

TITLE

Herbal Composition for Therapeutic Management of Asthma and Process of Preparation Thereof

FIELD OF THE INVENTION

The present invention relates to herbal composition for therapeutic management of the diseases of respiratory tract. In particular, the present invention relates to a herbal composition for the therapeutic management of asthma and related conditions of respiratory tract. The present invention further relates to process (es) for preparing such herbal composition in forms of formulation.

BACKGROUND OF THE INVENTION

Asthma is a chronic disease involving troubles in respiratory tract, specifically affecting bronchial tubes through which air enters and exits the lungs. The general causatives of the disease are a combination of genetic and environmental factors. Asthma, considered a serious chronic allergic disorder, and typically characterized by airway hyperresponsiveness, recurrent airflow obstruction and symptoms of cough, wheezing and breathlessness. Asthma is also responsible for significant mortality, particularly when not properly treated. It is generally accepted that asthma is characterized by chronic airway inflammation, varying degrees of airway obstruction that is usually reversible, and increases in airway responsiveness to a variety of stimuli. Muscle spasm, airway edema, abnormal mucus production and an inflammatory cell filtrate can often be observed during an acute exacerbation, frequently referred to by sufferers as "an asthma attack."

Asthma, remains a major health problem in developing countries like India. Asthma's prevalence is increasing, highlighting the need for effective treatments and prevention. Treatment of asthma is complicated by the variation in size of the patients. A range of different dosages has been necessary. Further, it has generally accepted that anti-muscarinic agents, given normally to asthma patients should not be given to children. The administration of anti-asthmatic drugs to children is associated with various problems, of which one is the difficulty in getting sufficient drug into the airways. Children are not prescribed, dry powder inhalers because they cannot suck sufficiently hard or for very long. The use of metered dose inhalers involves coordination problems, and pressurized inhalers are used with spacers.

There is found no medication giving a reliable, adequate effect on a child's typical inhalation; there is either an insufficient dosage or the risk of undesirable systemic side effects.

The diagnosis is usually based on the pattern of symptoms, response to therapy over time and spirometry. It is clinically classified according to the frequency of symptoms, forced expiratory volume in one second (FEV1), and peak expiratory flow rate. Asthma may also be classified as atopic (extrinsic) or non-atopic (intrinsic). There are various allopathic drugs for the treatment of acute and chronic bronchial asthma. There is no treatment for emergency asthmatic attack except allopathy.

Although inhaled corticosteroids (ICS) which are used in treatment of asthma, greatly reduce the side effects. Adrenal suppression, decreased bone metabolism, and decreased growth are a concern in children taking ICS. Corticosteroids also produce overall immune suppression, which results in increased susceptibility to infections. In addition, recent studies indicate that continuous daily treatment with (ICS) had no long-term therapeutic benefit in terms of lung function because although anti-inflammatory therapy reduced the incidence of asthma symptoms in subjects with persistent asthma, it did not alter progressive lung changes or prevent recurrence of symptoms shortly after discontinuation of therapy.

Drugs like Salbutamol, Deriphyllin, Ketotifen, Ephedrine are the commonly used bronchodilator drugs in allopathy, all the above drugs have their own serious side effects like palpitation, tremors, agitation, excessive sweating, dryness of mouth, due to its unwanted effects on other system viz., cardiovascular, central Nervous system, excretory system etc.

Another commonly used approach to treating allergic symptoms is the administration of histamine antagonists. These drugs are widely available in over-the-counter formulations, but unfortunately, they merely mask the symptoms of the allergic response rather than providing any type of permanent cure or protection against recurrence. The modern methods of treatment for asthma involve use of allopathic drugs that comprises of chemicals and in most case causes side effects. The principle of allopathy is to suppress the symptoms while in alternative treatment systems like herbal treatment attempts to remove the root cause of the problem. Many medicines and formulations are available for treatment of asthma. However, because of side effects of non-steroidal anti-inflammatory drugs doctors and patients are looking for alternative ways to treat with minimal side effects.

In view of this, there remains an unmet need to develop alternative, safe, effective asthma treatments that is cost effective, secure, and environmental friendly.

DESCRIPTION OF THE INVENTION

In view of the foregoing disadvantages inherent in the prior arts, the general purpose of the present invention is to provide an improved combination of convenience and utility, to include the advantages of the prior art, and to overcome the drawbacks inherent therein.

The present invention discloses an herbal composition effective for the treatment or prophylaxis of diseases of the respiratory tract and associated pulmonary conditions, comprising processed parts or extracts of parts of plants *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum*, in precise combination.

In an aspect, the present invention discloses processes of preparing herbal composition for therapeutic management of asthma and associated pulmonary disorders, comprising whole or parts of plants *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum* processed in one or more forms of formulation suitable for effective administration.

For the purpose of this invention, the whole and parts of plants *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum* were collected from Hazaribagh district of Jharkhand state, India.

In an aspect of the present invention, the associated disorders of the respiratory tract are selected from the group of diseases namely asthma, respiratory allergies, exercise-induced bronchoconstriction and inflammatory disorders.

In an embodiment of the present invention, said herbal composition may comprise of any chemical or functional equivalents or horticultural or botanical equivalents of the parts of plants *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum*.

In yet another embodiment, said herbal composition comprising processed plant or plant parts of *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum* as active constituents may also contain a blend of extracts of refined parts of other medicinal herbs as additional medicinal herbs to enhance

efficacy of said herbal composition for treatment and prophylaxis of asthma and associated conditions.

In an embodiment said herbal composition may comprises of one or more active ingredients extracted from said plants or plant parts of *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum*, in combination along with suitable or necessary pharmaceutical excipients, adjuvants or vehicles.

In an exemplary embodiment, said herbal composition may contain one or more pharmaceutically acceptable excipients, adjuvants, vehicles, solvents or any other range of suitable food additives in an effective concentration, which is suitable to formulate, said herbal composition in one or more forms of formulation.

In an embodiment, said herbal composition based of processed parts of plants *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum* can be formulated in various pharmaceutical formulations, wherein said forms of formulation includes (but not limits to) nano-formulations, encapsulations, parenteral formulations or any kind of enteral formulations.

In a preferred embodiment, said herbal composition can be formulated in one or more suitable forms of formulation selected from a group comprising powder, capsule, tablet, bolus, solution decoction, syrup, suspension or like.

In an aspect, said pharmaceutically acceptable excipients may be selected from a wide range of excipients acceptable for herbal formulations, including but not limited to preservatives, solvents, co-solvents, binding agents, sweetening agent, buffering agent, preservatives, binder, glidants, chelating agents, tonicity agents, coloring agents, etc.

In an aspect, said solvents may be selected from a wide range of solvents including polar, non-polar and semi-polar solvents. In a preferred embodiment, said suitable solvent can be water or a combination of water and any other water miscible solvents.

In an embodiment of the present invention, said herbal composition comprising processed plant or plant parts of *Bombax ceiba*, *Zingiber officinale* and *Piper nigrum*, in combination in an amount effective as active constituent, demonstrates its activity to manage and reduce complications associated with asthma and demonstrates how it contributes to manage normal respiratory health

In yet another important aspect of the present invention, is provided a quantified dose of said herbal composition for treatment and prophylaxis of asthma and associated respiratory conditions.

In an important aspect of the present invention, said herbal composition for treating asthma may provide a Broncho-protective effect.

In yet another aspect of the present invention, the claimed herbal composition can be used either alone as a medication or as an adjuvant therapy along with existing therapies to manage respiratory tract disorders including asthma and associated complications.

An object of the present invention is to provide herbal composition for treatment of asthma that does not have any adverse effects.

A yet another object is to provide a simple, fast and inexpensive process to obtain a mixture of herbal ingredients possessing biological activities useful in the treatment of asthma.

An object of the present invention is to provide a herbal composition that may be mass produced inexpensively and used in an easy, cost effective, environment friendly and productive way.

It is to be understood that this invention is not limited to particular methodologies and materials described, as these may vary as per the person skilled in the art. Further, it is to be understood that the present invention is not limited to the methodologies and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are described, as these may vary within the specification indicated. It is also to be understood that the terminology used in the description is for the purpose of describing the particular embodiments only, and is not intended to limit the scope of the present invention.

One skilled in the art will realise the disclosure may be embodied in other specific forms without departing from the disclosure or essential characteristics thereof.

Dated this the 17th day of April, 2017



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