Preparation and Standardization of Jatyadi Ghrita Rectal Suppository

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Abstract - Jatyadi Ghrita is a very well known formulation used for wound healing, anorectal disorders like fissure, fistula or any chronic wound. These wound healing properties of Jatyadi ghrita can be used in modern dosage form like suppository, suppositories are used to improve local effect of Jatyadi ghrita because of its easy application and minimum local discomfort. These suppositories are made by fusion or melt method by using cocoa butter as a base, and melted mixture of both are poured into molds and after cooling suppositories are collected from molds and stored in fridge. Temperatures plays major role in preparation of this fusion or melt method suppositories. An attempt has been made for preparation and standardization of Jatyadi ghrita suppositories. Standard Preparation method and Visual examination, melting point, liquefaction time of suppositories are studied under this project.

Keywords - Jatyadi Ghrita; Suppository; Suppository mold; Varti Kalpana.

Introduction -
Jatyadi Ghrita is a classical Ayurvedic formulation prepared from Jati (Jasminum officinale), Nimb (Azadirachta indica), Patol (Trichosanthes dioica), Kutaki (Picrorhiza kurroa), Darvi (Berberis aristata), Nisha (Curcuma longa), Sariva (Hemidesmus indicus), Manjishtha (Rubia cordifolia), Abhaya (Vetiveria zizanoides), Siktha (Bee’s wax), Tuttha (Copper sulphate), Yashtimadhu (Glycyrrhiza glabra), Karanja (Pongamia pinnata ), Ghrita (Clarified butter from cow’s milk) and Water¹.

This formulation is used for local application in Marmashrita vrana (Ulcers
in vital points), Klédí vrana (Oozing / weeping ulcer), Gambhíra vrana (deep-rooted ulcers), Sarúja vrana (painful ulcers), Raktája vrana (bleeding ulcers), Dushtá vrana (non-healing ulcers)².

Varti Kalpana has important role, Charaka described Varti kalpana in Chikitsa Sthan³ and Siddhi Sthan⁴. Sushrut also described Varti Kalpana in Sixty Upakramas of Vrana⁵, in Ashtang Sangraha and Ashtang Hriday Varti Kalpana has been mentioned as well.

The topic of Varti Kalpana has been explained in almost all the Ayurvedic samhitas like Vangasena, Vrunadhava, Gada Nigraha, Sharangdharana, Yogarantakara, and Bhavaprakasha.

Varti Kalpana has been widely explained in modern Ayurvedic texts like Bhaishajya Ratnawali, Rasa Tarangini etc. with a view to treat various diseases.

Guda Varti (Rectal suppositories) is used in cases of constipation, retention of enema, disorders of GIT causing obstruction to the flow of Vata and vitiating the Dosha and excretes Mala accumulated in the rectum. The diameter of Varti is made equal to the size of the thumb. When used, the Varti is first soaked in Ghrita and then is made to enter in the rectum slowly. Excretion of fecal matter result within 3-4 minutes after the use of Guda Varti⁶.

In modern science Suppositories are solid dosage forms of various weights and shapes, usually medicated, for insertion into rectum, vagina or urethra. Pharmaceutical formulations meant for insertion into body cavities other than the mouth. Drugs having systemic effects such as sedatives, tranquillizers and analgesics are administered by rectal suppositories; however the largest single use category is probably that of hemorrhoid remedies dispensed over the counter.⁷

The goal of the study is to prepare rectal suppository from Jatyadi Ghrita because Jatyadi Ghrita is indicated in the treatment of various types of ulcers. It has proven wound healing properties.⁸ This property of Ghrita can be used in Anal disorders like fissure, Hemorrhoids by making its rectal suppository, hence an attempt was made to develop standardized new formulation from Jatyadi Ghrita to improve the local effect in wound healing in suppository form.

Aims - To prepare and standardize rectal suppository from Jatyadi Ghrita.

Objectives -
1. Preparation of Jatyadi Ghrita.
2. Preparation of Rectal suppository from Jatyadi Ghrita.
3. Standardize Jatyadi Ghrita Rectal Suppository.

Materials and Methods
1) Preparation of Jatyadi Ghrita -
500Gm Goghrita were taken in steel vessel and kept for heating on mild fire, After it gets heated prepared kalka of fresh Nimbapatra, fresh jatipatra, churna of Patol, Kutaki, daruharidra, Haridra, Sariva, Manjishtha, Haritaki, Yashtimadhu, Karanja Beeja and shuddha Tuttha, Siktha each of quantity 9 gm were added to this heated ghrita and then 2 litres of water is added, heat was given at 50⁰C till siddhi lakshanas are obtained. Prepared Jatyadi ghrita is then filtered through muslin cloth and allow to cool⁹.
2) Preparation of *Jatyadi Ghrita* Suppository -
Suppositories are made by fusion or melt method. In this method the *Jatyadi ghrita* is dissolved in melted suppository base, the mixture is then poured into a suppository mold, allowed to cool and finished suppositories are removed by opening the mold.

Suppositories are usually formulated on weight basis so that the medication replaces a portion of the vehicle as a function of specific gravity. The density of prepared *Jatyadi ghrita* is 0.91023 wt/ml, hence according to formula, for 2 gm suppository with base of cocoa butter we have taken 0.5493 gm of *Jatyadi ghrita* and 1.4507 gm of cocoa butter. The fusion treatment of cocoa butter requires maximum temperature of 40-50°C to avoid crystal form at melting point. Hence, first cocoa butter is heated in heating mantle at 45°C then *Jatyadi ghrita* in given proportion is added to it and stirred properly at same temperature and poured into molds and kept for self cooling, because slow cooling allows direct crystallization of suppositories. After crystallization suppositories are stored in sterile container and kept in fridge. 250 gms of *Jatyadi ghrita* and 725 gms of cocoa butter is melted and from this mixture 400 suppositories are prepared.

3) Standardization of Suppositories -
Visual Examination -
Color - by using color chart actual color of the product is determined.
Shape - Shape of the suppository is continuous or not is determined.
Surface Condition - Product was observed to determine the smoothness, cracks, dark regions, bursts, air bubbles, holes etc.
Appearance - Dry, oily or moist appearance of the suppository is determined.
Feel - by touching the product stickiness hardness of the suppository is determined.
Odor - Odor was determined by smelling the suppository, a change in odor indicative of a degradation process.
Weight - Ten Suppositories are weighed on an automatic balance, and average weight of a suppository is calculated.
Melting Point - The melting point is determined by placing a small diameter wire into the mold containing the suppository melt before the form solidifies. The form is then immersed in water held by the wire and then temperature of the liquid is raised slowly about 1°C every 2-3 minutes until the suppository slips off the wire this is the melting point of suppository.
Liquefaction Time - It measures the time required for a suppository to liquefy when subjected to maximum temperature of 37°C.
Physical Stability - Weekly, observed the suppository for signs of discoloration, dryness, cracking, etc for eight weeks and recorded.

Observations and Results -

Table No. 1 - Physico chemical parameters of raw drugs of Jatyadi Ghrita -

| Sr.No | Name of The Drug | Latin Name            | Ash Value | Acid Insoluble Ash | Water Soluble Extractive | Alcohol soluble Extractive |
|-------|------------------|-----------------------|-----------|--------------------|--------------------------|-----------------------------|
| 1     | Jati             | Jasminum officinale   | 1.8026    | 0.4523             | 28.45                    | 20.63                       |
| 2     | Nimba            | Azadirachta indica    | 4.6572    | 1.2682             | 6.41                     | 8.12                        |
| 3     | Patol            | Trichosanthes dioica  | 12.3755   | 2.4318             | 27.58                    | 12.20                       |
| 4     | Kutaki           | Picrorhiza kurroa     | 6.4894    | 0.9245             | 22.58                    | 14.53                       |
| 5     | Darvi            | Berberis aristata    | 2.4933    | 3.6958             | 10.58                    | 7.23                        |
| 6     | Nisha            | Curcuma longa         | 6.9934    | 0.8546             | 20.87                    | 14.56                       |
| 7     | Sariva           | Hemidesmus indicus    | 3.5382    | 0.4726             | 15.63                    | 19.35                       |
| 8     | Manjishtha       | Rubia cordifolia      | 6.9325    | 0.4856             | 19.35                    | 3.95                        |
| 9     | Abhaya           | Vetiveria zizanioides | 3.2865    | 4.569              | 72.82                    | 56.82                       |
| 10    | Yashtimadhu      | Glycyrrhiza glabra    | 8.1330    | 2.1758             | 25.14                    | 12.58                       |
| 11    | Karanja          | Pongamia pinnata      | 2.1843    | 0.09852            | 20.335                   | 28.54                       |

Fig a. All Raw materials of Jatyadi Ghrita suppository
Fig b. Preparation of *Jatyadi Ghrita*

Fig c. *Jatyadi Ghrita*
Preparation of Jatyadi Ghrita -
Organoleptic Parameters -
Rasa - Tikta
Rupa - Harita Varna
Sparsha - Soft Sticky
Gandha - Ghrita specific
Analytical Testing Of Jatyadi Ghrita
Refractive Index - 1.458
Weight per ml - 0.91023
TLC -
2 gm of Jatyadi Ghrita is extracted from 20 ml of alcohol at about 400°C for 3 hours, after it cools, alcohol layer is separated and filtered, it concentrated to 5 ml. 10 ul of the extract was applies on TLC plate and developed the plate to distance of 8 cm by using toluene: ethyl acetate : hexane (6:3:1)as mobile phase. Then plate is kept for drying in air and sprayed with ethanol sulphuric acid reagent followed by heating at 1100°C for about 10 minutes. It showed spots at RF 0.12, 0.29, 0.5, 0.59, 0.69, 0.85 with different colors.

Standardization of Suppository -
Color - Green
Shape - Bullet shaped
Surface - Smooth surface with no cracks or dark regions
Appearance - oily appearance
Feel - Hard and oily
Odor - Odorless
Weight - Approximately 2 gms each
Melting Point - 36.3°C
Liquefaction Time - 7.32 minutes
Physical stability - Suppository was observed for eight weeks, the color and smoothness of suppository has not changed, it remained as before.

Discussion -
In present study standardized rectal suppository was formulated to replace the traditional ghrita dosage form. All Analytical study for raw drug standardization was carried out and it matches the standard values given in Ayurvedic Pharmacopoeia of India.
Prepared Jatyadi ghrita has green color because of fresh Jati and Nimba Leaves, and density of 0.91023 wt/ml, this density was helpful to determine the weight of cocoa butter in the suppository.

Cocoa butter is a frequently used base for suppositories which is easily available and this type of suppository is feasible to prepare. This fusion or melt method suppositories are formulated on a weight basis, in this medication Jatyadi ghrita is replaces a portion of the vehicle cocoa butter as a function of specific gravity. In this formulation, for preparation of 2 gm suppository 0.5493 gm of Jatyadi Ghrita and 1.4507 gm of Cocoa butter was used. The temperature plays main role in the preparation of such type of fusion or melt method suppositories especially with base cocoa butter that is theobroma oil, because cocoa butter is naturally occurring triglyceride about 40 % of fatty acid is unsaturated, it melts quickly at body temperature. Hence, in the preparation of suppositories if cocoa butter overheated, molded and chilled the suppositories will melt below 30°C, therefore it is prepared in temperature of 40°C to 50°C to avoid change in crystal form and melting point.

**Conclusion -**
Jatyadi Ghrita is locally used medicine for anorectal diseases as well as it has proven wound healing properties. This property can be used in rectal suppository form hence and attempt has been made to prepare the jatyadi ghrita suppository. It has standard parameters like Green color, Hard, Bullet shaped, Smooth and oily surface, without any odor, with 2 gm weight, Melting point 36.3°C, liquefaction time of 7.32 minutes.

It is necessary to do further study on this topic to have more corrective and different methods of preparation of suppository with different bases, also it gives the standard method and parameters for Jatyadi ghrita suppository.

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