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Fundamental Principle of *Bhaishajya Kalpana*

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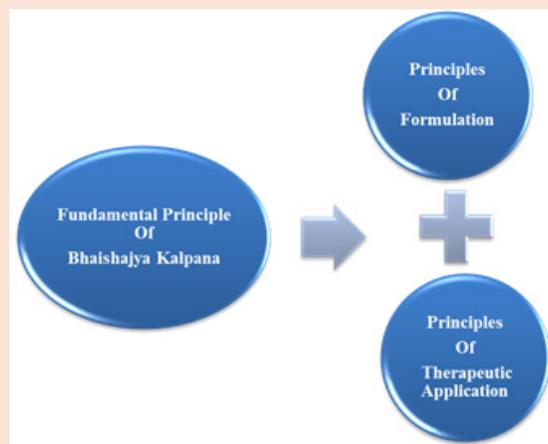
ABSTRACT

Fundamental Principles are essential concepts to understand the related subject. Every branch of science has its own basic principles. *Bhaishajya Kalpana*, a branch of Ayurveda is considered as Ayurvedic pharmaceuticals, also has its own principles regarding pharmaceutical Science (*Aushadha Nirmana*) and its formulations has been used in different therapeutics (*Aushadha Prayoga*) since ages but the principles associated with *Bhaishajya Kalpana* are not clearly indicated and are scattered. Therefore an endeavour has been made to review and reflect the fundamental principles of *Bhaishajya Kalpana* in systematic manner with their significance. Hence, the entire principles of *Bhaishajya Kalpana* are categorized into Principle of Formulation and Principle of Therapeutic Application. Complete understanding of these fundamentals is the prime key for successful research and development in Ayurvedic pharmaceuticals.

KEYWORDS

Fundamental principles, *Aushadha nirmana*, *Aushadha prayoga*, Pharmaceutical, Therapeutics.

PICTORIAL ABSTRACT



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1. INTRODUCTION

From the time immemorial, *Ayurveda* has given standard direction to mankind through their principles about art of living and science of health. *Ayurveda* aims to gain insight into the very core of a problem and seek to uproot the cause or problem with the help of *Ayurvedic* therapies and drugs (*Bhaishajya*). *Ayurvedic* drugs have traditionally been prepared as single or compound herbal/herbomineral with multiple dosage forms. Traditional formulations are enriched with a class of phytochemicals (chemical obtained from plant have proven biological action in animal body) possessing different medicinal properties. These phytochemicals are distinctly possible to have sophisticated and complex therapeutic properties which depend on their chemical composition.^[1] This is because the herbal formulation containing essential phytochemicals needs to be prepared strictly and deliberately following with Principles of *Bhaishajya Kalpana*. Principles of

Bhaishajya Kalpana (*Ayurvedic* pharmaceuticals) lay foundation for preparing the different types of basic single or poly-herbal and herbo-mineral *Ayurvedic* formulation and shows the path for unique management by utilizing ideally prepared formulation. These principles serve common ground for various formulation and therapeutics. Here, we require a greater understanding of concepts of pharmaceuticals to produce quality manpower for producing efficacious formulation and for their effective application.

1.1. Fundamental principle of *Bhaishajya Kalpana*

Bhaishajya Kalpana Adharbbuta Siddhanta can be called as fundamental principle of *Aushadha Nirmana*^[2] and *Aushada Prayoga* or *Art of Aushadha Nirmana and Aushadha Prayoga*.

Main aim of *Bhaishajya Kalpana* is to develop the quality dosage forms of *Ayurveda* formulation in order to achieve utmost therapeutical benefits but without the knowledge of proper

application of this formulation, desired therapeutic effects cannot be achieved. Hence principles of *Bhaishajya Kalpana* must include the principle for formulation and for application as well. Pharmaceutical study does not only include the drug manufacturing but also includes its dispensing to the patient in most suitable form and its application by the patients.

Thus, the comprehensive fundamental principles of *Bhaishajya Kalpana* are classified into following:

1.1.1 Principles for formulation (*Aushadha nirmana siddhanta*)

1.1.2 Principles for therapeutic application (*Aushadha prayoga siddhanta*)

1.2 Principle for the formulations

1.2.1 Paribhasha Siddhanta (terminology): Before acquiring the skill in pharmaceuticals, this is necessary to acquire the complete knowledge of *Shastra* and the terminologies mentioned in them. In *Ayurvedic* literature, certain technical terms are often used that are not precisely explained, some terms are not mentioned even or some are mentioned in brief form and some of the terms are much doubted. The appropriate adequate precisely explanation of these terms or statements are called *Paribhasha*. It is used to clarify the doubts regarding the description of drugs, manufacturing process and quantifying the ingredients described in classical texts. It enlightens the obscured meaning of context in classical statement.

1.2.1.1 Avyakta (hidden concepts): Some technical terms that needs to be deciphered for proper understanding, for instance, *tripbala* means here it indicates only three fruits but not names of the fruits. *Tripbala* are the combination of three fruits like *Amalaki*, *Haritaki* And *Bibhitaki*.^[9] Similarly there are many terms which needs to be completely enlightened.

1.2.1.2 Anukta (unspoken concepts): When there is no specific time is given in the *shastra* for taking medicine or collecting herbs, then it should be done during morning as depicted in *Sharangdhara Sambhita*.^[4] When there is no specific *Mana* of *Arishta Dravya* is mentioned then *Acharya Sharangdhara* stated as *Anukta manarishiesu dravdrone tulam gudam | ksodram kshipedgudadardham prakshepam dashamanshikam |*^[5]

1.2.1.3 Leshokta (less explained/concise): *Swarnadi lobapatranam suddhiresham prashasyate (rasa ratna sam.5/29)*^[6] here *swarnadi* is in concised form, indicates collectively the metals of *lauha varga* i.e *swarna*, *rajat*, *tamra*, *lauha*, *naag*, *vang*, *pittal kamsya*. and *varta lauha*.

1.2.1.4 Sandigdha (doubt/vague): If any ingredient is repeatedly told twice in shloka without giving their amount for the formulation then we must clear it by considering the amount of same drug as two times according to *Punarukta dravya mana siddhanta* mentioned in *sharangdhara sambhita*.^[7] Thus, getting hold of these terminologies with the help of *Paribhasha* will help in understanding concepts of *Ayurvedic* pharmaceuticals in better way.

1.2.2 Mana siddhanta (weight and measurement): Without the knowledge of *mana*, pharmaceuticals and

therapeutics will not be effective.^[8] *Mana* is certainly essential for manufacturing and dosing the medicines. In formulation, specific *mana* is mentioned for each drug especially in state of inclusive of *visha dravya* (poisonous drug). Improper ratio of ingredients (which is not mentioned in classical texts) in formulation will hamper the efficacy of medicine and may cause toxic effects whereas in therapeutic application if dose given is low then medicine would be worthless/ineffective and if dose is high it may produce adverse effects. Thus *Mana* plays a crucial role to formulate a medicine and for the management of the disease.

1.2.3 Panchmahabhuta Siddhanta (Five basic elements):

According to *Ayurveda*, every matter is made up of *Panchamahabhutas* (*akash*, *vayu*, *agni*, *jala* and *prithvi*). Therefore, each *Ayurvedic* drug is also made up of these *panchmahabhutas*.^[9] These *panchmahabhutas* concede the *Ayurvedic* drugs with multiple targets and properties by dint of pharmacological factors like *rasa*, *guna*, *virya* and *vipaka*. Target actions of each drug depend on the drug's intrinsic properties where these intrinsic properties in turn, partially depend on how the drug is collected and processed. Factors such as soil type, climatic conditions, storage, packaging and processing, influence the combination of *Panchamahabhutas*; which in turn affects intrinsic properties and target actions of the drug. Strict quality control is required for maintaining the intrinsic properties of the drug. Other relevant factors include correct identification and processing of the source herbs. Drug combination and dosage forms preparations are decided on the basis of *Panchmahabhuta*. Therefore this is more vital to understand the concepts of *Panchmahabhuta* in pharmaceuticals.

1.2.4 Aushadh vishishtata (qualities of medicine): Raw materials are the foundation of finished products hence it should be of good quality as stated by *Acharya Charak* that the *aushadhi* to be administered to the patient should possess the four ideal qualities 1.2.4.1 *babuta* (it should be available in abundant quantity) 1.2.4.2 *yogyatvam* (it should be effective) 1.2.4.3 *aneekavidha kalpana* (various pharmaceutical forms or multiple use) 1.2.4.4 *sampat* (richness in potency)^[10] and when formulation is prepared, it should possess the qualities as mentioned in *Charak Siddhi 6/15-16*^[11] With a smaller quantity of administration, the medicine should be capable of producing required effect, should have the potency to conquer more than one *dosha*, easily digestible, palatable medicines should be nutritive too, capable of skirmishing the disease, above all not antagonistic to the factors which are normal, should not cause any sort of discomfort on administration, should have acceptable qualities like colour, odour, consistency etc.

1.2.5 Rasa, Guna, Virya, Vipaka and Prabhav (Raspanchak): *Charak Sambhita* has described *dravya* to be the nucleus of *Ayurvedic* pharmaceuticals. *Dravya* is an essential and inevitable factor to human life. In *Ayurvedic* clinical practice it is essential to recognize the basic pharmacodynamics of the drug. So here, *rasa*, *guna*, *virya*, *vipaka* and *prabhav* collectively known as *Rasapanchaka* explains pharmacodynamics in *Ayurveda*.^[12] The assessment of these *rasapanchaka* helps in

understanding the probable pharmacological outcome of the drug. By knowing the pharmacodynamics the physician safely use the drug on apt conditions. *Rasapanchak* of single herb that are made up of combination of *panchmahabbutas* are the intrinsic properties responsible for their multiple action. A single drug performs different action through its *rasa, guna, virya, vipaka* and *prabhava*. Therefore the knowledge of *rasapanchaka* is very essential to formulate the medicines.

1.2.6 Panchvidha kashaya kalpana: *Acharya charak* mentioned *panchvidhakashaya kalpana* like *swarasa* (juice), *kalka* (paste), *kwath* (decoction), *hima* (cold infusion) and *phanta* (hot infusion)^[13] are the backbone of *Ayurvedic* formulation. These five fundamental preparation forms the basis for other preparation called secondary preparation.^[14] The potentiality of the medicines of the preceding category is greater than the succeeding ones,^[15] so these preparation should be prescribed with due regard to the strength of the patient and seriousness of the disease. Basic dosage forms are decided on the basis of *panchmahabbuta*. The *dravyas* having *apa mahabbuta* dominance will be more effective in cold infusion (*Hima kalpana*). *Dravyas* having *agni mahabbuta* dominance will be more effective in hot infusion (*phanta kalpana*).

1.2.7 Anukta visheshokta grahan siddhanta: When no time is specified in *the shastra* for taking medicine or collecting herbs, then it should be done during morning. When the part of plant is not specified then the root of the plant is to be used. When proportion in which different ingredients of recipe are to be added is not specified, then all the ingredients are to be taken in equal quantity. When kind of the *patra* (vessel) is not specified then the Clay pot is to be used. If the liquid to be used is not specified, then water is to be used. If variety of oil is not specified, then *tila taila* is to be taken.^[16] If in a formulation of *churna* or *ghrita* or *asava* or *avleba*, the type of *chandana* is not specified, then *sweta chandan* is to be used. If however, the recipe is a *kashaya* or *lepa*, then the *rakta chandan* should be used.^[17]

Vishesh siddhanta – *panchkool, vishesha* ingredients like *pippali, pippali-mula, charya, chitrak* and *saunth* are used in amount of 1 *koal* for each *dravya*.

This way one can make intuition for other words that are not specified in classical text. Hence this *siddhanta* is important to get understand the undescribed or unspecified terms.

1.2.8 Principles of taking raw drug

Identifi- Collection - Selection - Storage cation

1.2.8.1 Parichaya (Identification): Proper identification of raw materials is the first process of preparation of medicines. In *Sambhita* and *Nighantus* several synonyms are mentioned for drugs. Synonyms give an idea for the identification. For instance, *Pippali* (*Piper longum* Linn) has so many synonyms. *Magadhi* indicates place of abundant growth i.e. Magadha, *Krishna* describe external color i.e. black, *Kana* tell the external texture i.e. beaded appearances, *Usana* ascribe its pungent taste, *Upkuliya* is used for ecological description, *Koala* for its fruit weigh about 1 *Koal* (6gm)^[18]

1.2.8.2 Samgrahan (Collection): Action of *Ayurvedic* drugs depend on their intrinsic properties which in turn depends on how the drug is collected and processed. Factors such as soil type, agro-climatic conditions and *nakshttras*, influence the intrinsic properties of drugs.

1.2.8.2.1 Time of collection: In ancient time, it is advised to collect drugs facing towards East (east indicates vitalizing the plant energy through the sun) or North direction^[19] (the symbol of moon), it transfers its properties in plants and in *pushya, mrigshira, hastha* and *ashwini nakshatra*^[20] (these *nakshatras* are considered to be superior) mentioned in classical texts.

The general opinion for time consideration is that the time of collection should coincide when the active ingredients are at their optimum level and free from decomposition, example as latex of plants should be collected before sunrise or when they ooze out.^[21] Milky juice of *snubi* (milk hedge) is collected after two or three years old.^[22] *Bilva* fruits are collected just before their dehiscence^[23] and tamarind after their full maturity.^[24]

1.2.8.2.2 Collection of drugs: Characteristic of drug growing land: Ideal drug should be collected from perfect land. The characteristic feature of the land and region from where herbs are collected are mentioned in classical texts.^[25,26] Characteristic features of the herbs: The characteristic feature of the herbs to be collected are also mentioned in *Sushruta Sambhita*.^[27]

Collection of drugs as per *karma* (action): According to *Acharya Susruta, virechan dravya* (*purgatives*) should be collected from *prithvi and jala guna bhuyishta bhumi*, for *vaman dravya* (*emetics*)- *agni, akash, vayu guna bhuyishta bhumi* and for *samsaman dravya* (*palliatives*)- *akash guna bhuyishta bhumi*^[28] whereas *Acharya Sharangdhara* mentioned Collection based on *karma* w.s.r season that for *vaman and virechan* action, drug should be collected at the end of the *vasant ritu* and for the rest of the action in the *sharad ritu*.^[29]

Collection of drugs as per *virya* (potency): *Usna virya dravya* (*agneyaoushadha*) should be collected from *agneya bhumi* and *grishma ritu* and *Shita virya dravya* (*soumyaoushadha*) from *soumya bhumi and shita ritu*.^[30] Drug collection based on potency w.s.r *Vishesha sthan*- *usna and tikshna dravya* should be collected from *vindhyanchal* region and *shita prabhav dravya* should be collected from Himalayan region.^[31]

1.2.8.3 Selection of dravya (Dravya chayan siddhanta): Selection of different part of drugs and selection of these parts as per season: The active ingredients of particular part of the plants are at their optimum at particular season. Hence part should be selected accordingly. For *Dhataki* plant, flowers are to be selected, for *Snubi* plant, *kshir* (latex) is to be used, likewise for *Bijak* and *Khadir* plant, the *sara* (steam core) is to be selected.^[32] Different *Acharyas* given their different view regarding parts and season. For instance, According to *Acharya Charaka*^[33] in *sarad ritu* *twak* (Bark), *kanda* (Core wood), *kshir* (Latex) is selected whereas *Acharya Sushruta* mentioned only collection of bark in this season^[34] and in *Rajnighantu, Panchang* (whole part of plant) is to be selected.^[35]

1.2.8.3.1 Navin and prachin dravya grahan: In general, selected drugs should be fresh except *Vidanga* (*embelia ribes*),

Krishna (piper longum), *Guda* (jaggery), *Dhanya* (cereals and pulses), *Ajya* (ghee) and *Makshika* (honey)^[36] as potency of these drugs increases with the time.

1.2.8.3.2 Dry and wet dravya siddhanta: However, the general rule is to use a dry drug, only when it is freshly collected and dried whereas the wet drugs are to be used in double the prescribed quantity in all formulation^[37] barring the exceptions described below.

Ardra dravya prayoga (exception) General rule is to use all the wet drugs in double quantity except *guduchi*, *kutaj*, *vasa*, *kushmanda*, *shatavari*, *aswagandha*, *sabchari*, *shatpushpa*^[38] as given.

1.2.8.4 Abhava Pratinidhi dravya (drug substitution): It is the substitute drug in absence of original drug. The concept of *pratinidhi dravya* overcomes the problem of unavailability of the some drugs which are used in medicinal formulation. Substitutes are intentionally selected and utilize rationally to achieve the desired effect. The substitution is based on *Ayurvedic* principles that both the drugs should possess similar *guna* (properties) and actions means on the basis of pharmaco-therapeutically activity. For *astavarga dravya* can be substituted by *vidarikanda*, *shatavari*, *ashwagandha* and *varahi kanda*. Some instances shows similar morphological and chemical constitution of both *dravya* example *kushtha* (saussurea lappa) as substitute for *pushkarmool*.^[39] However, there are also instances where substitutes shows no similarities either in morphology or chemical constituents with the original drug example wood of *raktachandan* and root of *ushir*. In current period, the drug should be assessed on the basis of their *guna-karma* and further their analytical and clinical study to test its therapeutically efficacy, should be evaluated.^[40]

1.2.8.5 Storage of raw materials: To promote safety, efficacy and quality of raw material is the most important aspect in *ayurvedic* pharmaceuticals. This can be achieved by regulating the storage and handling of raw herbs for various *Ayurvedic* formulation. In ancient times, *Acharyas* were also concerned for proper storage of raw materials in order to protect from contaminants and to get ideal raw materials for the formulation. Storage house (*bheshajgraha*) should be free from dust and moisture and should be kept in proper container as mentioned in *Susruta Samhita* 38/82.^[41]

Nowadays strict rules and regulation are there in GMP for ASU drugs in T schedule of drugs and cosmetics act 1940 and rule 1945^[42] for storing the raw materials and finished products. Storage for raw materials should be free from cow webs, insects and rodents and should be under hygienic condition. Adequate provision of light and ventilation should be there, should be free from dampness and provide independent adequate space for raw material, packaging materials and finished products. Raw materials should be used in appropriate container to protect the quality of raw materials and to prevent from damage, dampness, contamination. Proper enclosures of raw materials by suitable cabin. Cabin refers to pots, jars, cartons etc. Raw materials of metallic origins, minerals, animal source, fresh herbs, dry herbs, volatile oil, perfume, flavors and plants extract or resin

are separately stored in suitable containers under hygienic condition.

1.2.9 Samskara: *Samskara* is an important concept and the prime essential of ancient ideology and is defined as transformation of the inherent attributes of a substance which leads to the addition of new properties according to *Acharya Charaka*.^[43] Usually *guna karma* of any *dravya* depends on conjugation and configuration of *mahabhutas* present in it. Hence with *samskara* modification occurs due to alteration in *panchmahabhuta* composition. This alteration may leads to addition of new properties and removal of impurities and toxicity of drugs as *Gunadbanam doshaparihara va Sanskarah*. Various new dravyas having different *guna - karmas* can be created by employing different *samskaras* to *dravyas*. This is created by dilution, application of heat, cleansing, churning, storing in a specific place, maturing, flavoring, impregnation.

Toya sannikarsh: *Jala mahabhuta* penetrates the *parthiv dravya* and loosens the molecular bonding and softens the hardness present in *parthiv dravya*. Thus allow the active principle to dissolve in water example *chincha panak*, *dhanyak hima*, *Agni sannikarsha:* *guru dravya* converted into *laghu dravya* with application of heat., *Shouch/shodhan* (purification): in *shatdhant ghrita*, *ghrita* is washed 100 times results in alteration of its intrinsic properties and *guggulu shodhana* in *Triphala Kwath*^[44] besides remove physical and chemical impurities, it also enhances the properties of *Guggulu*, *Manthan*(churning): This process also changes the property as given in example शोधकृत् दधि शोधयन् ससनेहमपि मन्थानात् |,^[45] *Desh:* refers to collection of drug from particular place example-*kesar* in kashmir, *pippali* in M.P and placing of *patra*, *Kaal* (duration- effect of season and time): time is to be given *mandak dhadhi*, *apakwa aam bilva* and season-collection according to season will have higher potency, *Vasan* (flavouring): *Vasana samskara* gives good fragrance to the finished product and increases therapeutic efficacy due to its volatile content e.g *kesar*, *kasturi*, *lavanga* in *avaleha* and *paka*, *Bhavana:* to increase potency of the formulation, it is necessary to impregnate the ingredient of a formulation with the juice or decoction of other drugs. When properly impregnated, even a small quantity of the drug becomes exceedingly effective. Therefore, ingredients should be impregnated with the juice or decoction of other ingredients having identical potency whereas Drugs of antagonistic potency are added to a recipe in order to impart desirable color, taste, touch and smell and as in case to reduce the *tikshna*, *ruksha*, *shita*, the juice of *viruddha guna* should be used, *Kaal prakarshopkram* (maturation): Some of the drugs should be collected when it gets completely matured as their potency also increases with time example *asava*, *dhatu*, *ras*, *Bhajanopkram* : *dadhi* and *ghrita* in *tamra patra* is harmful whereas water in *tamra patra* is very effective.

1.2.10 Designs of formulation (Yoga Nirmana) and Nomenclature (namakaran): *Ayurveda* has been considered all aspects of drug action, interaction synergism, antagonism in formulating the various yogas to make safe and acceptable. Preparation of ideal formulation includes four basic components are (i) *pramukh anshadha* (activator), (ii)

sabayak aushadha (potentiator) (iii) *updran*, *doshnashak prabhav dravya* (antidote) (iv) bioavailability enhancer. It may also includes (v) *dravya* for palatability (v) *dravya* for stability (vi) *dravya* for faster action. For instance, *Triphala Guggulu*.^[46] This is composed of *guggulu triphala* and *pippali* where *guggulu* is the main ingredient (activator) in this formulation possessing the main therapeutic action *shotbagna and vedanasthapana*, *triphala* (potentiator) due to its *vranashodhana and vedanasthapana properties* enhance the activity of the formulation and also it counteracts the side effects like constipation by its mild laxative action and burning sensation in eyes by its *chakshusya* action. *Pippali* act as bioavailability enhancer as it has *deepana pachana* action and due to its *yogavahi guna*.

Navayas lauba.^[47] This is composed of *triphala*, *trikatu*, *trimad* and *lauba bhasma* where *Lauba bhasma* is the main ingredient to treat *pandu*. *Triphala* –It facilitates absorption of *loba bhasma* due to its acidic media and counteracts the side effects of *lauba bhasma* like constipation and *triphala* acts as purgative. *Trikatu churna* -Increases appetite and improves digestion as it lacks in *Pandu*. *Madhu* and *ghrita* -These are used as *anupana* for *navayasa lauba* which are meant for fast action as well as palatability by virtue of their *yogavahi guna*.

Namakaran: For identification, distribution, verification and authentication of finished products, nomenclature is necessary. In Ayurveda nomenclature was given on the basis of drug name - *hinguleshwar ras*, *rogaghna* - *pramehantak vati*, *nirmata* - *nagarjuna ras*, *agustya haritki* but it has also seen that some of the formulation have similar name but having different ingredients so it is need to know about name along with ingredients and its indication. For patent medicines it is important to follow the guidelines of proprietary medicines for proper identification and verification.

1.2.11 Principles for different dosage Forms

1.2.11.1 Churna kalpana: Coarse powder is used for decoction in Ayurveda whereas fine powder (80 mesh size) is used for *churna* and *vati*. More finer the Particle more will be the absorption and also increases the bioavailability of *Ayurvedic* drugs.^[48]

1.2.11.2 Asava-arishta kalpana: Factors affecting kalpana are *Paatra* (containers) - in ancient time earthen pots considered but nowadays because of drawbacks of earthen pots, porcelain pots or stainless steels are used *Agni* (optimum temperature) and *kaal* (time duration).^[49]

1.2.11.3 Sneha kalpana: *Murchhana* - Before processing medicinal drug with any *sneha*, it must be previously gone through the process of *murchhana*, otherwise the therapeutic properties do not come completely in *sneha*. It removes disagreeable smell, removes *ama dosha* and increases potency of *sneha*.^[50]

1.2.11.4 Aushadh siddhi lakshana: The observance for the signs of siddha aushadha or finished products is the utmost important final stage of manufacturing after which there will be difficulty or hardly possible in alteration to the dosage forms. Hence the knowledge of proper *aushadha siddhi lakshana* is essential part of ayurvedic pharmaceuticals.

Nowadays besides classical parameter, the quality of dosage forms is being assessed only after through its analytical study and its compatible with their organoleptic characters different modern analytical parameters.

Classical parameter of different dosage forms are mentioned below

1.2.11.5 Sneha kalpana: the completion of *sneha paka* is conformed after (i) *varivat snehakaraka* (ii) *syat angulyavimardita* (iii) *shabdino agnikeshipta* (iv) *gandavarna rasotpatti* (v) *yada fenodhgamastaike fenshantishcha sarpishi*.^[51] (vi) *In mridu sneha paka* - "ishat saras kalke" *syu snehapaka mridu bhavet*, (vii) *in madhyam paka* "kalke niras komal" (viii) *in kbara paka* "ishat katin kalkashcha".^[52]

Avaleha kalpana: the criteria to determine the completion of *avaleha paka* are (i) *supakve tantumatvam syat* (ii) *avleho apsu majjati* (iii) *stbiratvam pidite mudra* (iv) *gandh varna rasodhbhar*.^[53]

1.2.11.6 Asava-arishta: the completion of fermentation process is conformed (i) when *prukshep dravya* will sunk completely (ii) no sound will be heard

(iii) no effervescence will be present (iv) the burning candle continue to burn, if it would brought near the fermenting media due to absence of carbon dioxide and so no change can be found in the lime water test (v) Nowadays it is also elicited by organoleptic tests and physico- phyto-chemical tests in order to obtain the consistent results.^[54]

1.2.11.7 Vati kalpana: The criteria to determine the final stage of vati preparation before making its pill is that it should not stick to the fingers when rolled in between two fingers. In modern era Parameters are given to evaluate the standard quality for vati kalpana such as hardness, disintegration time, dissolution time, water soluble extract, alcohol soluble extract.^[55]

1.2.12 Packing

Packing of drugs is considered as the art and science which incorporates manufacturing the articles for transport, storage, display and also for therapeutic uses. Although drug is prepared very efficiently and carefully but it is useless if not properly packed as it gets contaminated with extraneous substances and atmospheric changes and unsatisfactory packaging permits or fastens the degradation in the product. In *Ayurveda* while describing the *karana samskara*, *Charaka* has focused on *bhajana* to keep the materials.^[56] In *Susruta Sambita* it is advised to keep the products in tight cloth smeared with disinfectant materials made up of wood or mud.^[57] Packaging may consist of container, closures, carton. Different shapes and sizes of containers made from different materials are used for packing different types of formulation.

1.2.13 Storage of finished products

When medicine is prepared and if it is not stored properly then it will get spoiled thereby mentioned the qualities of the room in which finished products are to be stored. The room should have entrance towards East or North, should have free aeration, ventilation, there should be *gandha*, *dhupa*, *balikarmas*.^[58] conducted frequently. According to Schedule T

in GMP of Drugs and Cosmetic rule 1945, separate spaces for finished products are mentioned. Finished goods transferred from production area after proper packaging shall be stored in finished good stores within an area marked 'Quarantine. After checking the correctness of finished goods with reference to its packing and labelling as well as finished product quality as prescribed then it will be moved to "Approved Finished Good Stock area".

1.2.14 Saviryata Avadhi (Shelf life)

Ayurvedic medicines generally made up of herbs do tend to lose their herbal medicinal qualities over a period of time. It is important to gain the knowledge about shelf life of raw materials before undergo for processing and shelf life of finished products so as to abolish the expired drugs. It is the significant factor for dosing, storing and dispensing the medicines. The preservation and storage of *Ayurvedic* drugs is based on the shelf life. *Different Saviryata Avadhi* of different *Ayurvedic* dosage forms are mentioned in different classical books as in *sharangdhara sambhita*^[59] and *Vangsen*^[60] whereas in *Yogarajmakara*, *Saviryata Avadhi* for *swaras*, *kalka* and *kwath* are clearly considered as 3 hr^[61] and in current scenario the amendment of Rule 161 B of drug and cosmetic act 1940, specify the maximum Shelf life of *Ayurvedic* Medicine. The main factors affecting the shelf life are derivation of drugs, temperature, humidity, microbial contamination, dosage forms, storage and packing conditions.^[62]

1.3 Principle for therapeutic uses

1.3.1 Aushadha maatra (Therapeutic dose): Therapeutical property depends upon the dose. While administering the medicine, *matra* (dose) has to be decided, if the dose is too high it may cause harmful effects and if less dose is given, then it would not be effective. Hence the dose may be so regulated that the drug may produce the desired effects but may not harm the tissue.

1.3.2 Aushadha marga (Route of administration): The drug is administered through the channels of skin mouth eye, ear, nose, anus, urethra and vagina as per the disease and *dosha*. Nearby sites are selected for direct absorption and faster action of ideal prepared medicines example *basti*.

1.3.3 Aushadha sevan kaal (Time of administration): *Aushadha Kaal* also plays important role in absorption, for instance *abhakta*^[63] when drugs given on empty stomach, will have maximum effect on the body, as on an empty stomach the full of stomach and intestines are available which means more surface area for effective drug absorption. *Veerya Shakti* of *Aushadha* will not be changed enough in *Abhakta kala*, because it does not gets mixed with food.^[64] The rate of absorption of drug depends on *Agni*, presence and absence of food and also on surface area, hence affect the pharmacokinetic and pharmacodynamics of *Ayurvedic* medicines.

1.3.4 Anupan (Adjuvants): *Acharya Sharangdhara* has given the simile that the *anupana* along with base spreads in the body as the oil drop added to the water spreads in fraction of time.^[65] It indicates that when we administer the medicines with

anupana, it spreads quickly due to presence of *yogyabi* and *vyavayi* properties in it. It also enhances the potency of the medicine and brings about the desired effect when administered with suitable *anupana*. It increases digestion and absorption capacity.^[66]

2. CONCLUSION

Ayurveda has given standard parameter for manufacturing of ideal medicines through their principles. Without following these principles, achievement of efficacious formulation is not possible. An attempt has been made to collect all the scattered principles in proper way so as to follow them accordingly, hence classifying these principles in two groups are *Aushadha nirmana siddhanta* and *Aushadha Prayoga siddhanta*. Overall eighteen basic principles are there in this branch that is needed to be followed for their productiveness, quality and efficacy. Among these eighteen, above seven are cardinal principles and can be collectively called as *samanya* or general principles and remaining are the principles regarding formulation that includes from collection of raw materials and processing to the packaging and shelf life of finished products. Besides this, it is also important to have the knowledge of proper utility of *aushadha* including *aushadha matra*, *aushadha kaal*, *aushadha marga* and *anupana* since they incorporates in enhancement of efficacy of medicines and also to facilitate the faster absorption of medicines.

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The authors declare that there is no conflict of interest.

CONTRIBUTORS

Dr.Sani Mol Sunny did literature survey, data acquisition from various sources and design of the work. Dr Usha Sharma and Dr Shuchi Mitra contributed to provide valuable information and references. Dr Sushma Rawat contributed to conceptualization of the topic and manuscript editing. Prof. Khem Chand Sharma contributed to content editing and proof reading.

SUMMARY

In this present review an effort has been made to review and reflect the fundamental principles of Bhaishajya Kalpana in systematic manner with their significance In order to make

easy and in systematic manner, fundamental principles are categorized into principles of formulation (for preparation of medicines) and principles of therapeutic application (for clinical implication) and further formulation principles are comprised of general principles (paribhasha, maana, panchmahabhoota, ras-guna –viryya- vipaka), principles of raw drugs, principle of different dosage forms, shelf life, packaging and storage and the therapeutic principle includes dose, route of administration, time of administration and adjuvants. This way all the scattered principles are collected and formed in systematic manner and easy to understand.

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