teeth and tongue twice a day for two minutes each using a tooth paste. While this appears to be an easy to follow standard, but the same is very tedious to perform in critically ill patients or in population with special needs. For instance, poor oral hygiene in critically ill and immune compromised patients would lead to various conditions and/or diseases including but not limited to Ventilator-Associated Pneumonia (VAP) / nosocomial pneumonia / total deterioration of respiratory function leading to intubation - intubated patients suffering with xerostomia (dry mouth) and patients with overcrowded intubation (endotracheal tube, gastric tube, probe for measuring temperature, and oral airway) in the oral cavity. Since critically ill patients are unable to perform this essential oral care for themselves, they rely heavily on nursing staff for the same. Most importantly, providing oral hygiene for critically ill patients or patients with confined space in oral cavity (due to multiple intubations) is a challenging task for even an experienced nursing staff. Similarly, maintaining oral hygiene in long-distance travellers, globetrotters, on duty army personnel and astronauts is pretty challenging. Besides this, area's with poor supply or lack of clean water further worsens the task of having a good oral hygiene.

At present, oral care in critically ill patients is offered using traditional tooth brush (soft-bristled child brush) with tooth paste (non-foaming type), mouth rinse, sponge toothettes, foam sticks, cotton and foam swabs, suction catheters (flexible

type) are employed. Nonetheless, these methods suffer with various limitations such as poor drug release from the device/ formulation leading to lack of therapeutic activity, expensive, tedious and time consuming. Moreover, these existing methods are not user friendly and pose lot of difficulties to the nursing staff, patients and also to the families of the patient. Accordingly, there exists a strong need for a simple and easy to use device that is inexpensive with good drug release to provide oral hygiene to population with special needs in general and for critically ill patients in particular. Additionally, the information disclosed in this background section is only for enhancement of understanding of the general backdrop of the disclosure and should not be taken as an acknowledgement or any form of suggestion that this information forms the prior art already known to a person skilled in the art.

Objectives

First and foremost objective of the present disclosure is to provide a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device for maintaining oral hygiene in subjects who are in need thereof.

Second objective of the present disclosure is to provide a process for preparing the nanosponge based medicated finger sling device for maintaining oral hygiene in subjects who are in need thereof.

Summary

In one non-limiting embodiment of the present disclosure, it provides a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device for maintaining oral hygiene of a subject in need thereof. In addition, the device comprises of a first hollow member that is sealed at one end with a proviso for inserting index finger. Also, the external surface of the first hollow member is configured with medicated bristles for brushing teeth and for cleaning any predetermined area in oral cavity of a subject. Further, a second hollow member is sealed at one end with a proviso for inserting thumb and external surface of the second hollow member is optionally configured with medicated bristles to get under the gum line or in the crevices of palatal surface or the lingual surfaces of the teeth. Furthermore, the medicated bristles of the first and second

hollow members are loaded with a sustained release and medicated synergistic nanosponge composition comprising, by total weight of the composition, chlorhexidine at a concentration of 0.5 % to 8 %; clove oil at a concentration of 0.08 % to 2.5 %, and cinnamon oil at a concentration of 3.5 % to 30 %. Lastly, a support member of the finger sling device offers grip for wearing and using the same by a health care professional. Also, the finger sling device is provided/ configured optionally with a Velcro strap or button and press to form a tight grip.

In another non-limiting embodiment of the present disclosure, it provides an external surface of the finger sling that is impregnated with medicated nanosponges to deliver various active ingredients to the subjects who are in need thereof.

Brief description of the accompanying drawings

Figure 1: Finger sling device **(A)** shows front view of the device *per se* and a subject's left hand wearing the device **(B)** shows back view of the device showing medicated bristles on both index finger and thumb *per se* and a subject's left hand wearing the device, also shown are layers of the device thereof **(C)** shows back view of the device *per se* without medicated bristles on thumb and a subject's left hand wearing the device.

Figure 2: shows process flow chart for preparation of the product of the present disclosure

Figure 3: shows FT-IR spectra **(A):** A - clove oil, B - β-cyclodextrin (β-CD), and C - physical mixture; **(B):** A - cinnamon oil, B - β-CD, and C - physical mixture; **(C):** A - chlorhexidine, B - β-CD, and C - physical mixture.

Figure 4: shows DSC thermograms **(A):** A - clove oil, B - β-CD, and C - physical mixture; **(B):** A - cinnamon oil, B - β-CD, and C - physical mixture; **(C):** A - chlorhexidine, B - β-CD, and C - physical mixture.

Figure 5: shows graph of particle size distribution of nanosponges.

Figure 6: shows SEM images of **(A)** β-cyclodextrin-nanosponges (β-CD-NS), and **(B)** magnified surface of β-CD NS

Figure 7: shows *in vitro* drug release profiles of clove oil, cinnamon oil, and chlorhexidine loaded β-CD-NS.

Detailed description

Before explaining any one embodiment of the present disclosure by way of drawings, experimentation, results, and pertinent procedures, it is to be understood that the disclosure is not limited in its application to the details as explained in below embodiments set forth in the following description or illustrated in the drawings, experimentation and/or results. The disclosure is further capable of other embodiments which can be practiced or carried out in various ways. As such, the language used herein is intended to be given the broadest possible scope and meaning; and the embodiments are meant to be exemplary and not exhaustive. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Definitions:

The terminology used in the description of the invention herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention.

'Device'- shall mean the nano sponge based medicated finger sling device of the present disclosure for cleaning oral cavity of subjects in need thereof. The device is a finger sling to wear on two fingers namely: index finger and thumb – as detailed/ explained under examples section of the detailed description.

'Active agents'- shall mean Active Pharmaceutical Ingredients (APIs) or herbal ingredients with therapeutic activity. In the present disclosure, chlorhexidine, clove oil and cinnamon oil are employed as active agents. It is pertinent to state that clove oil is obtained from flower buds of *Syzygium aromaticum* and cinnamon oil is obtained from bark of the threes *Cinnamomum zeylanicum,* from regions in and around Mysuru, Karnataka, India.

'Portable' – shall mean the finger sling device of the present disclosure can be carried and used with ease by the subjects who are in need thereof to any location.

'Breathable' or *Breathable barrier'*– shall mean materials that are pervious to liquids and gases. Generally speaking, plant-based fabrics, like cotton, linen, and bamboo, are the most breathable fabrics – can be employed as materials either

alone or in combination to fabricate the finger sling device. Similarly, animal-based fabrics like silk and wool are also breathable, and all of the above allow for easy air circulation, and wick away perspiration. Biodegradable synthetic polymers also can be employed such as poly β-hydroxybutyrate–co-β-hydroxy valerate (PHBV). It is pertinent to state here that any similar type of materials can be employed by a person having skilled in the art in arriving at the product of the present invention.

'Disposable' – shall mean a product/ the finger sling device of the present disclosure that is intended to be thrown away after single usage.

'Biodegradable' – shall mean the ability of things to get disintegrated (decomposed) by the action of micro-organisms such as bacteria or fungi biological (with or without oxygen) while getting assimilated into the natural environment.

'Sustained release' or 'Prolonged release' or 'Extended release' – shall mean that the active agents after administration have a long-lasting effect as the active agents are released slowly from the nanosponge formulation loaded onto the finger sling device.

'Oral cavity'- shall mean and includes teeth, gums, tongue, mucous, membranes and lips.

'Oral cleansing' or 'cleaning' – shall mean to effectively clean the oral cavity with mechanically disrupting the plaque biofilm.

The present disclosure is in relation to a medicated nano sponge based finger sling device for cleaning a body cavity of a subject in need thereof. Most importantly, the present disclosure provides a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device for maintaining oral hygiene of a subject in need thereof. In addition, the device comprises of a first hollow member that is sealed at one end with a proviso for inserting index finger. Also, the external surface of the first hollow member is configured with medicated bristles for brushing teeth and for cleaning any predetermined area in oral cavity of a subject. Further, a second hollow member is sealed at one end with a proviso for inserting thumb and external surface of the second hollow member is

optionally configured with medicated bristles to get under the gum line or in the crevices of palatal surface or the lingual surfaces of the teeth. Furthermore, the medicated bristles of the first and second hollow members are loaded with a sustained release and medicated synergistic nanosponge composition comprising, by total weight of the composition, chlorhexidine at a concentration of 0.5 % to 8 %; clove oil at a concentration of 0.08 % to 2.5 %, and cinnamon oil at a concentration of 3.5 % to 30 %. Lastly, a support member of the finger sling device offers grip for wearing and using the same by a health care professional. Also, the finger sling device is optionally provided with a Velcro strap or button and press to form a tight grip.

In another embodiment of the present disclosure, it provides a first hollow member and the second hollow member comprise a hollow portion, hydrophilic layer, hydrophobic layer and zig-zag bristles layer loaded with nanosponges.

In another embodiment of the present disclosure, it provides the layers that are fabricated using breathable and biodegradable materials selected from a group comprising of plant-based fabrics like cotton, linen, and bamboo alone or in combination with animal-based fabrics like silk, wool and polymers such as poly β-hydroxybutyrate–co-β-hydroxy valerate.

In another embodiment of the present disclosure, it provides a process for preparing the finger sling device, as explained in the above embodiment, loaded with medicated nanosponge composition. The process comprising first and foremost step of reacting predetermined amount of anhydrous β-cyclodextrin with dimethyl carbonate at a temperature of 100°C for a time period ranging from 7 to 8 hrs followed by cooling, filtering and extracting (Soxhlet extraction) it with methanol to obtain a solid mass of β-cyclodextrin based nanosponges. In addition, the solid mass of β-cyclodextrin based nano sponges was purified and stored at a temperature of 25°C until further use. Second, dispersing predetermined concentrations of active agents – chlorhexidine at a concentration of 0.5 % to 8 %, clove at a concentration of 0.08 % to 2.5 % and cinnamon oil at a concentration of 3.5 % to 30 % in aqueous nanosponge suspension under continuous stirring for a time period of 24 to 28 hours to obtain a mixture. Third, centrifuging the mixture

obtained under second step at 2000 rpm for a time period of 15 to 20 minutes to obtain a supernatant. Fourth, collecting, filtering and freeze drying the supernatant obtained under third step to obtain a freeze-dried and medicated nanosponge. Fifth, storing the medicated nanosponges obtained under fourth step in a sealed vacuum desiccator at room temperature. Sixth, dissolving 2% of chitosan in 1% lactic acid solution to obtain followed by combining with medicated nanosponges obtained under step five under continuous stirring to obtain chitosan gel. Additionally, the chitosan gel is sonicated for a time period of 5 min to 10 min followed by cooling and preserving the cooled chitosan gel using methyl paraben as a preservative. Seventh, dipping and lifting the finger sling device into the chitosan gel obtained under previous step at a speed of 0.01 to 20 mm per second and is repeated multiple times for even coating of the gel onto the finger sling device; and evaporating solvent, if any, from the coated finger sling device and is suitably packed until further use.

The present disclosure is in relation to a medicated kit comprising the finger sling device as explained in the aforementioned embodiments. The kit comprising of a first hollow member, a second hollow member, and a support member; wherein the first hollow member is sealed at one end with a proviso for inserting index finger and external surface of the first hollow member is configured with medicated bristles; wherein the second hollow member is sealed at one end with a proviso for inserting thumb and external surface of the second hollow member is optionally configured with medicated bristles; wherein the medicated bristles and of first hollow member and second hollow member are loaded with a sustained release synergistic nano sponge composition; a support member, wherein the support member offers grip for wearing and using the device by a health care professional; and the device is optionally provided with a Velcro strap or button and press to form a tight grip; and an instruction manual having instructions to use the kit.

In yet another embodiment of the present disclosure, the finger sling device is fabricated using breathable and biodegradable materials.

Example 1: Finger sling device fabrication and loading of medicated nanosponges to the device

Example 1a: Synthesis of nanosponges – β-CD-NS were synthesized via a hot melt method using β-CD polymer and the crosslinker dimethyl carbonate (DMC). This approach involved varying molar ratios of polymer to crosslinker for NS preparation. In a nutshell, anhydrous β-CD was introduced into DMC at approximately 100°C, and the mixture was allowed to react for several hours, 7 hours to 8 hours. Afterwards, the resulting product was left to cool, and the solid material obtained was collected through filtration. Subsequently, the solid mass was finely ground, and any remaining unreacted crosslinker or impurities were eliminated via ethanol extraction using a Soxhlet apparatus. An excess cross-linker was employed in the reaction, and the resulting nanosponges were purified and stored at 25°C for future use. In the above process, β-CD polymers that have cup-like shape and hold hydrophilic molecules at exterior and hydrophobic molecules in interior cavity (see **Figure 2**). The cyclodextrin polymers are as such soluble in water but post cross-linking with the cross linkers they become insoluble in water. The sustained release from nanosponges can be corroborated to the degree of cross-linking in nanosponges. The mechanism of drug release from nanosponges is polymer erosion or degradation over an extended period of time, hence, extended release is experienced.

Example 1b: Drug loading - Precisely measured amounts of the medicaments - clove oil, cinnamon, and chlorhexidine—were individually dispersed in aqueous nanosponge suspensions, and the mixture was magnetically stirred for 24 hours. Following this, the unbound drug was separated from the suspensions by centrifugation at 2000 rpm for 15 minutes to isolate it from the colloidal supernatant. The drug-loaded nanosponges were obtained by subjecting the filtered supernatant to freeze-drying. Subsequently, the freeze-dried nanosponges were preserved for further investigation in a sealed vacuum desiccator at room temperature. Overall, the prepared nanosponges will have encapsulation efficiency in the range 82.54 % to 86.32%. Based on which the required quantity of drug loaded nanosponges will be coated onto the finger sling device of the

present disclosure for antibacterial/bactericidal action (which must be above the MIC i.e. minimum inhibitory concentration and MBC i.e. minimum bactericidal concentration). Accordingly, based on the MIC and MBC values for chlorhexidine, clove oil and cinnamon oil the concentrations employed as - Chlorhexidine 0.5 to 8 µg/ml, Clove oil 0.08 to 2.5 mg/ml, Cinnamon oil 3.5 to 30 mg/ml – at these concentrations the composition was showing synergistic inhibitory activity that what is shown by the components individually. Accordingly, the above concentration based compositions were developed for loading onto the finger sling device of the present disclosure.

Example 1c: Formulation of NS-based gel - A chitosan gel was created using a 2% high molecular weight chitosan dissolved in a lactic acid solution (1% v/v). CD-NS formulations were incorporated into these chitosan-based gels. Additionally, methylparaben was introduced as a preservative. The ingredients were thoroughly mixed, and the resulting gel solutions underwent sonication to eliminate any trapped air bubbles.

Example 1d: Design and development of finger sling device – First and foremost, the finger sling device/ glove of the present disclosure is an outcome of extensive clinical investigations performed by the Applicant of the present invention. More particularly, the finger sling device was uniquely designed to create a proviso to wear on two fingers namely: index finger and thumb finger. The rationale behind the design of the device is to ensure that the two fingers move in conjunction with each other in order to center the object grasped in the middle of the gripper or support member. The proposed design of the flinger sling device is effective to get under the gum line or in the crevices, palatal surfaces or the lingual surfaces of the teeth. Therefore, having slings on both the index finger and the thumb allows the appropriate amount of pressure to be delivered on to the tooth surfaces. Additionally, the two finger design helps in cleaning the tongue surface and the buccal mucosa effectively. Since the present innovation is intended to be used by care giver, guardian or mother to the subject it aids in the sequential cleaning without letting any surface untouched during the oral hygiene maintenance process. Incorporation of the medicament can be distributed between

the two fingers just sufficient to clean all the surfaces. Therefore, these requisites are fulfilled with two finger uniquely designed finger sling device of the present disclosure. Breathable and biodegradable materials (see definitions section of the specification for details or examples of materials employed to fabricate) were employed to fabricate the finger sling device of the present disclosure.

Example 1e: Coating of gel onto the finger sling device – Dip coating is a technique involving the immersion of a substrate into a carefully prepared precursor solution. In this process, the sling is delicately dipped into a precisely formulated gel solution, and then slowly lifted vertically from the solution at a controlled rate within the range of 0.01 to 20 millimetres per second, with specific time intervals. This sequence is carried out multiple times to ensure a thorough and even coating of the sling. Once the gel has been successfully deposited, a subsequent step involves the evaporation of the solvent, meticulously executed to achieve a consistent and uniform layer thickness.

Example 2: Characterization studies

Example 2a: Fourier transform-infrared spectroscopy (FT-IR) – The FT-IR spectra of clove oil, cinnamon oil, and chlorhexidine were acquired using an FTIR spectrophotometer through the KBr pellet method. The pure drug was blended with KBr in a ratio of 1:100 and compressed using a high-pressure press to create a small pellet. Spectra for each drug were captured over the range of 4000 to 400 cm^{-1}. Data analysis was performed using IR Solutions software. The comparison of FT-IR spectra of pure clove oil, β-CD, and physical mixture is depicted in **Figure 3**. The spectrum of clove oil (**Figure 3A**) showed all the characteristic absorption peaks, as at 3427 cm^{-1} (OH group), 2932 cm^{-1}(alkyl CH stretch), 1723 cm^{-1} (ester group), 1617 cm^{-1}(aliphatic alkenes), 1512 cm^{-1} (aromatic group), 145 cm^{-1} (methylene group), 1358 $cm^{-1}$and 1205 cm^{-1} (methyl group), 1043 cm^{-1} (C-O bond), 916 $cm^{-1}$and 760 cm^{-1}(CH_2 and C=C, respectively). The spectrum of cinnamon oil (**Figure 3B**) showed all the characteristic absorption peaks, as at 3000 $cm^{-1}$and 3100 cm^{-1}(aromatic CH bond), 3020 cm^{-1} and 3080 cm^{-1}(CH alquenes), 1640 cm^{-1} and 1680 cm^{-1}(C=C), 1690 cm^{-1} and 1760 cm^{-1}(C=O). The spectrum of chlorhexidine (**Figure 3C**) showed all the characteristic absorption

peaks, as at 2542 cm^{-1}, 2956 cm^{-1} (N-H stretch), 1519 cm^{-1}(N-H bending), 1259 cm^{-1} (C-N stretch), 1093 cm^{-1}(C-N bending), and 2947 cm^{-1} (C-H vibration).The physical mixtures of clove oil with β-CD, cinnamon oil with β-CD, and chlorhexidine with β-CD reveal the presence of distinct peaks corresponding to both the drug and the polymer, alongside a broad OH stretch peak. This collective observation implies that there is no interaction between the drug and the polymer.

Example 2b: Differential scanning calorimetry (DSC) - DSC was used to obtain thermograms of the pure drugs. Approximately 5.00 mg of the pure drug sample was accurately weighed, placed in aluminium pans, sealed, and then subjected to heating at a rate of 20°C per minute, ranging from 10°C to 400°C. To ensure efficient heat transfer, purging with nitrogen gas at a rate of 40 ml per minute was carried out during the process. DSC proves to be an exceptionally valuable tool for investigating the thermal behaviour of NS. It provides comprehensive insights into the physicochemical state of the drug-loaded within the NS, offering both qualitative and quantitative information. The DSC thermograms of clove oil, cinnamon oil, chlorhexidine, β-CD and their physical mixtures are shown in **Figure 4(A) – A, B, C** - **Figure 4(B) – A, B, C** and **Figure 4(C) – A, B, C.** DSC analysis of pure clove oil (**Figure 4(A) - A**) resulted in gradual enthalpy change producing a linear sharp endothermic peak at temperature 260°C which is indicative of its melting temperature. This endothermic peak was also traced with respect to the NS physical mixture (**Figure 4(A) - C**) but with lesser intensity. DSC analysis of pure cinnamon oil (**Figure 4(B) - A**) exhibited distinctive thermal behaviour, characterized by an exothermic peak at 55°C, as well as two distinct endothermic peaks at 145°C and 285°C, which is indicative of its melting temperature. This endothermic peak was also traced with respect to the NS physical mixture (**Figure 4(B) - C**) but with lesser intensity. DSC analysis of pure chlorhexidine (**Figure 4(C) A**) resulted in gradual enthalpy change producing a linear sharp endothermic peak at a temperature of 132°C which is indicative of its melting temperature. This endothermic peak was also traced with respect to the NS physical mixture (**Figure 4(C) - C**) but with lesser intensity.

Example 2c: Particle size, zeta potential and polydispersity index – The average particle size, particle size distribution, Zeta potential, and polydispersity index (PI) of the formulated NS were assessed using a particle size analyzer (ZS Nano, Malvern, USA). These experiments were conducted with a clear disposable zeta cell, with water employed as the dispersant, having a refractive index (RI) of 1.330 and a viscosity of 0.73 cP at a constant temperature of 25°C. The average diameter, polydispersity index and zeta potential of clove oil β-CD NS were found to be 477.56± 0.1 nm, 0.171 and −21.22±1.5 mV respectively. Similarly, the average diameter, polydispersity index and zeta potential of cinnamon oil β-CD NS were found to be 453 ±0.9 nm, 0.145 and −20.32±1.3 mV respectively. And the average diameter, polydispersity index and zeta potential of chlorhexidine β-CD NS were found to be 480 ± 0.6 nm, 0.156 and −22.33 ±1.6 mV respectively. The particle size distribution of NS is depicted in **Figure 5**.

Example 2d: Scanning Electron Microscopy (SEM) - The morphology and surface topography of the prepared nanosponges were investigated using a scanning electron microscope. The size and surface morphology of the optimised nanosponge formulation were further investigated using SEM. The analysis indicated that the optimized NS formulation exhibited a roughly spherical shape with a spongy nature (**Figure 6**).

Example 2e: Analytical method - HPLC method development of clove oil - Reverse-phase HPLC (RP-HPLC) analysis of clove oil and a standard eugenol sample was carried out using an HPLC system from Shimadzu Prominence, Japan. Clove oil, with a concentration of 10 mg/ml, and the standard eugenol sample at 1 mg/ml were both prepared in methanol for the chromatographic analysis. The analysis was conducted under isocratic mobile phase conditions, with a mixture of methanol and water in a ratio of 75:25. The samples were eluted from the column at room temperature, with a constant flow rate of 1 ml/min, and the eluates were detected at a wavelength of 254 nm. The LC Solution software was utilized for the chromatographic analysis. The identification and quantification of eugenol were confirmed by evaluating the peak areas obtained

from the HPLC analysis, allowing for accurate determination of the eugenol content in the samples.

HPLC method development of cinnamon oil - HPLC analysis was conducted using a Shimadzu LC 2010 HPLC system, Japan. This system was equipped with a Shimadzu LC 2010 UV-VIS detector featuring a thermostatted flow cell and two selectable wavelengths, covering the range of 190–370 nm and 371–600 nm. The detector's output was recorded by a Shimadzu LC 2010 integrator. For the analysis, a C18 block heating-type Shim-pack VP-ODS column with dimensions of 4.6 mm inner diameter and 150 mm length was employed. The column contained particles with a size of 5 µm. Cinnamaldehyde was effectively separated using a mobile phase consisting of a water-methanol mixture in a ratio of 40:60 (v/v) at a flow rate of 1.0 mL/min. The column was maintained at a constant temperature of 35°C during the analysis. Each injection consisted of 20 µL of the sample, and detection was performed at a wavelength of 260 nm.

HPLC method development for chlorhexidine **-** A Zorbax SB Phenyl column with dimensions of 75 mm in length and 4.6 mm in inner diameter, packed with 3.5µm particles, was employed for the separation in this chromatographic analysis. The mobile phase used for elution consisted of acetonitrile and a buffer solution in a ratio of 35:65 (v/v). This mobile phase was pumped isocratically at a flow rate of 0.6 ml/min. The buffer solution was prepared using 0.08 M sodium phosphate monobasic and contained 5 ml of triethylamine (0.5%). The pH of the buffer solution was adjusted to 3.0 using 85% phosphoric acid. For detection, a wavelength of 239 nm was selected, which was based on the absorption spectra of the component being separated. This wavelength was used for monitoring and quantifying the compound of interest in the chromatographic analysis.

Example 2f: In vitro release studies - *In vitro* release studies were conducted employing a USP Type I dissolution apparatus, with the coated sling securely positioned within a rotating basket. A 250 ml volume of pH 6.8 buffer solution was introduced into the vessel, with the temperature of the dissolution medium maintained at 37 ± 0.5°C. The rotational speed of the basket was consistently set at 100 rpm. Periodic sampling was performed, followed by subsequent analysis of

the samples. *In vitro* drug release studies offer crucial information about the anticipated behaviour of a formulation under *in vivo* conditions. The findings from these studies revealed a notable extension in drug release, indicating a sustained and controlled release profile. The release of clove oil, cinnamon oil, and chlorhexidine significantly decreased. Prolonged release from the formulation for up to 12 hours was observed (**Figure 7**). In all formulations, a sustained release of medicaments was observed without any abrupt initial burst. The release mechanism from NS can be attributed to the gradual erosion of the NS and the simultaneous diffusion of the drug into the surrounding polymer matrix.

Example 3: Finger sling device

The device of the present disclosure may be called as Finger Sling Device or just as sling or as glove (hereinafter referred as device). The following paragraphs describe the present disclosure with reference to **Figure 1 (A) to (C).** In the figures, the same element or elements which have similar functions are indicated by the same reference numerals or signs.

Figure 1 (A) provides front view of a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device (100) *per se*. Also, shown is the finger sling device (100) when worn (left hand side) by the subject for maintaining oral hygiene of a subject in need thereof. A similar device (100) can also be developed that can be worn by the subject on right hand side. Moreover, the device (100) comprises of a first hollow member (200) of which one end of it is sealed with a proviso for inserting index finger. Further, a second hollow member (300) is having one sealed end with a proviso for inserting thumb and external surface of the second hollow member (300) is optionally configured with medicated bristles (300a) to get under the gum line or in the crevices of palatal surface or the lingual surfaces of the teeth.

Figure 1 (B) shows back view of a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device (100) *per se*. More particularly, here the device (100) is configured with medicated bristles (200a) and (300a) that are loaded with medicated nanosponge based composition comprising of chlorhexidine, clove oil and cinnamon. Also, shown is the back

view of the finger sling device (100) when worn (left hand side) by the subject for maintaining oral hygiene of a subject in need thereof. A similar device (100) can also be developed that can be worn by the subject on right hand side. The external surface of the first hollow member (200) is configured with medicated bristles (200a) for brushing teeth and for cleaning any predetermined area in oral cavity of a subject. The external surface of the second hollow member (300) is configured with medicated bristles (300a) to get under the gum line or in the crevices of palatal surface or the lingual surfaces of the teeth. Furthermore, the medicated bristles (200a) and (300a) of first hollow member (200) and second hollow member (300) are loaded with a sustained release synergistic nano sponge composition as explained in the examples 1 to 2. The medicated, synergistic and sustained release nanosponge formulation of above examples 1 and 2 is loaded onto the finger sling device (100) of the present disclosure for maintaining oral hygiene of a subject in need thereof. The first hollow member (200) and the second hollow member (300) comprise a hollow portion (200aa and 300aa), hydrophilic layer (200ab and 300ab), hydrophobic layer (200ac and 300ac) and zig-zag bristles layer (200ad and 300ad) loaded with nanosponges, wherein said layers are fabricated using breathable and biodegradable materials selected from a group comprising of plant-based fabrics like cotton, linen, and bamboo alone or in combination with animal-based fabrics like silk, wool and polymers such as poly β-hydroxybutyrate–co-β-hydroxy valerate.

On the other hand, **Figure 1 (C)** shows back view of a portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device (100) *per se* wherein the second hollow member (300) is free from medicated bristles (300a) and the medicated bristles (200a) can be seen only on the external surface of the first hollow member (200). Also, shown is the back view of the finger sling device (100) when worn (left hand side) by the subject for maintaining oral hygiene of a subject in need thereof. A similar device (100) can also be developed that can be worn by the subject on right hand side.

While various aspects and embodiments have been disclosed herein, other aspects and embodiments will be apparent to those skilled in the art. The various aspects

and embodiments disclosed herein are for purposes of illustration and are not intended to be limiting, with the true scope being indicated by the following claims.

Reference numerals:

Description	Reference number
Device	100
First hollow member	200
Medicated bristles on first hollow member	200a
Second hollow member	300
Medicated bristles on second hollow member	300a
Support member or grip	400
Velcro strap	500
Cuff	600

We claim:

1) A portable, breathable, disposable, biodegradable and medicated nanosponge based finger sling device (100) for maintaining oral hygiene of a subject in need thereof, the device (100) comprising:

a first hollow member (200), wherein the first hollow member (200) is sealed at one end with a proviso for inserting index finger and external surface of the first hollow member (200) is configured with medicated bristles (200a) for brushing teeth and for cleaning any predetermined area in oral cavity of a subject;

a second hollow member (300), wherein the second hollow member (300) is sealed at one end with a proviso for inserting thumb and external surface of the second hollow member (300) is optionally configured with medicated bristles (300a) to get under the gum line or in the crevices of palatal surface or the lingual surfaces of the teeth;

the medicated bristles (200a) and (300a) of the first hollow member (200) and the second hollow member (300) respectively are loaded with a sustained release synergistic nanosponge composition comprising, by total weight of the composition: an antiseptic and disinfectant, wherein said antiseptic and disinfectant is chlorhexidine at a concentration of 0.5 % to 8 %; an analgesic and antibacterial agent, wherein said analgesic and antibacterial agents are clove oil at a concentration of 0.08 % to 2.5 %, and cinnamon oil at a concentration of 3.5 % to 30 %;

a support member (400), wherein the support member (400) offers grip for wearing and using the device (100) by a health care professional; and

the device (100) is optionally provided with a Velcro strap (500) with cuff (600) to form a tight grip.

2) The finger sling device (100) as claimed in claim 1, wherein the first hollow member (200) and the second hollow member (300) comprise a hollow portion (200aa and 300aa), hydrophilic layer (200ab and 300ab), hydrophobic layer (200ac and 300ac) and zig-zag bristles layer (200ad and 300ad) loaded with nanosponges, wherein said layers are fabricated using breathable and

biodegradable materials selected from a group comprising of plant-based fabrics like cotton, linen, and bamboo alone or in combination with animal-based fabrics like silk, wool and polymers such as poly β-hydroxybutyrate–co-β-hydroxy valerate.

3) A process for preparing the finger sling device (100) loaded with medicated nanosponge composition as claimed in claims 1 and 2, the process comprising steps of:

a) reacting predetermined amount of anhydrous β-cyclodextrin with dimethyl carbonate at a temperature of 100℃ for a time period ranging from 7 to 8 hrs followed by cooling, filtering and extracting it with methanol to obtain a solid mass of β-cyclodextrin based nanosponges;

b) dispersing the predetermined concentrations of each of active agents namely chlorhexidine at a concentration of 0.5 % to 8 %, clove at a concentration of 0.08 % to 2.5 % and cinnamon oil at a concentration of 3.5 % to 30 % in aqueous nanosponge suspension under continuous stirring for a time period of 24 to 28 hours to obtain a mixture;

c) centrifuging the mixture obtained under step (b) at 2000 rpm for a time period of 15 to 20 minutes to obtain a supernatant;

d) collecting, filtering and freeze drying the supernatant obtained under step (c) to obtain freeze-dried β-cyclodextrin based nanosponges of chlorhexidine, clove oil and cinnamon oil followed by storing in a sealed vacuum desiccator at room temperature;

e) dissolving 2% of chitosan in 1% lactic acid solution to obtain the chitosan based gel followed by combining it with β-cyclodextrin based nanosponges of chlorhexidine, clove oil and cinnamon oil obtained under step (d) under continuous stirring to obtain the active agents loaded chitosan gel; and

f) fabricating the finger sling device (100) followed by dipping and lifting the device (100) into the chitosan gel obtained under step (e) at a speed of 0.01 to 20 mm per second and is repeated multiple times for even coating of the gel onto the finger sling device (100) followed by evaporating

solvent, if any, from the coated finger sling device (100) and packaging it until further use.

4) The process as claimed in claim 3, wherein said chitosan gel is sonicated for a time period of 5 min to 10 min followed by cooling and preserving the cooled chitosan gel using methyl paraben as a preservative.

5) The process as claimed in claim 3, wherein said extraction is Soxhlet extraction.

6) The process as claimed in claim 3, wherein said solid mass of β-cyclodextrin based nano sponges was purified and stored at a temperature of 25℃ until further use.

7) A kit comprising the device (100) as claimed in claims 1 to 6, comprising of:

a) a medicated nano sponge based finger sling device (100) comprising of a first hollow member (200), a second hollow member (300), and a support member (400); wherein the first hollow member (200) is sealed at one end with a proviso for inserting index finger and external surface of the first hollow member (200) is configured with medicated bristles (200a); wherein the second hollow member (300) is sealed at one end with a proviso for inserting thumb and external surface of the second hollow member (300) is optionally configured with medicated bristles (300a); wherein the medicated bristles (200a) and (300a) of first hollow member (200) and second hollow member (300) are loaded with a sustained release synergistic nano sponge composition; a support member (400), wherein the support member (400) offers grip for wearing and using the device (100) by a health care professional; and the device (100) is optionally provided with a Velcro strap (500) with cuff (600) to form a tight grip; and

b) an instruction manual having instructions to use the finger sling device (100) stored in the kit.

Dated this 16th day of November 2022

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[Digitally signed]
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ABSTRACT

Title: A medicated nano sponge based finger sling device and a method of preparation thereof

The present disclosure provides a solution to the limitations associated with maintaining oral hygiene. More particularly, the present disclosure provides a portable, breathable, disposable, biodegradable and medicated nano sponge based finger sling device (100) for maintaining oral hygiene of subjects including but not limiting to long-distance travellers, globetrotters, on duty army personnel and astronauts. The finger sling device (100) comprises of a first hollow member (200) for inserting index finger and external surface of the first hollow member (200) is configured with medicated bristles (200a). Also, the device (100) comprises of a second hollow member (300) for inserting thumb and external surface of the second hollow member (300) is optionally configured with medicated bristles (300a). The medicated bristles (200a) and (300a) of the first hollow member (200) and the second hollow member (300) respectively are loaded with a sustained release synergistic nanosponge composition comprising chlorhexidine, clove oil and cinnamon oil.

Accompanying figure is Figure No. 1