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Challenges in the standardization of pharmaceutics and therapeutics of *Panchavidha Kashaya Kalpana*

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ABSTRACT

Rasa shastra and *Bhaishajya kalpana* (Science of Ayurved pharmaceutics) are the most important pillars of Ayurvedic therapeutics. .*Aushadh* (Medicine) is a major weapon in hands of competent *Vaidya*. Hence Ayurvedic medicines whether it is mineral based or plant based medicine demands quality control. As the processing of medicines requires time and manpower, practice of dispensing self-prepared medicine is ceasing which ultimately keeps no option to prescribe medicines from pharmacy. But due to increasing deforestation, changing weather conditions due to global warming, increasing demand of herbal medicines, commercialization of drugs sets in Pharma industries so quality is the big concern for *Ayurved* fraternity.

Panchavidha Kashaya Kalpana i.e. *Swarasa, Kalka, Kwatha, Hima* and *Fanta* in *Bhaishajya kalpana* are the most basic dosage form for any secondary dosage forms such as *Avaleha, Snehapak kalpana, Sandhana Kalpana* etc. Various pharmaceutical challenges such as proper collection of raw drug, particle size, filtration techniques needs to study for good pharmaceutical practices. While using for therapeutic purpose, factors like use of adjuvants, posology, palatability and dose optimization is necessary in order to get intended results. In today's scenario it is quite challenging to combat these issues. Present paper is an attempt to discuss various challenges in pharmaceutical and therapeutically related issues with respect to *Panchavidha Kashaya Kalpana.*

Keywords: *Aushadh, Panchavidh Kashaya kalpana, Avaleha*

INTRODUCTION

Rasa shastra and *Bhaishajya kalpana* (science of Ayurved pharmaceutics) are the most important pillars of Ayurvedic therapeutics. According to ancient classic *Charaka Samhita* there are four aspects of Ayurvedic therapeutics i.e. *Vaidya* (Doctor),.*Rugna* (Patient), *Paricharaka* (paramedical staff) and

Aushada (Medicine)[1]. These are important for therapeutic success of Ayurvedic treatment. Among these *Aushada* play major weapon in hands of competent *Vaidya*. Hence Ayurvedic formulations whether it is mineral based or plant based medicine demands quality. Earlier *Vaidya* himself used to prepare medicines skillfully for their patients. As the processing of medicines requires time and manpower, practice of dispensing self-prepared medicine is ceasing which ultimately keeps no option to prescribe medicines from pharmacy.But due to increasing deforestation, changing weather conditions due to global warming, increasing demand of herbal medicines, commercialization of drugs sets in Pharma industries hence quality is the big concern for *Ayurved* fraternity. Standardization can serve a number of purposes, including batch-to-batch consistency, confirmation of the correct amount of extract per dosage unit and positive control to indicate possible loss or degradation during manufacturing. While ensuring consistent marker content is an important aspect of standardization, it does not in itself equate to a standardized product.[2]Also due to use of various high speed machinery in processing techniques of Ayurvedic formulations, changing pattern of secondary dosages form while putting aside the pharmaceutical principles, less use or no use of proper adjuvant, not following proper diet instructions, therapeutic efficacy is always questionable.

Panchavidha Kashaya Kalpana[3] (*Swarasa, Kalka, kwatha, Heema and Fanta*) in *Ayurved* Pharmaceutics are the most primary and basic form of Dosage form for any secondary dosage forms such as *Avaleha, Snehapaka kalpana, Sandhana Kalpana* etc. Quality control of these dosages form are dependent on basic formulations. There are certain parameters which are decided in Ayurveda Classics for standardization of *Panchavida kashaya kalpana*. Quality of these *Panchavidha kashaya kalpana* is always compromised due to unavailability or poor availability of drugs which hamper its quality and ultimately secondary dosage form. Hence basic principles of medicine preparation are not justified in current era.

Therapeutic principles of *Panchavidha Kashaya kalpana* are dependent on *Agni* (Metabolic fire), *Kala* (Time of drug administration), *Bala* (Physical and mental strength),*Vaya* (Age), *Prakruti* (Constitution)[4]etc. Five dosage form are used according to its digestion capacity of patients, nature of raw drug used and stages of diseases. Use of adjuvant is necessary while using these dosage form. Rampant use of these medicament leading to serious consequences. so it is very important to set uniform guidelines to standardize these dosage form from raw drugs, processing techniques and therapeutic uses. In today's scenario it is quite challenging to combat these issues, hence present paper will discuss standardization related issues and probable solutions with respect to *Panchavidha Kashaya Kalpana*.

PHARMACEUTICAL CHALLENGES

1. Unavailability of Raw drugs

In *Panchavidha Kashaya Kalpana* availability of authentic raw drugs is a major challenge. Fresh raw drug is preferred for *Kalka* (Paste of raw drug) and *Swarasa Kalpana* (Juice) and dry drug for *Kwath* (decoction) and *Heema-Fanta* (Cold and Hot Infusion) but as per requirement of standard raw drugs it is quite difficult to get at the time of processing specially fresh drug for *swarasa*. It is well documented that the quantity and nature of secondary metabolites in medicinal plants is influenced by growth, season, stage and environmental factors. Therefore, there is a need to develop quality parameters of raw drugs, proper collection and processing along with HPTLC/HPLC finger printing to get desirable quality of raw material.[5]It needs to develop standards for fresh drugs for optimum potency.

2. Kala (Duration of Collection)

According to the *Ayurveda* Principles of pharmaceutics Drug standardization is utmost important in terms of its habitat, season and time of collection, storage conditions [6]etc. while preparation of *swarasa* fresh drug is required but most of time it is compromised with available dry drugs which may affect its quality. According to *Ayurveda* collection of raw drugs should be according to season, timeand potency[7]etc. Also various plant parts need to be collected at particular time duration in order to get maximum phyto constituents. Sometimes it is quite difficult to get that drug as per its requirement especially in case of fresh and wet drug for *Swarasa* preparation hence other optional methods of *Swarasa* are practiced but whether the standards of both optional methods of *Swarasa* are matched or not with original technique is the matter of exploration.

3. Various techniques of processing

Standards of various optional techniques of *Panchavidha Kashaya kalpana* are not mentioned. *Swarasa* and *Kwatha* is the most potent form among *Panchavidha kashaya Kalpana*. *Swarasa* is the basis of many secondary dosage forms such as *Avaleha* and *Asava* preparations. It is also main component in preparation of various Herbo minerals formulations as a *Shodhana* (Purification), *Bhavana* (Trituration) *Marana* (Incineration) purposes. In classical texts standard *Swarasa* is prepared by just picked fresh raw drugs to be crushed by manual or mechanical pressure and filtered with the help of Cloth.[7]Alternative methods includes Infusion[8], decoction[9] and *putapaka*[10] method.Sometimes it may be necessary to add water to extraction of *Swarasa* which may influence water soluble portion in *Swarasa*, percent yield and Total solid content in *Swarasa*. It may also directly influence the dilution of *Swarasa* and ultimately influence its therapeutic potency.[11]

In case of *Kalka Kalpana* fresh or dry drug should be pounded with the help of water to make a thin paste[12]. If fresh drug is not available then dry drug is used for *Kalka* preparation. In *Kwatha Kalpana* one part of raw drug to be boiled with sixteen times of water to remain one eighth portion.[13] In *Ayurved* decoction is widely used hence have many alternatives according to the consistency and proportion of raw drug.[14, 15]

Fanta[16]and *Heema*[17]*Kalpana* (Cold and Hot infusions) are not widely used as a basis of secondary dosage form and seldom used by practitioners.

Different methods of processing may have different standards which is not taken into consideration while using for therapeutic purpose or dispensing to the patients.

4. **Particle size of raw drug**

In conventional techniques of *Panchavidha Kashaya Kalpana*, exact particle size is not mentioned hence it is quite difficult to judge the perfect particle size of raw drug or it often ends in personal perceptions. In these *kalpana* generally course powdered is used but coarseness is rarely measured. Hence there is no uniformity in particle size of raw drug. As the number of wanted and unwanted phyto constituents is directly proportional to particle size of raw drug, it is very necessary to decide standard particle size.Less the size of particles more will be the surface area ultimately encouraging phyto-constituents to enter in the solvent (water) and vice versa. Repeated study of these *kalpana* on different particle size will help to decide proper particle size. The exact mesh size can be decided after Pharmaceutico-analytical study from various particle sizes.[18]

5. Filtration techniques

In *Panchavidha Kashaya Kalpana* except *Kalka* all four dosage formsare filtered after processing for further use. In Classical methods fine cloth is mentioned for filtration. Now a days different types of sieves are used. Method of expression (manual/mechanical), standard of cloth for squeezing or sievefor filtration (if used) may also affect the parameters [suspended particles in plants structures other than liquid], Total solid contain of etc.[19]Hence qualitative parameters may be different for different filtration techniques.

THERAPEUTIC CHALLENGES

Efficacy of drug is depend upon palatability, consistency(drug form), dose, time of drug administration, route of drug administration and use of efficient adjuvants.

1. Use of Adjuvants

Use of *Anupana* in *Ayurved* plays important role in treatment. Due to anupana certain changes occurs in a substance along with which it is administered. However, its importance and practical utility does notfully recognized and applied at any rate. *Anupana* is a fluid vehicle taken with or after medicine or eating and which aids or assists the action of main ingredient, a synergist, an adminiculum, and a vehicle to enhance antigenicity – Immunology.[20]It control adverse drug effect and drug allergies due to anticorrosive action and minimizing action of toxicity.[21]

Panchavidha Kashaya Kalpana needs to be taken exclusively with various *Anupana* (Adjuvants) as indicated accordingly. But now a days due to false publicity on the name of herbal drugs having no side effects, these preparations are taken illogically without consultation of Ayurvedic experts.

2. Posology –Time of Drug Administration

According to the *Ayurveda* Classics time of drug administration is depends upon natural cycle of *Doshas*, pathogenesis of *Doshas* ,state of disease according to the vitiated *Doshas*, physical and mental state of patient etc.[22]Due to modified dosage form these factors are not taken into consideration at the time of drug administration. Also patients reluctant to follow proper regime of medicines decided by *Ayurved* physicians due to changing life style.

3. Palatability of dosage forms

Palatability of *Panchavidha kashaya Kalpana* is major challenge especially for patients at pediatric age group due to peculiar taste of various decoctions and Juices. Use of various adjuvant with these medicaments lessen these problem, but still patients unwilling to take these remedies.To use these formulations in this present era it require effective modifications into new dosage form with more shelf life and palatability that suits to patients without compromising the underlining basic principles and by which the effective basic preparations can be available to treat many number of disease.[23]

4. Dose Optimization

Dose of *Panchavidha Kashaya Kalpana* is stated in classics according to ancient period but now various factors have changed with the time. Dose of Medicines not only depends upon disease but also *Kaala, Agni, Vaya, Bala, Prakruti, Doshas* and *Desh*.[24] Due to Changing environmental conditions, Physical and mental strength of the patients is reduced *Agni* (Digestive power) of the patient is lessen as compared to ancient time hence the dose decided for these *Kashaya kalpana* need to reduce accordingly. In presents era dose optimization is very important to get desired therapeutic effect of that dosage forms.

Discussion:

Ayurveda classics have mentioned about the ideal qualities of a drug i.e. it should be suitable for preparing many recipes, should have potency and should be readily available**.** *Panchavidha Kashaya Kalpana* are polished b**y** our Ancient Acharya in such a way that all the other dosage forms can be easily prepared from it. Hence if the fresh drugs are not available at the time of processing then optional methods with dry drugs can be practiced. Biggest challenge faced by pharmacologist is availability of authenticdrugs. Hence it is of utmost importance that the manufacturers firmly adhere to good agricultural and collection practices (GACP), GMP and good laboratory practice standards, establish appropriate specifications for their products, intermediates and starting materials and gather a complete documentation on pharmaceutical development and testing. The producers must keep pace with the current knowledge with regard to manufacturing and marketing.[25]The compromise solution to this dilemma is to select a marker compound(s) and then ensure that each batch contains the equivalent amount of that marker compound(s). This approach for ensuring consistency is based upon the assumption that the

content of other constituents will vary in proportion to the marker compound; that if each batch contains the same standardized amount of marker, the content of other constituents will also be relatively consistent.[26]Also at each and every step phytochemical profile have to be generated and a multi-marker -based standardization strategy needs to be adopted to minimize batch to batch variation to maintain the quality.[27]Duration of collection of raw drug can be sort out by Good Collection Practice and Good Storage practice. Various optional methods of *Kashaya kalpana* can be practiced but needs to ensure its quality with different biomarkers. Hence at each and every step phytochemical profile have to be generated and a multi-marker -based standardization strategy needs to be adopted to minimize batch to batch variation to maintain the quality.[28]Basic Preparation with different particle size require quality control study for specification of particular mesh Size. Also common filtration practices in case of *Swarasa*, *Kwatha*, *Heema* and *Fanta* will give constant phytochemical profile of that drug formulation.

In therapeutic practice of *Kashaya Kalpana* importance of various adjuvants, Posology need to prove with preclinical and clinical study. Palatability can be alter with mild modification in primary dosage form without disquieting basic principles. Also dose optimization is essential in present era in order to get intended result and avoiding side effects of particular dosage form.

CONCLUSION

Panchavidha Kashaya Kalpana are the most primary and basic dosage form. It is very important to standardize these Dosage form at every stage in order to get quality of secondary dosage form. There is need to develop uniform guidelines for good manufacturing practices for various optional method of preparation by usingvarious analytical markers, quantification of marker compound, multiple marker based evaluations. For therapeutic success modification in dosage form along with use of proper adjuvant, dose optimization is requisite in current era.

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