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Gel - A new drug dosage form for Ayurved medicines

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ABSTRACT

Rasashastra and Bhaishajya Kalpana is the science dealing with processing of Ayurved medicines. Due to globalisation of Ayurved science it is need of time to convert our dosage form into palatable and convenient form towards the patient without compromising the effect of the medicines. So here an attempt was made to convert a medicine *Rasakarpura Drava* into new dosage form *Rasakarpura Gel*. It is also thought that other raw materials like *Tuttha*, *Sphatika*, *Tankan* etc; some water soluble formulations like *Rasakarpura* etc; and some water based dosage form like *Arka*, *Hima*, *Phant* etc. can be converted into gel form due to its water solubility and external skin absorbent nature. Is it possible?

Key words: Gel, *Rasakarpura Gel*, New Dosage Form.

INTRODUCTION

History reveals that topical application of drug has been an ancient practice as evident by application of ointment on various part of the body for various purposes. Now a days, also a range of topical preparations like gel, ointments, creams etc. are used. Theoretically drug can be applied topically as powders, sprays or solutions. The topical preparations generally carry drugs for local action on tissues near the site of application.

The skin is a vast multilayered tissue extending over an area of approximately 20,000 sq. cm. and weighing about 4 kg in an average human adult.^[1] Well known layers of tissue consulting the skin are the epidermis,

the dermis and the subcutaneous fatty layer. The skin forms barrier between the organism and its external environment. The skin, the target tissue of drug treatment is also the route of drug administration. It can function as a drug reservoir. It also acts as a site for drug metabolism. Finally application of drugs to the skin can alter the function of internal organ.

Gel

The word gel was coined by 19th century Scottish chemist Thomas Graham by clipping form gelatine.^[2]

A semi rigid jelly - like colloide in which a liquid is dispersed in a solid - non drip paint is a gel.

Gels are equally used by men and women. Majority of gels in the market are aqueous or occasionally aqueous/alcoholic. Carboxyvinyl polymers are the most important and while their prime function is to create the clear gel base, they also have some fixative powers and contribute to the overall hold of the formulation. A wide range of polymers are normally included as the primary film formers. The basic requirements are good water solubility, clarity in solution and compatibility with the carbomer resins.^[3]

Carbomer 940, which gives the clearest gels, is compatible with many other polymers only when fully or partly neutralized. This must be considered when manufacturing such products. Polymers used should

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be diluted with water before addition and added slowly.^[4]

Since clear gel preparations are preferred to be packed in transparent plastic tubes or jars, the carbomers are needed to be protected from UV light degradation by adding a UV-absorber like benzophenone-4. If the carbomer is degraded, there is a likelihood of loss of viscosity and clarity of the product. Another problem encountered during manufacturing is the aeration of the product which occurs due to the vigorous agitation required to dissolve the unneutralised carbomer. Gels prepared from carbomers are influenced by the choice of neutralizing agent.

Sodium hydroxide gives a very stiff gel, while amines give a softer gel. The hydroxy amines, specially Triethanolamine (TEA) are the most widely used.^[5] Triethanolamine is a colourless liquid with a familiar ammoniacal odour. It is viscous hygroscopic, with a boiling point at 277° C. It is readily soluble in water. It is an organic base and combines with acids and acidic materials. It is less alkaline than ammonia. It has a pH between 10 and 11 in an aqueous solution. It is not harmful or caustic to the skin.^[6]

Principles of drug application to the skin

To be effective, a drug must enter the skin in adequate concentration. Topical drug treatment aims at providing high concentrations of the drug at the site of application with minimal systemic absorption, so as to avoid systemic adverse effect.

The absorption of drugs into the skin depends on;

1. The partition coefficient of the drug → between the vehicle and the stratum corneum (upper epidermis layer) which depends upon the lipid solubility of the drug.
2. The step of hydration of the stratum corneum → increased hydration increased penetration.
3. Drug concentration in the vehicle.
4. Thickness of the skin → the thicker the skin the lower the drug penetration, this is important as the thickness of the skin varies in different regions

of the body (e.g. face and intertriginous areas verses the palms) and with age. The skin in the neonates is highly permeable to drugs. On the other hand the ageing skin is relatively less permeable to drug.

5. Quantity of the preparation applied → which partly depends on the extent of the skin lesion. Large amount of very potent drug can cause serious systemic toxicity.
6. The presence of inflamed skin → which allows higher penetration of a drug.
7. Physical state of the skin → in an injured or broken skin, the outer horny layer (stratum corneum) becomes discontinuous resulting increased permeability of the drugs.

Vehicles

Skin therapy is usually symptomatic and topical. Topical preparations consists two parts i.e. 1) active ingredient and 2) the base (vehicle). The important constituents of vehicles are liquid, powders, oil and ointment/crème basis.

- They form a reservoir for the active ingredients.
- They allow local release of suitable amount of the active drug.
- They provide a reasonably safe infrastructure for practical application.
- Many vehicles are also useful for their physical action such as soothing, lubricating, cooling, drying, moisturizing, hydrating or protective effect.

Factors determining the choice of a vehicle

- It's hydrating or drying property.
- Its ability to assist in the absorption of the active ingredient.
- The stability of the final formulation.
- Its physical and chemical interaction with the stratum corneum.

Depending upon the vehicle, the skin preparations can be grouped as powders, wet dressings, lotions,

paints and lubricating preparations such as creams, ointments and pastes.

Advantages of drug input through transdermal drug delivery system^[7]

- Provide relatively steady and sustained drug concentration in plasma in contrast to the conventional system where peak and troughs are common features.
- Variability due to factors such as pH intestinal motility, food intake etc. which make vast difference in the bioavailability of the drugs given through oral route are nonexistent.
- The hepatic first pass metabolism is avoided.
- The constant rate of absorption is possible in a vast variety of adverse patient population.
- Easy administration and patient convenience.
- Drug input terminable by more removal of the transdermal patches.
- Absence of side effect of drugs.

Drawbacks of drug input through transdermal drug delivery system^[8]

- It can be used only for drugs which require very small plasma concentrations for action.
- Local irritation or allergic responses possible.
- Enzymes in the epidermis or derived from microorganisms present on the skin surface may denature the drugs.

Material and Methods

One formulation of Ayurved medicine was tried to convert in gel form i.e. *Rasakarpura Drava*. The name of new dosage form of this formulation is given *Rasakarpura Gel*.^[9]

Ingredients

- *Rasakarpura* - 2 g
- Carbopol - 20 g
- Triethanolamine - 20 g
- Distilled water - 1958 g

Procedure

Rasakarpura Gel was prepared by *Anubhut* method. For the preparation *Rasakarpura Gel*, 2 g *Rasakarpura* was diluted in 1 kg distilled water and added 20 g of Triethanolamine in it. In another vessel remaining 958 g of water and 20 g of Carbopol was mixed by using hand blender. Both mixtures mixed well till it become semisolid ointment. Total 16 batches were prepared (Table 1) (Figure 1). Approx 1987.3 g gel was achieved by following this method.^[10]

Table 1: Results obtained during preparation of *Rasakarpura Gel*

Batch Code	<i>Rasakarpura</i> (g)	Triethanolamine (g)	Carbopol (g)	Distilled water (g)	Obtained <i>Rasakarpura Gel</i> (g)
1	2	20	20	1958	1980.0
2	2	20	20	1958	1990.0
3	2	20	20	1958	1988.0
4	2	20	20	1958	1986.0
5	2	20	20	1958	1990.0
6	2	20	20	1958	1992.0
7	2	20	20	1958	1984.0
8	2	20	20	1958	1985.0
9	2	20	20	1958	1988.0
10	2	20	20	1958	1988.0
11	2	20	20	1958	1986.0
12	2	20	20	1958	1988.0
13	2	20	20	1958	1990.0
14	2	20	20	1958	1984.0
15	2	20	20	1958	1990.0
16	2	20	20	1958	1988.0
Average	2	20	20	1958	1987.3

Figure 1: Rasakarpura gel



DISCUSSION

Delivery of drugs to the skin is an effective and targeted therapy for local dermatological disorders. Topical gel formulations provide a suitable delivery system for drugs because they are less greasy and can be easily removed from the skin.

Gels are used to achieve optimal cutaneous and percutaneous drug delivery. They can avoid gastrointestinal drug absorption difficulties caused by gastrointestinal pH. Gels are having property to avoid enzymatic activity and drug interaction with food and drinks. They can substitute for oral administration of medication when the route is unsuitable. They can avoid the first pass effect, that is, the initial pass of drug substance through the human body. They avoid systemic and portal circulation following gastrointestinal absorption. Gels are not deactivated by liver enzymes because the liver is bypassed. They are non-invasive and have patient compliance. They are applied over skin for slow and prolonged absorption. Gels have also been applied in pharmacy to some viscous suspension for oral use for example Aluminium hydroxide gel. They have localized effect with minimum side effects. Due to above benefit of such dosage form it is the need of time to develop and introduce our Ayurved formulation in facilitate form.

Gels have possibility of allergenic reactions. Enzyme in epidermis may denature the drugs of gels. Drugs of

larger particle size do not absorb through the skin. They have poor permeability of some drugs through the skin. Selection of area is examined carefully during application of gels. Gels which are used for the introduction into body cavity or the eyes should be sterilized. They may cause application side reactions. They may cause skin allergy during application. So it should be used carefully.

1 part *Hingulottha Parada* (mercury extracted from cinnebar) was heated with 1.5 parts of 98.08% concentrated sulphuric acid to make *Parada Churna* (mercuric sulphate). This *Parada Churna* was mixed with equal quantity of *Saindhava Lavana* (Rock Salt). This mixture was filled in *Kach Kupi* (glass bottle) and sublimed in *Valuka Yantra* (a specific heating furnace). After self cooling of bottle *Rasakarpura* was collected from the neck of the *Kupi*.^[11]

Rasakarpura is used in diseases like *Phiranga* (syphilis), *Atisara* (diarrhea), *Twak Vikara* (skin diseases) etc.^[12] In *Twak Vikar* it is used in the form of *Rasakarpura Drava*. It was found that *Rasakarpura Drava* was either quickly absorbed or evaporated over skin within few minutes.^[13] Increased contact period of the drug, possibly enhance the efficacy of the drug too, so here an attempt has been made to retain the drug over skin for a larger period of time. Therefore, a different dosage form i.e. *Rasakarpura Gel* was planned to prepare.^[14] It is also safe in dispensing and transportation.

On the base of above experience it is thought that the drug which is water soluble and used for external use should be converted into gel form for the easy dispensing, transformation and convince in applications to the patients. Examples of such drugs are *Tuttha* (copper sulphate), *Tankan* (borax), *Kasis* (iron sulphate), *Spatika* (alum) etc.

It can be also thought to convert some water base *Kalpanas* like *Hima Kalpana* (cold infusion), *Phant Kalpana* (hot infusion), *Arka Kalpana* (distillates formulation) into gel form. Like *Kumari Arka*, *Gulab Arka* etc. can be converted into *Kumari gel* and *Gulab gel*.

CONCLUSION

As the gel is easy to prepare and convenient to apply, this form must be introduced in Ayurved medicine. The raw material, which is water soluble and absorbed through skin, must be converted into gel form. The raw material like *Tuttha* and formulations like *Rasakarpura* and *Kalpana* like *Arka*, *Hima*, *Phanta*, *Drava* (solutions) may convert into gel form.

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