#### REVIEW ARTICLE



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# Medicated ointments: Methods of preparation, Mode of Action, Physico chemical characteristics- An overview

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#### **Abstract**

Skin protects our body against the entry of microorganisms as well as serves as a barrier to loss of salts, body fluids and maintains our body temperature. The need for efficient drug delivery system through the skin is essential to reduce systemic toxicity. This has been achieved to a certain extent by the advent of oinments/ malahara (as has been coined in Ayurveda). This review provides a detailed overview on the preparation, properties, mode of action and therapeutic use of oinments/malahara/malham in the treatment of various skin disorders. Though there are articles published on ointments and Malahara separately, a review connecting the herbal ointments to Malahara has never been done before. This article aims to fill that gap

### 1. Introduction

The healing properties of plants has been extensively exploited and explored from the very early stages of evolution (Guglielmi, Pontecorvi, and Rotondi). The plants were not only considered as a source of food and shelter but were also rich in several vital resources (S, Pillai, and Joy). Plants have been used from time immemorial to cure common infectious diseases. Nearly half of the world's medicinal compounds are extracted from plants (Sasidharan et al.). It is worth mentioning that most of the effective medicines of the last five decades, were first isolated from plants. Incorporation of herbal products in Traditional Chinese Medicines, Unani and Ayurvedic formulations were put into practice from ancient times (Deepak et al.). Herbal products include a wide range of plant-based preparations that fall into the categories of food, nutritional supplements and cosmetics (Suroowan and Mahomoodally). Phytotherapy is the oldest method of treatment (Desantis et al. Zeena, Pillai, and Joy) and is often used as the primary provider of healthcare in low- and middle-income countries. Herb based medicines have become more common in developing countries in recent decades (Srivastava). For example, Quinine is obtained from the bark of Cinchona tree. the derivatives of which are widely used for treating Malaria. (Wen et al.) Curare, a fast-acting poison is a plant leaf extract which is extracted from the plant family Strychnos toxifera and Strychnos castelnaea (Tyrrell, Scurr, and Davison). Interestingly, scientists discovered that Curare could be used to relax the muscles of patients undergoing surgery (Essa et al.). The Cocoa tree which grows in rain forests produces about 150 different chemicals. The chemicals thus derived from them are used in medications to treat fevers, coughs, and wounds (Slotten and Venicia). More than twothirds of anti-cancer drugs are derived from rainforests (Nelson et al.). Owing to the prevalent belief

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that "natural" means "harmless" (Bent), Ayurveda has been practised from time immemorial (Vyas). A herbal product cannot be termed as being Ayurvedic. Just because a medicine is sourced from a plant, it does not become Ayurvedic medicine. Any formulation can be categorised as Ayurveda, only when it sticks to the classical method of preparation as mentioned in the text books or when mild modifications are made to the basic concept and then prepared. Malahara is a classical dosage form explained by the ancient textbooks of Ayurveda. But in the context of discussing ointments, Malahara bears the closest resemblance. When it comes to the use of Ayurvedic formulations, the ease of consumption or application needs to be taken into consideration very seriously. Another dosage form that is commonly referred to as 'Lepam' in Ayurveda, if converted to ointment will definitely gain popularity. In Ayurveda, the dosage form that bears a close resemblance to ointment is 'Malahara', which has a semi solid consistency and is applied to the external parts of the body. The term "Malahara" initially appeared in the text 'Yogaratnakara,' as well as in Bhaisajya Ratnakara, Rasatarangini, Rasatantrasara and Sidhaprayoga Sangraha (R. Dr and Angadi) This is also referred to as 'Malham' in Unani treatment (K. R. Dr and Reddy). The base used for the preparation of each ointment determines its dosage form. The Malahara does have two main ingredients, one is the base and the other is medicament. The base used maybe ghee or mixture of gingelly oil and bee wax in a particular ratio. The preparation and therapeutical application of 54 Malahara are explained in the Rasa textbooks of ayurveda (Savrikar and Ravishankar). The therapeutical application varies according to the ingredients (Akhil et al.). Though this is a very potent dosage form, this is not as commonly used as the rest of the dosage forms. In states like Tamilnadu and Kerala, we see very little use of Malahara in clinical practice.

This review focuses on various classification of ointments based on the preparation, therapeutical activity, physiochemical characteristics and mode of action. It also throws lights and cites several examples on Malahara which is an analogous type of medication in Ayuveda.

#### 2. Ointments

Ointments are gel like semisolid formulation which on direct application heals, protects or soothes the skin. (Mohiuddin) They act as both protective and therapeutic agents which help to transport the medicines to the infected area (Ashara et al. Mark et al. Purnamawati et al.). Due to its occlusive qualities, oleaginous ointments are recommended for dried chapped skin in low humid environments. Physical tests such as absorption rate, non-irritancy, penetration, drug release, rheological property, and material uniformity, along with microbiological tests such as microbial content and preservative effectiveness, are used to assess ointments. (S. Sharma and S. P. Singh) Apart from the base oil or fat, very few ingredients are present in ointments thus posing a low chance of sensitization and discomfort. (Lodén)

# 3. Types of ointments

Based on medicinal value, ointments can be classified into medicated and non-medicated ointments. Drugs with local or systemic effects are used in medicated ointments. (Leppert et al.) The various types are shown in Figure 1.

# 3.1. Dermatological ointments

Dermatological ointments are usually applied on the surface of the skin to moisturize or prevent dryness or itchy scalps. These are of three types-Epidermic, Endodermic and Diadermic. Epidermic ointments are used to treat infection from fungus or yeast on the surface of the skin (Garg et al.).

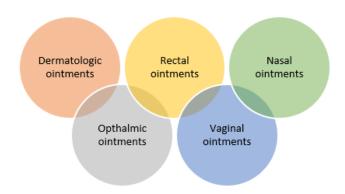


FIGURE 1. Type of ointments

Ketoconazole is a typical epidermic ointment widely used for dandruff treatment. Endodermic ointments like Demodex operate by penetrating the skin's deeper layers [30]. Diadermic ointments penetrate to the deeper layers (Hypodermis) of the skin and has a systemic effect. (Eg:nitroglycerine) [31] A schematic representation of different layers of the skin is depicted in Figure 2.For example skin diseases such as ring worm infestation, allergic dermatitis, foot cracks and fungal infection are treated using Gandhaka Malahara. Key Ingredients of the same are Shudha Gandhaka (sulphur powder), Karpoora (Camphor) and Tankana Shudha (Borax).

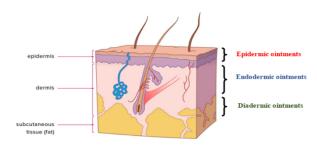


FIGURE 2. Layers of Skin

# 3.2. Ophthalmic ointments

Ophthalmic ointments are used to treat eye infections, dry eyes and inflammation of eyelid (Sen et al.). Depending upon the ailment, specific types of ophthalmic ointment is used: (a) Antibiotic ointment helps to kill the bacteria which cause infection. (b) Lubricating ointment helps to keep the eye moist in case of dryness. Some commonly recommended ophthalmic ointments (Messmer) include Ciprofloxacin ophthalmic which is used to treat corneal ulcers and inflammation (keratitis) (Hyndiuk et al.) Bacitracin, Polymyxin B, Neomycin, Tobramycin and Erythromycin are antibiotics used to treat eye and eyelid infections. (Abelson et al.)

## 3.3. Nasal ointments

The Nasal ointments are used to cure breathing related problems, nasal congestion etc (Keller, Merkel, and Popp). The ingredients in the nasal ointments get absorbed into the bloodstream through the nasal lining (J. Metz et al.). For example ipratropium bromide ointment is used to treat wheezing and shortness of breath (Kotaniemi-Syrjänen et al. S. Sharma and Rasatarangini).

# 3.4. Vaginal ointments

These ointments are used to treat against infections in the vaginal area caused due to fungal infection which results in irritation and intense itching (El et al.). Example for vaginal ointments are Rala Malahara and Vranamrita Malahara that are said to be effective in vrana (wound) caused by Upadamsha (syphilis) and inflammation of the urinary tract (Biswas).

## 3.5. Rectal ointments

These ointments are used to treat the perianal area or the anal canal (Hegde, Trombold, and Dominguez). A combination of White paraffin, PEG 300, cetyl esters, cetyl alcohols are used as bases. (Trusha, Purohit, and Sara) Sulfacetamide sodium ointment is used to treat Seborrhea dermatitis; Sarjarasamalahara and ArshoharaMalahara are used to cure haemorrhoids (Shailesh, V. Singh, and Naini).

# 3.6. Based on therapeutic uses

Therapeutic effect of an ointment is the ability to inhibit or kill pathogens and to cure other disease conditions. Based on their function they are classified into four groups (H et al.).

Antibiotic ointments (Goswami et al.) are applied topically on the skin to restrict the growth of bacteria (Elliott et al.). They prevent infections that may happen when the skin is injured. (Elliott et al.) The medication though absorbed through the erupted skin, doesn't seem to be useful for treating infections in the deeper layers (Negut, V. Grumezescu, and A. Grumezescu). Polysporin, Neosporin, and bacitracin are useful for minor skin injuries (Tong et al.). Antibiotics such as mupirocin (Bactroban), metronidazole (Metrogel), are prescribed for deeper wounds (Manohar et al.)

Antifungal ointments (de Castro et al.) can be used to treat fungal infections, which are usually found in skin, hair, and nails (Youngnamkang et al.). Even though fungi are found in all kinds of environments, not all species cause illness (Jyothi, Koland, and Priya). A group of fungi referred to as Dermatophytes cause infections to skin and mucous membrane (Walsh and Dixon). Topical antifungal medication is usually in the form of a lotion, cream, solution, spray or gel (Ameen) .Topical antifungals initially kill the fungal cells and later on arrest their growth (Gamage et al.).

Antipruritic ointments, (M. Metz and Staubach) are used to treat eczema, dermatitis, allergies, rashes etc (Hong et al.). Hydrocortisone acetate which is a mild corticosteroid is found to reduce

swelling, itching, and redness associated with the ailments (Vempati and Sobel).

Anti-inflammatory ointments (Thais et al.) can be used to treat several symptoms of pain and inflammation, including: Short-term strains or sprains, Muscle aches or pain, Tendon pain, Joint pain from health conditions like osteoarthritis (Vandana Garg). A non-steroidal antiinflammatory drug like Voltaren works by blocking an enzyme called cyclooxygenase (COX) (Kitzen COX is responsible in the producet al.). tion of prostaglandins, which cause inflammation (Nagaich and Vandana Chaudhary). Voltaren gel is used to treat actinic keratosis, arthritis pain in joints (Kyuki et al.). The anti-inflammatory effect of diclofenac-sodium ointment was researched upon by H Fujimura et al (B. Nair and Taylor-Gjevre Menassé et al.). The anti-inflammatory effects of different batches of diclofenac-Na ointment prepared with three kinds of bases: lipophilic, emulsion (cream) and gel bases were compared. The cream was found to have the most potent effect in comparison with indomethacin gel (IM gel), bufexamac cream (BM cream) and mobilat ointment (ML ointment) (Pandey et al. Mohammed et al.). It was found to impart analgesic effect, inhibit proliferation of granulation tissue, reduce swelling (Komeh-Nkrumah et al. Jurca et al.).

## 4. Types of Ointment bases

Ointment Base can be referred to as the drug carrier part (Sadozai, Zafar, and Sajjad). The Quality of the medicine, the stability and the area of the application can be determined by the ointment base. There are mainly three classes of ointments and they are differentiated based on the physical composition (Rahimi et al.).

# 4.1. Oleaginous ointment base

The oleaginous ointment base is a mixture of liquid, semisolid or solid hydrocarbon derived from plants, animals or petroleum (Nwamaka et al. Widhiantara et al.). They possess a wide range of melting point and viscosity (D et al.). The major hydrocarbon bases include petroleum, paraffin and lanolin. Oleaginous ointments have the following characteristics (Yeoh and Goh).

- Possess emollient effect.
- Difficult to be removed from our body.
- Do not get dried up quickly, as there is small

amount of aqueous portion in it.

- Oleaginous base help in increasing the contact time of the medication ingredients with the skin.
- Can act as Air and water tight medical dressing in first aid (Ueda)

Some of the common examples are white petrolatum, yellow ointment, white ointment.

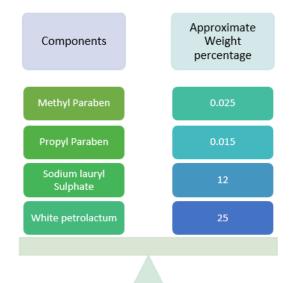
# 4.2. Absorption base

The emulsifying property of an ointment is referred to by the term 'absorption base'They are generally insoluble in water and anhydrous lanolin .

Water in oil emulsion or oleaginous bases allows the incorporation of aqueous solution .They cannot be easily washed off with water (Ajala, Eraga, and Akin-Ajani) e.g. Anhydrous Lanolin and hydrophilic petrolatum are used for emollient applications (Allafi et al.).

#### 4.2.1. Water-removable Bases

Water-removable bases have a semi solid consistency. The external phase of the emulsion being aqueous can be easily washed off from the skin and are referred to as 'water-washable bases. Hydrophilic ointment, USP consists of the following ingredients. For the preparation of about 1000 g of the ointment, following ingredients are required (Figure 3) (Annaji et al.)



**FIGURE 3.** Approximate percentages of different ingredients in ointments

For preparing this ointment, stearyl alcohol and white petrolatum are fused together. Sodium lau-

ryl sulphate (SLS) is the emulsifying agent usually used (Kang et al.). Stearyl alcohol, Methyl paraben, propyl paraben and white petrolatum constitute the oleaginous phase (S. J. Hassan et al. Kumar, Shankar, and Mishra).

#### 4.2.2. Water-soluble Bases

Water-soluble bases are completely water-washable and are 'greaseless'in nature. (Pandey et al.). Polyethylene glycol ointment, is an example of water-soluble base. Polyethylene glycol (PEG) is a polymer which exists in liquid, semisolid or solid form based on its average molecular weights the greater the molecular weight, the greater the viscosity (Conway, Brown, et al. K et al. Bhagurkar et al.). Selection of appropriate base in the ointment is based on a) stability of the drug b) characteristics of the skin surface to be treated c) release rate of drugs into the ointment d) stability of the drug (Krysiak and Stachewicz).

# 5. Other essential ingredients

## 5.1. Preservatives in ointments

In order to increase the shelf life of an ointment it has to be prevented from being contaminated by bacteria and fungi (O Diovu et al.). The Irritancy and toxicity of the ingredient on the tissue to which the ointment is applied need to be checked thoroughly before using the product (T. Sharma et al.).

It is noted that the Nasal passages will get irritated by methyl and propyl parabens ingredients; Boric acid exposure in nasal passage turns out to be dangerous (Stjepanovic et al.). The preservatives that we add may be absorbed by the plastic containers or rubber closures, limiting their availability for antimicrobial action. (Arora, Vats, and Verma) A constant check on the preservative properties have to done in order to ensure the purity of the ointment. (Stan et al.)

## 5.2. Antioxidants

Antioxidants should be used to prevent the oxidation of the base. It is preferrable to use two antioxidants rather than one. (Zaitsev et al.) When a base has both aqueous and oil phases, the concentration of antioxidants can be estimated only by their partition coefficients between the two phases. Butylated hydroxy anisole, propyl gallate, Dihydroguaiaretic acid, are commonly used (Choudhary et al.).

# 5.3. Chelating agents

Small amounts of chelating chemicals such as citric acid, maleic acid, and phosphoric acid, can be added to trap metal ions which are known to catalyse oxidative degradations (Mahato et al.).

# 5.4. Perfumes

Introducing aroma to the ointments can increase its commercial value (Mohamed). The perfume should be carefully chosen as it needs to blend well with the rest of the ingredients. Essential oils from Jasmine, rose, lily, and gardenia are among the floral scents in this group. Sandalwood and cedar wood are among the woody species (Volpert and Perfume).

# 5.5. Cosmeceutical Activity

The use of Ayurvedic beauty products is quite common among both men and women. Such cosmeceutical ointments can be used for different purposes (Chandra, Sodiyal, and Patil). Some of them are;

- 1. Nurturing and Enhancement of skin These ointments are used to give a balanced nourishment to the skin. The ingredients includes Grapefruit extract which are the natural source of vitamin A, C and E (Deshmukh et al.).
- 2. Anti Ageing activity 'Vayasthapana' means arresting age and maintaining youthfulness. These are the ointments which provide optimum physiological functions which encourage the arresting of the ageing cycle and provide youthful skin. These ointments are rich in vitamin C, Gallic acid and Tannins. It also improves cell migration and cell binding which known as 'Sandhaniya' and improves the skin complexion known as 'Kantikara'. It also has adaptogenic agent known as 'Rasayana' (Mangal).
- 3. Providing Radiant Skin These ointments has the ability to provide radiance or bright complexion. These ointment herbs are known as 'Varnya' which includes Sandalwood, Vetiver etc. Jeevanthyadimalahara is said to be very good for improving the complexion (Trak and Chauhan).

# 6. Preparation of ointments

Three methods are commonly adopted for the preparation of ointments. Incorporation method, fusion method and emulsification method, the selection of which depends on the physical and chemical characteristics of the ingredients. (Phatale et al.)

# 6.1. Incorporation method

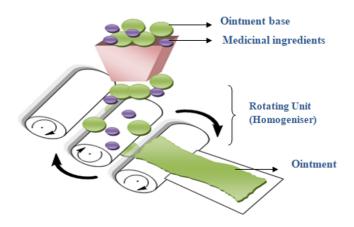


FIGURE 4. Preparation of ointment using homogeniser

For a small scale preparation the components are mixed using a spatula on a glass slab or porcelain plate. Rubber spatula can be used in case the ingredients react with the metal spatula. A uniform mixture is prepared by mixing a small portion of the finely powdered component with a portion of the base. It is important to note that the components are finely powdered to avoid grittiness. This may be done by levigation process The levigating agent, (for eg. mineral oil, glycerine) used should be physically and chemically compatible with the drug as well as the base. (Bharskar and Siddheshwar)

#### 6.2. Fusion

Here the ingredients are fused together and then cooled with constant stirring. In order to avoid decomposition or volatilization, heat - labile ingredients are added only towards the end. The base present in such medicated ointments include stearyl alcohol, high molecular weight PEG, bees wax etc. (A. Nair et al.).

# 6.3. Emulsification method

Emulsification is the process of mixing two or more incompatible liquids into a semi-stable combination . An aqueous solution of thermally stable material are heated to the same temperature. After that the solution is gently added to the melted bases with constant stirring until the mixture cools down. . As we mentioned before, in Ayurveda, the 'Malahara' is prepared by using the most suitable base into which the ingredients are added. In the case

of 'Nimbadi Malahara' the base is SiktaTaila commonly known as bee wax. To this the other ingredients like Goghrta which is cow's ghee, 'Nimbapatrasvarasa' which is fresh juice extracted from neem leaves and Rasakarpura an ayurvedic medicine containing mercury are added. This is mainly used in the case of infectious wounds. In a similar manner, there are different Malahara with different therapeutic indications.

Some of these 'Malahara' and their therapeutical properties are as follows

# 1. Sinduradi Malahara / Sinduradi lepam

These are prepared by melting bee wax (Madhuchista) in coconut oil. Other ingredients includes Sindura, Rasa Sindura, Rasa Karpura. These are mainly used to treat skin diseases such as eczema and dermatitis.

2. Gandhakadya Malahara / Gandhaka Malahara

It contains Girisindhura, Naga sindura, Gandhaka, Tankana, Coconut Oil and pure Bee wax. They are used for treatment of ailment of skin like ringworms infection and fungal infection.

## 3. Sarja Rasa Malahara

These Malahara are effectively useful in reducing pain, Inflammation, Itching, the ingredients being Tila Tila, Sarajarasa and Spatika.

# 7. Physiochemical properties of ointments

The use of drug in the outer layer of the skin is an age-old method. . It is still used due to its ease of access, large surface area, vast exposure, and non-invasive nature of treatment. An ideal ointment has the following physiochemical characters.

# 7.1. PH of ointment

The concept of pH was introduced by a Danish chemist Sorenson. Based on his definition pH of an ointment is a measure of how acidic or basic the ointment is. Usually, ointments with pH less than 7 are considered acidic in nature and te ones with pH greater than 7 is basic in nature. pH of ointment varies with formulations that constitutes the components. A pH range between 6 and 8 is safe to use . Its formulations are determined by a digital pH meter or using a pH indicator paper.0.5g of weighed formulation is dispersed in 50ml of distilled water and pH is determined. . The following equation can be used for finding pH.

$$pH = -log_{10}\{\frac{(H^+)}{(1molL^{-1})}\}$$
 1

# 7.2. Homogeneity

The homogeneity of ointment indicates uniform composition throughout the mixture. Homogeneity of an ointment is also known as dose uniformity which is a primary requirement of an ointment. The assessment of homogeneity enables calculation of particle size . The concept of homogeneity is applied to those systems which are prepared by dispersion methods .

# 7.3. Viscosity

The thickness of a fluid is often referred to as viscosity. Viscosity is the consequence of interactions between molecules in a fluid at the molecular level. It can be considered as the friction between the molecules. Viscosity of the ointment is generally measured in centi poises. A D Maru et.al. evaluated the viscosity of ointment which contain sunflower wax. S Patnayak and co-workers evaluated the viscosity of herbal ointments formulated with methanolic extracts of C ajanus Scarabaeoides plant.

## 7.4. Water number

At a particular temperature, the water number is the maximum quantity of water that can be added to 100 grams of base (Holzman). It was determined by constantly swirling the ointment base by adding distilled water till no more water is absorbed as is evident by the presence of water droplet in the container.

## 7.5. Spreadability

The ease with which a product may be distributed is known as spreadability. It's a desirable feature in margarines, butter, jams, chocolate spreads, and other foods, but it's also significant in ointments, lotions, and waxes (Sibi and Anna). Time is used to measure separability. A tiny quantity of sample was put between the two glass slides, and a significant amount of weight was applied to these glass slides. A weight is placed on the top of the upper slide. The time required to separate the two slides was noted (S. Singh, Zaidi, and Maurya Swathi et al.)

Spreadability was calculated using the formula:

# $S = M.L/T \qquad (2)$

Where, M is the weight tied to the upper slide, L is the length of glass slides,

T is the time taken to separate the slides

#### 8. Mechanism of action of ointments

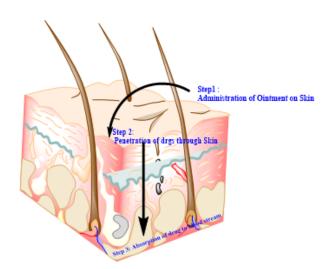


FIGURE 5. Mechanism of ointment action

The ointment is applied to the skin topically. Diffusion allows the ointment's active ingredients to reach the skin's inner layers (Figure 4). The medicaments penetrate deep down and enter into the blood capillaries. They enter into the systemic circulation and produce desired effects. (Shinde et al.)

# 9. Characteristics of an ideal ointment

An ideal ointment must be chemically and physically balanced. It should be noted that the finely powdered ingredients should be mixed thoroughly and uniformly with the base oil. When rubbed through the skin surface these ointment should melt and distribute through the body surface uniformly at the body temperature.

#### 10. Conclusion

Despite the fact that the term "ointment" only became common with the development of modern medicine, it had been known to mankind for many years prior to that, in Unani as Malham and in Ayurveda as Malahara, as from the studies it is stated that Yoga Ratnakara was the first prepared Malahara Kalpana to Ayurveda (R. Dr and Angadi K. R. Dr and Reddy). At present even Taila (Medicated Oil) are being processed into Malahara to make it convenient for the patient, as oil application is very tedious. The Bee wax used as an ingredient in ointment also has therapeutical properties. Despite being used topically, this treatment is just as beneficial in Ayurveda as any other dosage form, even internal ones 149]. These ointments are also used as

chelating agents, used in perfume industries and also in cosmeceutical fields. Without causing any harm, ointments can target particular areas. As mentioned before there are some major requirements like the oil base, the powdered ingredients and the binding base which makes the correct consistency and provide maximum action to the affected area. It is also to be noted that the ratio of these oil base and ingredients are different for different Malahara and is recommended to follow some precaution to provide uniform consistency of the ointment in order to provide maximum action of the particular ointment . It is to be noted that the ingredients which are used to make the ointments are finely powdered before adding to the base carrier. The melting point of these ingredients should be higher than the base carrier. This review explains numerous specifications of ointments and their mode of action (Oblong and Jansen). South India being a rich source of flora and fauna, detailed research on the mechanistic aspects of plant based ointments in the treatment of various diseases needs to be carried out. In the current scenario Ayurveda turns out to be safer mode of medication with low or any side effects.

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