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(54) Titre: NOUVEAU MEDICAMENT ANTIASTHMATIQUE (ASMAKURE) TIRE D'HERBES INDIGENES POUR TRAITER L'ASTHME

(54) Title: NEW ANTI-ASTHMATIC DRUG (ASMAKURE) FROM INDIGENOUS HERBS TO CURE THE DISEASE ASTHMA

(57) Abrégé/Abstract:

Asthma is defined as a chronic inflammatory disorder of the airways of the respiratory organ. It is characterized by reversible airflow obstruction causing cough, wheeze, chest lightness and shortness of breath. The inflammation of bronchial wall together with increased eosinophilis and other inflammatory products of the mast cells and lymphocytes further induce the hyper responsiveness of the bronchi so that it in turn, narrows more rapidly in response to a wide range of stimuli. Asmakure the anti-asthma drug has properties with proven pharmacological use for alleviating common cold and persistent cough and finally building up of immunity against recurrence of Asthma. One of the ingredients Adhatoda Vasica Nees (Basak) has a definite expectorant action. In acute bronchitis, it is found to afford immediate relief especially when the sputum is thick and tenacious. The depression of the Vagal terminals further relieves irritation and spasm of the bronchioles.





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NEW ANTI-ASTHMATIC DRUG (ASMAKURE) FROM INDIGENOUS HERBS TO CURE THE DISEASE ASTHMA

FIELD OF INVENTION

The conventional treatment of asthma is mostly focused on managing the disease rather than finding a permanent solution to the problem . Asmakure is distinctive in its formulation as it covers all mediators acting as broncho-constrictors while other prevalent herbal medicines largely aim at only single mediator called leukotrienes. Asmakure , thus goes to the root of asthmatic disorder and eliminates it in a unique manner. Further, with regular use of Asmakure, patients who are on oral steroid therapy, inhaled steroids and bronchodilators or in extreme cases on inhaled adrenoreceptor agonists etc. , would gradually find themselves weaned away from the use thereof. All these unique features of Asmakure constitute its field of invention as a unique medicine.

BACKGROUND OF INVENTION WITH REGARD TO THE DRAWBACK OF ASSOCIATED WITH KNOWN ART

Asthma is an inflammatory disorder of respiratory system with breathing difficulties. There are some drugs available in the modern medicines (steroid, ß adrenoreceptor agonist, mast cell stabilizer, brochodilator) to treat asthma. All the modern drugs have restriction of their treatment due to their high toxicity. And none of them are curative medicines for treating asthma. After a prolonged period of extensive research, our group of scientists have ultimately invented one unique anti asthmatic drug which has no side effect. Clinically it has been revealed that this new invention has positive curative value in asthma treatment.

DESCRIPTION OF THE INVENTION

Modern drugs have limited curative effect in the treatment of asthma as they hardly offer a permanent relief from the dreaded disease. Having seen the helplessness of the suffering humanity, we have finally come out with our research based anti-asthmatic drug, which is 100% natural and aims at complete control and elimination of the disease.

As asthma is defined as a chronic inflammatory disorder of the airways, we have now invented a herbal based drug with ingredients which have known properties for expectorant action and promoting expulsion of bronchial secretions. Further aided by ingredients having carminative and astringent properties, Asmakure has ability to offer complete curative treatment for people suffering not only from Asthma but also builds up complete and full immunity against comman cough and cold.

DETAILED DESCRIPTION OF THE INVENTION WITH REFERENCES TO THE DRAWING

Procurement of raw materials:

Raw materials were procured from authentic sources. *Phytochemical tests for checking the raw materials*: Chemical tests for carbohydrates, tannins, alkaloids, anthraquinones, fixed oils and fats, volatile oils and resins, were performed. Morphological and anatomical studies were carried out with the different parts of the material. For powdered drugs, microscopical examinations were done. Thus through the phytochemical tests, quality of the herb materials was authenticated.

Process for leaf extract preparation of Adhatoda Vasica:

Fresh leaves of the plant *Adhatoda Vasica* were collected in the month of Oct-nov. The leaves were washed with double distilled water (with preservative to check any microbial contamination) and dried leaves were grinded in a pulverizer and passed through the mesh # 100. The grinded leaves powder were then extracted in a soxhlet extractor with water and alcohol at pH 6.5. The extracted materials were then dried in a spray drier. The specification of the leaf extract is as follows:

- 1. Loss on drying 3.36% 4.15
- 2. 60% Al. Soluble Extractives 89.62% -95%
- 3. Heavy Metals

 Complies
- 4. Arsenic

Complies

Microbial Count
 Complies
 Total Alkaloids (By HPLC Method)
 1.50%

Mixing:

The sieved nine powdered herb materials (e.g. talishpatra, ada, golmorich, Bara-elaichi, dachini, Pipul, nisadal, etc.) were separately weighed and mixed thoroughly in a Double Cone Mixture (National Engg. Make) for 15 minutes (20-24 rotation/min). Properly mixed material was then collected in a closed container to avoid catching of moisture from the environment. Bulk density of the material was calculated (0.451 gm/cc) following the standard methods. The room temperature was maintained at 24+ 1° C before filling.

The Powder filling in bottles:

The powdered mixture was then filled into bottles by semi-automatic powder filling machine. Bottle sealing and labeling:

The filled bottles were transferred to a bottle sealing machine. After sealing, they were transferred to an automatic Capping machine and labeling machine.

QC Testing: The sample was taken at random from the sealed bottles for QC testing like phytochemical test, pharmaceuticakl test (water content, etc).

CLAIMS

We claim -

Asmakure as a unique anti-asthmatic herbal formulation, the first of its kind in permanently curing asthma-the chronic inflammatory disorder of airways where the modern medicines have restrictive application due to their high toxicity. The herbal formulation Asmakure acts as a mast cell stabilizer along with bronchodilator. Due to dual mode of action, Asmakure is a unique antiasthmatic drug.

The formulation unique as claimed in claim 1 wherein as many as nine (9) different authentic herbs (medicinal plants and other natural products) in the dry condition have been mixed thoroughly to form dry-dry powder form to get maximum efficacy.

The formulation as unique as claimed in claims 1-2 wherein the mesh size (#) of the powder is uniformly kept below 20.

The formulation as unique as claimed in claims 1-3 wherein the solubility of the powder is kept above 75% w/v in water.

The formulation as unique as claimed in claims 1-4 wherein the bulk density of the powder is kept around 0.750 gm/cc.

The formulation as unique as claimed in claims 1-5 wherein the strict manufacturing process also ensures that the dry powder form remains below 4% (v/w) and its microbial count within limit.

The formulation as unique as claimed in claims 1-6 wherein the formulation contains the extract of *A. Vasica* with alkaloids concentration not less than 1.5% (total alkaloids).

Asmakure the research, based product, thus, has high efficacy in the treatment of asthma with no side -effect making it a unique formulation offering permanent relief to such patients.

AMENDED CLAIMS

[Received by the International Bureau on 30 December 2002(30.12.02); Original claims replaced by new claims 1 to 6 (2 pages)]

We claim to have invented a new anti asthmatic drug (ASMAKURE) from indigenous herbs to cure diseases, asthma.

CLAIM NO. 1:

A polyherbal formulation invented is designed to mitigate "Atopic Chronic Inflammatory Airways Disorders (ACIAD)" causing asthmatic attack based on the following claims which also include a unique processing technology.

CLAIM NO. 2:

Water extract of *A. Vasica* is forced through a high r.p.m nozzle to get fine uniform droplets. The droplets are dried by hot laminar air flow. The materials are dried and passed through 60 – 80 mesh screens to get uniform micro granules. After dry granulation, the natural lubricant is added as fine powder and it is desirable for each micro granule to be covered with the lubricant. The lubricant tends to make surface of micro granules less susceptible to adhesion. This unique process called "Single Compartment Microgranulation Technology (SCMT)" ensures unification of water extract of a herb with several selective dry herbs.

CLAIM NO. 3:

- Abies webbiana is high altitude herb found in the most difficult terrains of the Himalayas with a very high anti-ACIAD property, i.e. "anti-Atopic Chronic Inflammatory Airways Disorders"
- Adhatoda vasica is herb to combat bronchial disorders. The principals of plant are alkaloids vasicine (mw 188,C₁₁H₁₂H₂₀), vasicinone and vasicinol. The alkaloids are used as bronchodialators
- Zingiber officinale is a herb containing essential oil like zingiberine and alphaterpinone. These essential oils have potent antibacterial properties which reduce the acuteness of bronchial infection.
- Piper longhum is another kind of traditional herb whose active ingredient, monocyclic sesquiterpenes has counter irritant and analgesic properties for reducing muscular pain and inflammation. Thus, found in research most effective in bronchial spasm and inflammation.
- Piper nigrum is a medicinal herb containing piperine which enhances bio-availability of other herbs used in the formulation.
- 6) Cinnamomum zeylanicum is the herb having depressant action on central nervous system (CNS) and thus, reduces stress induced asthma.
- 7) Ammomum subulatum is the herb which provides soothing effect on broncho pharangial region and has a broncho sedative action.
- Nishadal is a kind of white crystalline natural substance which has mucolitic (i.e. liquifying effect on dry cough) and expectorant (i.e. expels liquefied cough) properties.

CLAIM NO. 4:

Asmakure's "Multi-Dimensional Clinical Approach (MDCA)" is based on the unified action of the eight (8) indigenously found herbs as mentioned in claim 3 because:

It ensures mucolytic and expectorant functions leading to bronchodilation on one hand and on the other hand the poly herb preparation acts a complete mast cell stabilizer inhibiting release of broncho constricting chemicals like histamine, cytokines, prostaglandins (PGD₂) etc. This "Multi-Dimensional Clinical Approach (MDCA)" of this poly herb preparation has not been matched by other existing formulations in the peer group.[IJPC, Vol3(No.7), December 2002.

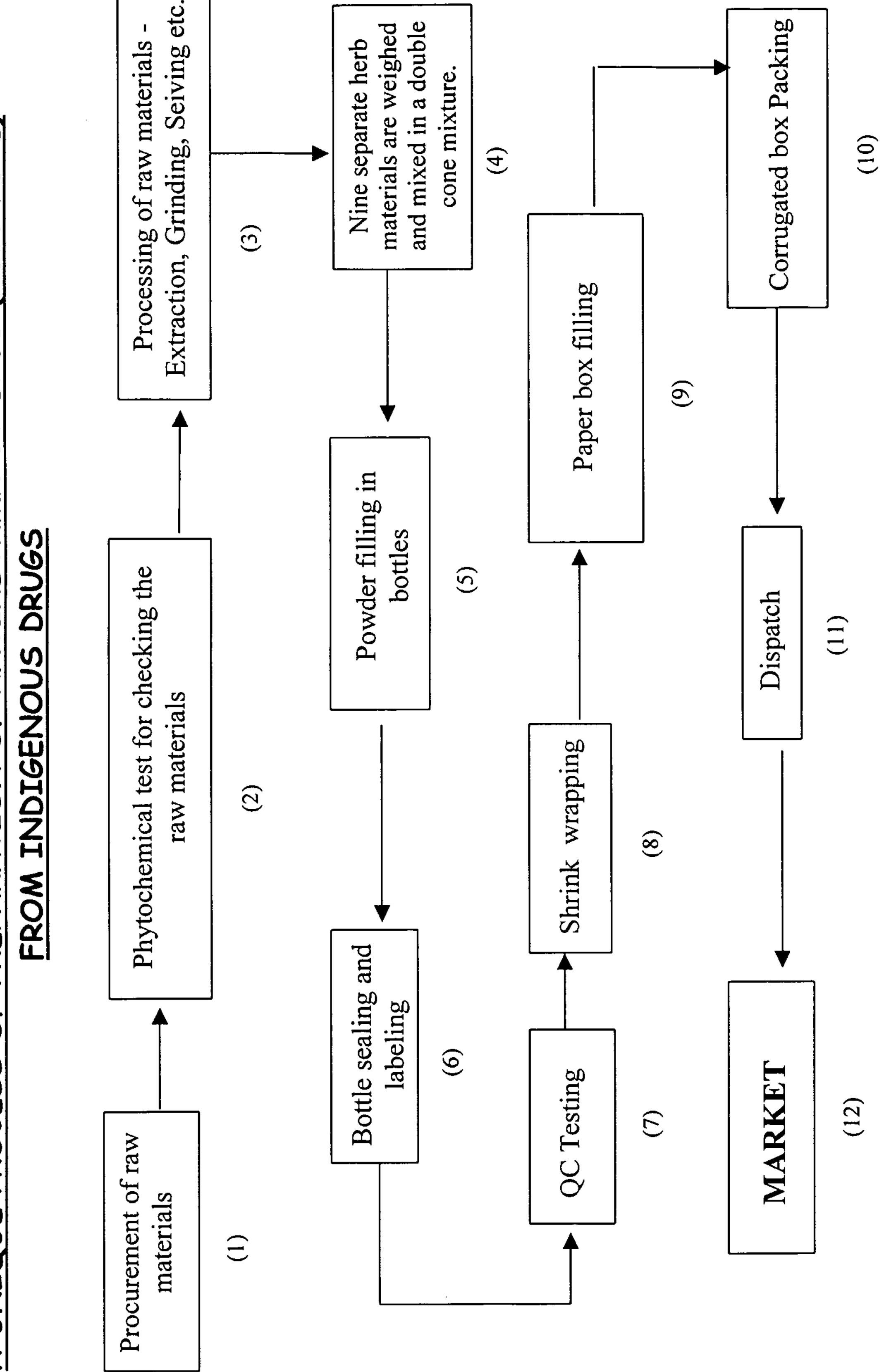
<u>CLAIM NO. 5</u>:

The poly-herb preparation apart from containing Vasicine alkaloid has herbs with active ingredients like monocyclic sesuiterpenes, Zingiberine piperine ensuring anti-bacterial action, reduction of bronchial spasm and inflammation. The presence of piperine has enhanced the bio availability of the formulation.

CLAIM NO. 6:

The formula is unique as claimed in Claims 1-5 because the polyherbal preparation ASMAKURE is first of its kind in permanently curing "Atopic Chronic Inflammatory Airways Disorders (ACIAD)" where other medicines have restrictive application due to their high toxicity.

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Signature of the Applicant -

PREPARATION OF LEAF EXTRACTORS OF Adhatoda vasica

