Evaluation And Safety Parameters Of Polyherbal Formulation (Vlc01) Using Lung Disorder

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Abstract : The development of analytical parameters is the traditional way of medicines which involves various crucial steps in establishing good quality of herbal products. Ayurvedic medicines like Aegle marmelos, Glycyrrhiza glabra, Rosa centifolia are used to treat alveolar damage in lungs. As per standardized API guidelines for the finished product and polyherbal formulation (VLC01) the major raw material analysis is carried out and the ash value, microbial load , heavy metals ,pH, bulk density, are studies. The raw material analysis is more important for industrial purpose.

Keyword: Physicochemical, Analytical parameters, Microbial load, Heavy metals.

1 INTRODUCTION:

The herbal crude drugs and its formulations quality control is found to be important and justifies the modern system of medicine. Polyherbal formulations, are therapeutic agents which includes anti-diabetic[1], lipid lowering and hepatoprotective agents. Some people prefer natural food as well as herbal medicines for healthy life. Use of natural remedies for the treatment of lung diseases has a history of treatment, which starts with the ayurvedic treatment and gets extended to the Chinese, European and other systems of traditional medicines. In spite of the various advances made, there is no significant and safer agents which are now available in modern therapeutics. Therefore, various methods of importance has been given world wide to develop plant based lung drugs which are effective against a variety of lung disorders. Standardization is an important aspect for maintaining and assessing the quality and of the polyherbal formulation as combinations of more than one or two herb to attain the desire therapeutic effect. Around globe all countries insisting to do standardization of herbal products by using standard protocols. During this process we can check the quality of product as well as screen the safety parameters such as microbial and heavy metal tests, which play major role health concern for the utilization of herbal products. As a part of research (Aegle marmelos, Glycyrrhiza glabra, Rosa centifolia) are used to treat the lung disorder as a form of polyherbal formulated drug. These are established through quality check using various physiochemical parameters as specified by Ayurveda, Siddha etc.

2.MATERIALS AND METHODS:

2.1Plant materials :

Aegle marmelos (fruit), Rosa centifolia (flower), Glycyrhiza glabra (root) were procured from the gifted samples from the rumi herbals pvt ldt.

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2.2Raw material and quality assessments :

Raw materials is one of the basic analysis is used to study the potential of parameters and standard maintain as per ayurvedic and siddha pharmacopeia, Govt. of India.

2.3 Foreign matter:

Drugs should be free from moulds, inserts, animal fecal matters and other contaminations such as earth, stones and extraneous materials. The foreign matter was weighed and spread out in a thin layer. The foreign matter was detected, separated by inspection with the unaided eye or by the use of a lens (6x) and weighed.

2.4 Total Ash:

Take plant sample 2 to5 grams coarse powder was incinerated in a silica dish between the temperature at 420-450 ºc in the muffle furnace until carbon ash free and cooled down after weigh the sample% Total ash = (weight of total ash)/(Weight of the crude drug taken@)*100

2.5 Acid insoluble ash:

The ash obtained was boiled for 5minutes with 25ml of dilute hydrochloric acid .the insoluble matter was collected on an ash less filter paper /whatsman filter paper and ignited to constant weight .In the same muffle furnace temperature not exceed above 420-450 ºc. The acid insoluble ash was calculated using formula[2].
% acid insoluble ash value =(weight of acid insoluble ash)/(Weight of the crude drug taken@)*100

2.6 Water soluble ash: The ash were obtain from above test. Take 25 ml of distilled water the insoluble matter was collected in the ash less filter paper. In the same muffle furnace temperature not exceed above 420-450 ºc for 30 minutes. After take the sample cool it down for 30 minutes and weigh the sample see the different between the samples. The percentage of water soluble ash was calculated using formula. % water soluble ash value=(weight of total ash-weight of water insoluble ash)/(Weight of the crude drug taken@)*100

2.7Alcohol Extractive value: An approximately 5 grams of spray dry poly herbal sample were weight and measured the ethanol 100ml mixed in the iodine flask for 24(for first 6 hours occasional shaking in shaker and balance 18 hours kept it allowed at rest). After filter the extract and measure

the amount of the value. Collected sample in a porcelain dish and dried at 100-105 degree and weighed.

2.8 Water extractive value: An approximately 5 grams of spray dry poly herbal sample were weight and measured the water 100ml mixed in the iodine flask for 24(for first 6 hours occasional shaking in shaker and balance 18 hours kept it allowed at rest). After filter the extract and measure the amount of the value. Collected sample separately is used to study for phytochemical analysis .

2.9 Loss of dry: Moister content is determined to know the presence of excess water in the sample, because suitable moisture will lead to the activation of the enzymes and gives optimal conditions to the proliferation of living organism. The selected poly herbal plants is made into coarse powder was taken in a pre-weighed petri dish and placed in a hot air oven/hot dryer at 105ºc . This procedure was repeated until constant weight was obtained .the percentage of loss on drying was calculated.
% moisture content =(Loss in weight of the sample)/(Weight of the sample) * 100

3.PRE-FORMULATION STUDIES:

3.1pH: Individually, 5% solution was made and the pH was checked by using digital pH meter .

3.2Microscopic Characteristics: The samples were observed in the microscope under 10x magnification to see the shape of the granules.

3.3 Observations under UV light: the formulated polyherbal VLCO1 material were mixed with 10% NAOH and 5% HCL and observe under uv light 254 nm and also observed greenish in colour .

3.4 Bulk density
Bulk Density was determined by pouring a weighed quantity of powder into a graduated cylinder and measuring the volume and weight(fig A).
BD = Weight of the powder / volume of the packing

Figure A : *Bulk density*

3.5 Tapped density:
Tapped density was determined by placing a glass graduated cylinder, containing a known mass of plant powder. The cylinder was allowed normal after plant powder . The tapping was continued until no further change in volume (fig b).
TD = Weight of the powder / volume of the tapped packing

Figure B: *Tapped density*

3.6 Compressibility indices: The bulk and tapped densities were used to calculate the compressibility indices (Carr's index and Hausner ratio) which provide the flow properties and compressibility of powders. The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular material.
Hausner ratio = Tapped density /Bulk density

3.7 Microbial load : Microbial load was carried out under the standard as per Ayurvedic pharmacopoeia of india. Total bacterial count(Total plate count agar),Total yeast moulds(Rose bengal agar),Escherichia coli(Macconkey agar), Salmonella(Brilliant green agar),Staphylococcus(Mannitol salt agar),Pseudomonas(Pseudomonas agar) as per norms AYUS guidliness[3].

3.8 Heavy metals:
Preparation of samples by acid digestion method: Accurately weighed 2 g of sample was taken in Kjeldahl flask. Acid mixture of Nitric acid: Perchloric acid (4:1) was added in the flask and heated continuously till the solution became colourless. The sample was then transferred to a 25 ml volumetric flask and the volume was made-up with distilled water. Reagent blank was synchronously prepared according to the above procedure. The standards of Lead, Cadmium, Arsenic and Mercury were prepared as per the protocol in the manual. The samples were analyzed for the presence of Pb, Cd, As and Hg using Atomic Absorbance Spectrophotometer (AAS) (SHIMADZU).

4 .RESULTS AND DISCUSSION:

The selected and formulated medicinal plants were screened individually and identify the purity were given the specifications with in the limits as per API guidelines (Table:1).the ash contents were below the level of the values were less contamination the moisture is less than 5% which is good indicators and such bulk and tap density levels are equal to API guidelines [4].

S.no	Specification	Aegle marmelos		Glycyrhiza glabra		Rosa centifolia		Vlco1	
		API		API		API		API	
1	Foreign matter	NMT 1	Nil	NIL	nil	NMT 2	nil	NIL	nil
2	Total ash	NMT 6	4.2%	NMT10	7.5%	NMT 7.5	5.5%	NIL	6%
3	Acid insoluble ash	NMT 1	0.54	NMT2.5	1.5	NMT 1	0.62	NIL	1.5
4	Water soluble extract	NLT 7	6	NLT20	15	NLT 24	11	NIL	16
5	LOD%		13.22%		20.22%		20.28%		4.2%

Table 1: *physiochemical parameters of formulated and individuals plants.*

The herbal samples were viewed in different ways like texture ,colour ,odour ,taste,pH,uv observation(table 2) etc., The pH 6.45 its indicates suitable for human use.

s.no	Characteristics	Aegle marmelos	Glycyrhiza glabra	Rosa alba	Vlco1
1	Texture	Fine powder	Fine powder	Fine powder	Fine powder
2	Colour	Brown	Dark brown	Light brown	grey
3	Odour	Indistinct	Indistinct	Indistinct	Indistinct
4	Taste	Bitter	Bitter	Bitter	Bitter
5	pH(5%)	6.67	6.78	6.99	6.45
6	Under uv light	Greenish brown	Greenish brown	Greenish brown	Greenish brown

Table 2: *pre-formulation characteristics study.*

The individual samples microbial load and heavy metal toxic profile were seen and formulated as shown in table 3&4. The total bacteria count and yeast moulds were under 10 cfu/g respectively. The major bacteria cause is in the plant. Escherichia coli, salmonella sp., staphylococcus aureus, Pseudomonas organisms were absent in those formulations. The heavy metal contaminations were found to be in the limits of the toxic levels. Mercury is is harmful for the human body like nervous system and immune system. But lead contained to be more effective to brain, liver, kidney and bones. Arsenic causes cancer and skin lesions .

S.no	Name of the organisms	limits	Results
1	Total bacterial count	$1*10^5$cfu/g	Nil
2	Total yeast moulds	$1*10^3$cfu/g	Nil
3	Escherichia coli	Absent	Absent
4	Salmonella	Absent	Absent
5	Staphylococcus	Absent	Absent
6	Pseudomonas	Absent	Absent

Table 3: *Microbial load activity for poly herbal formulation.*

S.no	Name of the metals	Calculation on parts per millions	Permissible limits ppm-Parts Per million
1	Mercury	Not detected	1ppm
2	Lead	Less than 2ppm	10ppm
3	Cadmium	Not detected	0.3ppm
4	Arsenic	Not detected	3ppm

Table 4: *Heavy metal for poly herbal formulation.*

Based on this study, Aegle marmelos, Glycyrrhiza glabra, Rosa centifolia was studied using pharmacognostic standardization which includes morphological, microscopical, physicochemical, fluorescence analysis, microbial load and heavy metals [5]. This evaluation provides simple, quick and cheap methods to evaluate the identity and purity of drugs. It acts as a reliable tool for detecting adulteration. Herbal technology is based on pharmacognostic studies, ensures plant identity as it lays down the standardization parameter and helps to prevent

adulterations[6]. These studies will also help in authenticating the plants and reproducible quality of the products which are produced herbal and may lead to safety as well as efficacy of the natural products.

5.CONCLUSION:

To identify proper and correct drug, standardization of a crude drug is very important. The parameters studied and evaluated in the present work will act as diagnostic parameters to identify the plant. It will also ensure authenticity and prevent adulteration as well as mishandling of the crude drug can be avoided. The final conclusion of this study proves that the therapeutic efficacy of the plant can be maintained using the herbal product.

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