Research Article

Standardization and Evalution of Marketed Satreetha Shampoo of Denajee

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ABSTRACT

A shampoo is a cleaning aid for the hair and is counted among the foremost beauty products. Today's shampoo formulations are beyond the stage of pure cleaning of the hair. Additional benefits are expected, e.g., conditioning, smoothing of the hair surface, good health of hair, i.e., hair free of dandruff, dirt, grease and lice, and above all, its safety benefits are expected. In the present scenario, it seems improbable that herbal Shampoo, although better in performance and safer than the synthetic ones, will be popular with the consumers. Standardization of herbal formulation is essential in order to assess the quality, purity, safety and efficacy of the drug. The present research study deals with the standardization and evaluation of marketed Satreetha shampoo formulation from Denajee health care. The standardization of this formulation, the organoleptic characters, physical properties, the various physico-chemical properties such as moisture content, total ash , total solid, surface tension, specific gravity, IR examination of non-volatile matter, test for ammonia, test for basic nitrogen compound, determination of water by toluene distillation, Libermann Burchard reaction were carried out. Heavy metal content study was also carried out to ascertain the quality, purity and safety of this herbal formulation.

Keywords: Standardization, Denajee Satreetha Shampoo, Physico-chemical parameter.

INTRODUCTION

Nature always stands as a golden mark to exemplify the outstanding phenomena of symbiosis. Today about 80% of people in developing countries still relay on traditional medicine based largely on the different species of plants for their primary health care. About 500% of plants with medicinal uses are mentioned in ancient literature and 800 plants have been used in indigenous system of medicine. The various indigenous system such as Ayurveda, Siddha, Unani use several plant species to treat different ailments[1,2,3]. Herbal medicines make up an important component of the trend toward alternative medicine. A Harvard study recently found that one in three respondents acknowledged use of at least one alternative therapy within the past year. Extrapolated, these findings suggest that up to $13.7 billion were spent in 1990 alone for these treatments[4]. Tyler defines herbal medicines as "crude drugs of vegetable origin utilized for the treatment of disease states, often of a chronic nature, or to attain or maintain a condition of improved health"[5]. Current demands for herbal medicines have resulted in an annual market of $1.5 billion and increasingly widespread availability[6].

Potential Benefits of Herbal Drugs

Historically, herbal medicines have played a significant role in the management of both minor and major medical illnesses. One example is foxglove, which contains cardiac glycosides, and serves as a classic treatment for congestive heart failure. Even now, physicians still use many drugs that possess botanical origins. Huxtable notes that one-quarter of the prescriptions currently written in the United States are for plant products, while one quarter is for agents based on botanical compounds. The therapeutic potential of herbal medicines cannot be ignored and is highlighted in the three examples provided next[7].

Advantages of Herbal Medicine

- They have large amount of use.
- They have better patient tolerance as well as acceptance.
- The medicinal plants have renewable source of cheaper medicines.
- Improvements in the quality, efficacy and safety of herbal medicines with the development of science and technology.
- Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
- They are cheap in cost.
- They are not harmful.
- They are more effective than any synthetic drug.
- Throughout the world herbal medicines have provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form as well as a pure chemical upon which modern medicines are constructed[8,9].

Need of Standardization

The quality control of herbal crude drug & formulation is important in justifying their acceptability in modern system of medicines. Standardization of synthetic drugs offers no problem with very well defined parameters of analysis. It is not uncommon to have as many as five or more different herbal ingredients in one single formulation. The batch to batch variation starts from the collection of the raw materials itself in absence of any reference standard for identification. WHO has emphasized the need to ensure quality control of medicinal plants products by using modern techniques and by applying suitable standards and parameters. Standardized products and services are valuable. User confidence builder's being perceived as:

- Safe
- Healthy
- Secure
- High quality
- Flexible

Standardization brings important benefits to business including a solid foundation upon which to develop new technologies and an opportunity to share and enhance existing practices. Standardization also plays a pivotal role in assisting Governments, Administrations, Regulators and the legal profession as legislation, regulation and policy initiatives are all supported by standardization[10-13].

MATERIALS & METHODS[14-18]

Introduction of Sample

Sample Name : - Denajee Satreetha Shampoo
Biological Name : - *Sapindus laurifolia*
Family : - Sapindaceae

The shampoo is probably the largest unit scale amongst the hair care product since shampoos are one of the cosmetic products used in daily life. Shampoos are primarily been product aimed at cleansing the hair and scalp. The soap nut comes from the soap nut tree (*Sapindus laurifolia*). The pulps of the fruit have been traditionally used for washing the hair and skin. The pulps used for detergent contain something called *saponin*, which works as a natural surfactant. Surfactants reduce the surface tension of the water, essentially making it wetter and easier to penetrate into soiled fabrics. This combined with the agitation of machine or hand washing, removes the dirt or particles, and then keeps them away from clothing until rinsing occurs. It contains two saponin glycosides. Detergent action cleanses the hair, removes accumulated debris and a *sebaceous* material, further more imparting speculiar reflection and hair luster. Saponin is one of the natural washing agents that help to absorb excess sebum without causing adverse reactions. In addition to the emollient effect of saponins their *antibacterial* and *antifungul* properties are important in cosmetic application.

Fig. 1:

Development of Standardization Parameters for Denajee Satreetha Shampoo:

1. Study of organoleptic characters

a) Colour
b) Odour
c) Taste

2. Determination of physico-chemical parameters

a) Moisture content
b) Total ash
c) Total solid
d)

3. Quantitative estimation of selected Phyto-Constituents

a) Glycosides

4. Evaluation of shampoo.

a) Net contents
b) Dirt Dispersion
c) Foaming Ability and Foam Stability
d) Wetting Time
e) Surface tension
f) Specific gravity
g) IR examination of non volatile matter
h) Test for ammonia
i) Test for basic nitrogen compound
j) Determination of water by toluene distillation
k) Libermann Burchard reaction.
l)

5. Determination of pH

6. Establishing the safety pertaining to Heavy metals

METHODS

1. Study of Organoleptic Characters

The polyherbal formulation is studied for organoleptic characters like color, odour and taste using the sensory organs of our body.

2. Determination of Physico-Chemical Parameters

a) Moisture Content at 105ºC

Weight about 1gm of material into large weighing bottle and heat on a steam bath under a jet of air for 30 min. Continuous heating at 105˚C in oven for 2hrs, cool in desiccator, weight and report non volatile matter.

b) Ash Content at 600ºC

Weigh 5ml of material place in a flat bottom platinum dish and heat on a steam bath under a jet of air for 1hr. Remove and add 1gm of ash less cellulose powder, keep the material in dish and heat in a 1k heating lamp till 600ºC in muffle furnace. Note the difference in weight.

c) Determination of Total Solid

A clean dry shallow flat bottom flanged dish, about 75mm in diameter and about 25mm deep of nickel is used for this analysis. Accurate 5ml shampoo was taken out and placed in the dish and evaporated at low temperature as possible on a water bath until the solvent was removed and the residue is apparently dry. Then the disk is placed in an oven and dries to constant weight at 105^0C. After that dish was provide with fully fitting cover and it was cool in the desiccator. Term total solid is applied to the residue obtained, where the prescribed amount preparation is dried to a constant weight.

3. Quantitative Estimation of Selected Phytoconstituents

Test for Reetha

- **Foam test**
  Shake the drug/sample extract vigorously with water. Persistent foam observed, confirms the presence of saponins.
- **Hemolytic test**
  Add drug/sample extract or dry powder to one drop of blood placed on glass slide. Hemolytic zone appears.

Test for Amla

- Aqueous Extract of the drug/sample gives blue color with $FeCl_2$ solution.

Test for Henna

- Aq. Extract of the drug/sample gives blue color with $Fecl_2$ solution.

Test for Shikakai

a) **Saponification test**
Add few drop of 0.5 N alcoholic KOH to a small quantity of various extract along with a drop of phenolphthalein separately and heat on a water bath for 1 hour the formation of alkali indicate the presence of fixed oil and fats.

b) 5 drop of sample, add pinch of sodium hydrogen sulphate, pungent odour indicate presence of glycerin.

4. Evaluation of Shampoo

a) Net Content
At the beginning of experiment mark the outside of bottle at the surface level of liquid, at the end of experiment empty the bottle and note the volume of water required to fill it to the mark.

b) Dirt Dispersion
Two drops of shampoo were added in a large test tube contain 10 ml of distilled water. 1 drop of India ink was added; the test tube was Stoppard and shakes it ten times. The amount of ink in the foam was estimated as None, Light, Moderate or Heavy.

c) Foaming Ability and Foam Stability
Cylinder shake method was used for determining foaming ability .50 ml of the 1% shampoo solution was put in to a 250 ml gradually cylinder and covered the cylinder with hand and shaken for 10 times were recorded. The total volume of the foam contents after 1 minute shaking. The foam volume was calculated only. Immediately after shaking the volume of foam at 1 min intervals for 4 minutes were recorded.

d) Wetting Time
The canvas was cut into 1 inch diameter discs having an average weight of 0.44 g. The disc was floated on the surface of shampoo solution of 1% w/v and the stopwatch started. The time required for the disc to begin to sink was measured acutely and noted as the wetting time.

e) Surface Tension Measurement
Measurements were carried out with a 10% shampoo dilution in distilled water at room temperature. Thoroughly clean the stalagmometer using chronic acid and purified water, because surface tension is highly affected with grease or other lubricants. The data calculated by following equation given bellow:

$R_2 = (W_3-W_1)\ n_1 \times R_1\ (W_2-W_1)\ n_2$

- Where W_1 is weight of empty beaker.
- W 2 is weight of beaker with distilled water.
- W3 is Weight of beaker with shampoo solution.
- n1 is no. of drops of distilled water.
- n2 is no. of drops of shampoo solution.
- R1 is surface tension of distilled water at room temperature.
- R_2 is surface tension of shampoo solution.

f) Specific Gravity

The two methods are commonly used for determination the specific gravity of liquid one method use the hydrometer and instrument that gives a specific gravity reading directly.

A second method called a bottle method uses a specific gravity bottle that is a flask makes to hold a known volume of liquid at a specified temperature usually 20˚C. The bottle is weighed filled with the liquid. Whose specific gravity is to be found and weight again. The different weight is divided by the weight of equal volume of water to give the specific gravity of the liquid.

g) IR Examination of Non Volatile Matter

Obtain of IR filler spectrum of non volatile matter on a salt crystal may be done by slurring the non volatile matter with alcohol place the filter of mixture on a salt crystal and dry at 105˚ C in oven for 5 min. Examine the spectrum for the possible presence of soap, alkyl sulphate, alkanolamine, fatty acid, alkalonamines, condensates, polyoxy ethylene compound and quaternary ammonium compound.

h) Test for Ammonia

Make a portion of shampoo strongly alkaline with 30% NaOH, note whether odour of ammonia can be detected. Alternative hold a piece of moisten red litmus paper over the shampoo which has been made strong alkaline, it turns paper blue.

i) Test for Basic Nitrogen Compound

Mix 1gm shampoo with 8gm of anhydrous Na_2CO_3 in a large pyrex tube. Cover with another 2gm of Na_2CO_3 and heat the mixture strongly over a gas flame. If moist red litmus paper turn blue when it held in vapour confirm nitrogen compound present.

j) Determination of Water By Toluene Distillation

Transfer 10-20 gm sample to 250 ml round bottom flask, add 50 ml of toluene and 2gm of lamp rosin and few glass heads, connect to distillation unit. Distil until no more water is collected in the receiver. Cool, read the volume of water under the toluene at room temperature and calculate % water content.

Water content = volume of water (ml) X 100 / weight of sample

k) Libermann Burchard Reaction

Dissolve small portion of material in 10 ml of chloroform add 5ml of acetic anhydride followed by 5-10 drop of H_2SO_4, stir well. The appearance of green colour indicated the presence of lanolin or sterol.

5. Determination of pH

pH was determined at the temperature of 27ºC ± 2ºC. In the case of liquid shampoo, pH was read directly in the sample in the pH meter.

6. Heavy Metal Test

For Cadmium

Table 1:

Experiment	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	p/o cadmium
Potassium Ferro cyanide is added	White ppt is absent	p/o cadmium

For Bismuth

Table 2:

Experiment	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	p/o bismuth
H_2S gas is added	Dark brown ppt is absent	p/o bismuth

For Lead

Table 3:

Experiment	Observation	Result
Dil HCL add in a sample solution	White ppt of $CaCl_2$ is absent	p/o lead
KI is added	Yellow ppt is absent	p/o lead

RESULTS AND DISCUSSIONS -

1. Determination of Organoleptic Characters

Table 4:

Colour	Brownish
Odour	Characteristics
Taste	Salty

2. Determination of Physico-Chemical Parameter

a) Moisture Content/ Loss on Drying

Table 5:

Serial No.	% loss on drying (S.E.M.)
1	0.74 ± 15.40

b) Ash Content

Table 6:

S. No.	Type of ash	% ash of values (S.E.M.)
1	Ash content	0.41 ± 9.28

c) Total solids

Table 7:

S. No.	Total Solids
1	24.83 ± 2.15

3. Qualitative Analysis

Table 8:

S. No.	Chemical Constituents	Water extracts
1	Glycosides	++
2	Alkaloids	-
3	Tannins	-
4	Saponins	++
5	Phytosterols	-

4. Evaluation of Shampoo

a. Net contents

b. Dirt Dispersion: Moderate.

c. Foaming Ability and Foam Stability: Good foaming

Table 9:

Time (in minutes)	Foam Volume (in ml)
1	160
2	158
3	155
4	155
5	153

d) Wetting Time: 172 ± 0.04.

e) Surface tension:

Table10:

S.No.	Surface tension dynes/cm (S.E.M.)
1	30.26 ± 1.74

f) Specific gravity:

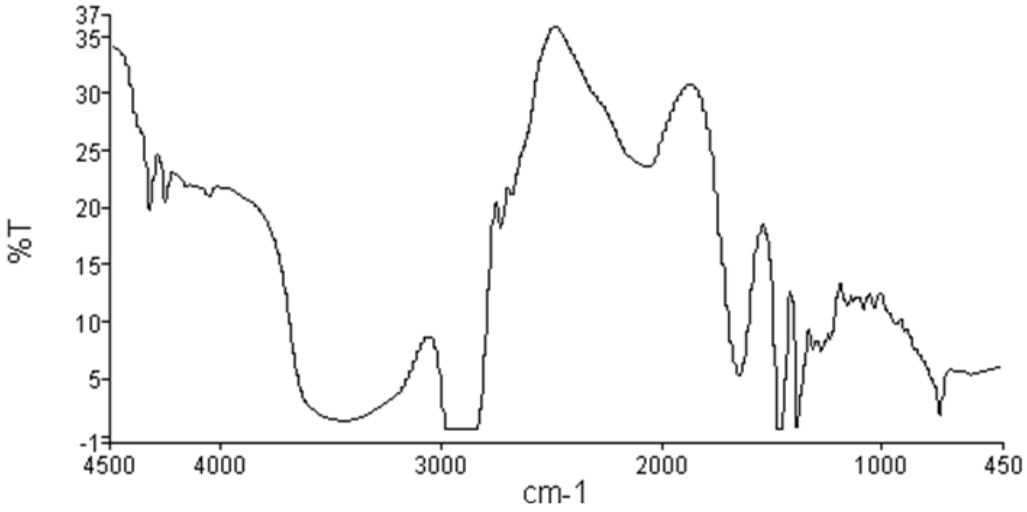
Table 11:

S.No	Density gm/cm^3 (S.E.M.)
1	1.06 ± 2.98

g) IR examination of non-volatile matter

Table 12:

Functional Group	Frequency in (cm^{-1})	Reported range in (cm^{-1})
Amines & Amide (stretch)	3500-3100	3435
Alkynes	2250-2100	2177
Aromatic Aldehyde	2800-2700	2725
Amines & Amines (bend)	1640-1550	1639
Nitro	1550-1350	1455
Sulfones, Sulfonyl Chloride, Sulphonamide	1375-1300	1375
Sulfoxides	1050	1022
Chloride	785-540	721



Graph. 1: IR Spectra for Non-Volatile Matter

h) Test for Ammonia: Not Present

i) Test for Basic Nitrogen Compound: Not Present

j) Determination of Water by Toluene Distillation

Table 13:

S. No.	% of water content (S.E.M.)
1	17± 4.65

k) Libermann Burchard Reaction: Lanolin or Sterol absent.

5. Determination of pH –

Table 14:

S. No.	pH (in 1%)
1	6.31

6. Establishing the Safety for Heavy Metal Test For Cadmium

Table 15:

Experiment	Observation	Result
NH4OH add in a sample solution	White ppt is absent	Absence of Cadmium
Potassium Ferrocyanide is added	White ppt is absent	Absence of Cadmium

For Bismuth

Table 16:

Experiment	Observation	Result
NH4OH add in a sample solution	White ppt is absent	Absence of Bismuth
H2S gas is added	Dark brown ppt is absent	Absence of Bismuth

For Lead

Table 17:

Experiment	Observation	Result
Dil HCL add in a sample solution	White ppt of $CaCl_2$ is absent	Absence of Lead
KI is added	Yellow ppt is absent	Absence of Lead

CONCLUSION

Globalization is the need of today and the world market will open for all by 2005. The world market is also moving towards herbal medicines for health care, health foods and for cosmetic purposes including hair preparations. India is rich heritage for cultivation and production of herbal medicines due to its diversified climatic conditions. Indian traditional literature and ethanopharmacological studies present a number of plants/ formulations with proven efficacy for hair care preparations.

Present investigations was carried out to develop few parameters for quality and purity of herbal shampoo based upon traditional knowledge and Although these studies are preliminary but presented evaluation parameter will be useful for the standardization of herbal shampoo.

The herbal shampoo were standardize and evaluated by various standardization parameters such as physicochemical standards like moisture content, total ash, total solid, surface tension, specific gravity, IR examination of non-volatile matter, test for ammonia, test for basic nitrogen compound, determination of water by toluene distillation, Libermann Burchard reaction were carried out.

It can be concluded that the formulation of Satreetha shampoo contains all good characters of an ideal shampoo and it was found to be harmless, more effective, and economic. The marketed samples have been standardize and evaluated on the basis of the above mentioned parameters which show satisfactory results, but the efficacy of the products can only be judged by doing the pharmacology, which is suggested as future scope of R & D.

The study shows that the contents of formulation presents within the permissible limits as per WHO, all these investigations are not specified in the standard literature such as in pharmacopoeia, which could helpful in authentication of Satreetha shampoo.

The result of present study will also serve as reference monograph in the preparation of herbal shampoo.

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