

Significance of Excipients.....A Review

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Abstract

An excipient is a non-therapeutic substance and active ingredients which are essentially included in the development and designing of drug products. It is used for bulking up solid formulations and long-term stabilization. Excipient plays an important role in formulation that decide dosage form as well as Pharmacokinetics and pharmacodynamics of medicine. It also improves dissolution rate and bioavailability of the drug and also improve bulkiness, disintegration. Excipients can initiate, participate or propagate in chemical or physical interactions with drug compounds. Excipients as like other active pharmaceutical ingredients also need to be standardize and stabilize. Specific excipients are best suited for a particular dosage form so proper selection of the excipients is very much important as various interactions take place during its course of stay in formulation.

Keywords: Excipient, Formulation, bioavailability, pharmaceutical ingredients.

INTRODUCTION: Excipient are the substance or compound, other than the active pharmaceutical ingredient and packaging materials that affect finished product quality, in some cases making up almost entire formulation¹. It also ensured the physical characteristic of medicinal product like weight, consistency and volume that are necessary for the correct administration of the active principle and alter some of pharmacokinetic profile too². Excipients play a contributory role in presentation of medicines on account of their pharmaceutical properties which will ultimately effect on pharmacokinetics and pharmacodynamics of medicines. Thus, these have a considerable impact on therapeutic properties of drug. Perception of excipients in ancient Ayurvedic dosage form and compulsions of the excipients in modern pharmaceuticals are compared and analysed all parameter of pharmaceuticals. This may be amazing to note that in Ayurvedic pharmaceuticals, multi ingredient were included in same formulation to give maximum therapeutic effect as some are main ingredient and some may be considered as excipient in Ayurvedic formulation.

So, the concept of excipient is not new to the world of Ayurveda, as in reference of comprehensive research of excipients from authoritative book of D & C Act 1940 (The Drug and Cosmetic Act 1940) Schedule I, it was found that they were used since thousands of years with different names like Anupana, saha-pana, prakshep, yoga-opvahi etc. in Ayurvedic science. Definition of excipient are changing over time and approaching toward concept used in present scenario.

Aim and Objectives:

To study the concept of Excipients.
To study the systematic approach of Excipients.
To study the importance of excipients in drugs formulation.

Materials and Methods:

Ayurvedic and Modern Texts have been used to study concept of excipients.
Conceptual Study: Present study explains the importance of Excipients in Drug formulation.

Rationality in Concept of Excipient:

Excipient, the term comprises with verb 'excipere' which means to receive, to gather or to take out³.

This is very important property of excipient by which the medicine gets proper weight, volume & consistency. WHO has defined excipient --as the substance which is different than the active medicine which is accurately evaluated for stability & or included in a drug delivery system⁴

1. During manufacture process, when excipient is added, it aids in processing of drug delivery system
2. Protect, support and enhance stability, bioavailability or patient acceptability.
3. Assist in product identification
4. Enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.

International Pharmaceutical Excipients Council (IPEC) defines excipients as the substance other than the active pharmaceutical ingredients (API) used in pharmaceutical formulation, is appropriately worked out for the safety in order to help in processing, manufacturing, supporting & protecting so that the final product gets proper bioavailability, stability & patient acceptability. It also assists in product identification, effectiveness of drug delivery system & also improves features of safety of product.⁵ In Ayurvedic science, since clear cut description on the name related to the excipient was not found as such because of science driven by the concept that each natural material has Panchmahabhoota composition (Prithvi, Jala, Agni, Vayu and Akash) and have unique Rasa, Guna, Virya, Vipaka, Prabhava and Karma and every natural material have some property that may help in maintaining health as well as curing disease⁶. But in light of comparison with contemporary science, many ingredients in the Ayurvedic formulation may be considered as excipients that complies with recent concept of excipient.

Concept of Excipients according to Ayurvedic point of view

According to Ayurveda, Hetu (etiology), Ling (sign & symptoms) and Aushadh (medicine), are the three pillars of sick as well as healthy persons⁷. Out of which Aushadh is considered as main factor for the sake of diseased persons and also it plays an important role in Chikitsachatuspada (four basics of practice of medicine)⁸. Basically, their origin is from plant, metals & minerals and animals and with help of proper technology they are changed in the desired formulations and then it became suitable for consumption. Our Ancient text book give the complete

knowledge about to create the new formulation according to patient strength as well as disease strength. Ayurvedic physicians mainly gives combination of two or more drugs rather than a single drug, because due to combination (samyoga) properties of individual drug get enhance and it give optimal result.

The enhancing effect of drug due to combination of two or more is called is known as synergistic (sarvakarmaja) and opposite to that is, the antagonistic effect (dwandwakarmaja). Patients who strongly dislike to take medicine, for that there are some preparations with food materials which support with medicines. Example lehya (confectionaries), utkarika (bolus) etc.

Basically, Formulations were prepared according to the requirement. Example There are various formulation of Guggulu which are given according to need of patients. for example, Kanchanara Guggulu is given in lymph nodular swellings, whereas Triphala Guggulu for obese patients with arthritis and Punarnava Guggulu is use to treat arthritis associated with excessive swelling of the joints. Dridhabala added 12 chapter in original Charak Samhita which include kalpa sthana and siddha sthana which include group of medicine on the basis of type of ailment and strength of the patient⁹. and also, formulation which come under the group of excipients. While the designing the formulations, it is seen that number of ingredient varies from one text to another with their indication, some of them act as agonist/antagonist activity some act as sweetening agent in case of Avaleha, some are targeted as per etiopathology of that disease, and some used as binder for manufacturing of vati, Several ingredients are used in Ayurvedic formulation out of which some are main ingredient, some acts an antidote (tankana for vatsanabha), some are binders, some are bioenchancers, some acts as synergism (Yogavahi), etc. After

critical analysis of Ayurvedic formulation it is observed that lipid substance acts drug delivery substances rather than medicinal value while alcoholic medium play role in faster distribution of drugs and in bio absorption

Due to its unique features and its pharmaceuticals, Vati kalpana (tablet like dosage form) are oftenly used but it cannot possible without help of binding agent. Natural polymer like starch, gelatin, ascacia, pregelatinized starch and gums are used as binding agent¹⁰. They have also the properties like filler, sustain release, disintegrants and also are much safer and economical. In contemporary science bioenhancer and binder is considered as excipient. Example shunthi, marich, pippali, honey etc. Pippali (ingredient of Trikatu)¹¹ trikatu etc improve palatability and are bio enhancer which considered as excipient in contemporary science¹².

According to requirement of patients manjistha trijatak, manjistha etc used as flavouring agent. In case in paediatric preparation for better palatability flavouring agent are used e.g. Avaleha, syrup. Similarly, in sandhan Kalpna alcoholic substances which are formed during process act as preservative and also support for better absorption¹³. Ayurvedic formulations are designed according to need of the patients. Some ingredients play major role as per disease condition, some act as drug delivery system and ingredients, some ingredients interact to each other to subside adverse effect of other and get optimal result.

After comprehensive analysis of literature in Ayurveda, it was found that many ingredients that can be called as probable excipient [Table 1 and 2]. In herbo-mineral formulation, water, cow urine, kanji, tail are used to remove toxicity and also, they add some properties like porosity, brittleness, and also increase surface area because of the

presence of herbal exudate like tannins, alkaloid.

Table No .1 Probable Excipients in Ayurvedic Formulation

Sr no.	Ayurvedic Formulation	Probable excipients in correlation with Guideline of IPEC
1	Swarasa	Prakshepdavya
2	Kalka	Prakshepdavya
3	Kwath	Prakshepdavya and anupana
4	Churna	supportive ingredient for taste and flavour, Anupana, sahapana
5	Vati	Smoothing agent like ghee and Bhavnadravya, sometimes enhancer, binder,
6	Avaleha	Sugar, prakshepdavya, ghee, tail
7	Snehadravya	Some herbal constituents, Tail, Ghee(Lipid content)
8	Asava/Arista	Self-generated Alcohol during procedure and some herbal constituents, water

Proper anupan were indicated with the above formulations, this may be also called as excipient.

Bhavna dravya were used in some metallic preparation which acts as chelating agent which result to give less toxic medicament in final product e.g. Triphalakwath in loha [iron] In this shodhan process chelates iron and copper and which reduces UV-induced erythema¹⁴. Similarly, bhavnadravya which is used in bhasma preparation it also remains after bhasmikaran procedure that

cause attached with metallic medicament and probably encircled it¹⁵.

“Yogvahi” may be call another name for excipients which use as bioenhancer .example in “Trikatu”. Here piperine was one of the ingredients as “Yogvahi” where Black pepper is supporting evidence. Naturally occurring excipient are relatively safe and also increase the bioavailability and absorption of the co-administered drugs.

The term excipient was not only used in the Ayurvedic classics but also in Shastra.

Table No.2 Probable Excipients in Ayurvedic Formulation

Sr no	Formulation	Excipients	Line of action	Reference
1	Amrita swaras	Honey, Turmeric	Prakshepdavya	Sha. S. M 1/7
2	Vishnukranta Kalka	Honey, sugar and ghee	Prakshep, sahapana	Sha. S. M 5/17

3	Abhayadi Kwath	Pippali	Sahpana, prakshep	Sha. S. M 2/ 32-34
4	Dhanyak Hima	Sugar	Sahpana	Sha. S. M 4/7
5	Amradi Phant	Honey	Sahpana	Sha. S. M 3/6
6	Kuberakshadi Vati	Jala	Bhavana Dravya	Bhai.R. Parisista/57-60
7	Prataplankeshwa rasa	Adrakswarasa	Bhavanadravya	Bhai. R. 5/839- 857
8	Eladigutica	Dalchni, Mulethi, Pippali	Flavours, Sweeteners, Flavours, Bioenhancer	Bhai. R. 13/42- 45
9	Sanjivanivati	Gomutra, Adrakswarasa	Bhavanadravya/ Anupana	Sa. S. M 7/18- 21
10	Yogarajguggulu	Dhanyak and Dalchni	Flavours	Chakradatta 25/27-32

[Sha. S M (Sharangadhar Samhita Madhyam Khand), Bhai R (Bhaisajya Ratnawali)]

Concept of Excipients according to Modern point of view:

Now a day manufacturer has several excipients, which are of plant origin, like guar gum, pectin, acacia, cellulose, starch, agar, xanthan gum and gelatine. These are used as protective add, colloids, thickening agents, gelling agents, binding agents, disintegrates, sustaining agents,

Now a day Natural excipient can be used in drug delivery system based on their properties example, alginate [matrix type alginate gel beads, in liposomes, in modulating gastrointestinal transit time, for local applications and to deliver the bio molecules] and gums [for different NDDS application]¹⁶. pectin [ethyl cellulose film makes it colon drug delivery system, control fragrance release], polysaccharide [degradable in colon by microbial flora], These are chip, easily available, nontoxic and has capacity to chemically modify, biocompatible, biodegradable¹⁷.

Role of Excipient in Development of Dosage Form:

Now a day Ayurvedic dosage form are becoming more advance and their chronological development from swarasa to most recent capsule and aerosol is generally based on the excipient which used for proper desirable effect. In Bhaisajya Kalpana there are five basic kalpana [pharmaceutical dosage form] in which some ingredients were also work as excipients. In the basic dosage form like Swarasakalpana prakshepdravya was also mentioned in order to for enhance therapeutics effect or for taste to make it palatable¹⁸. In Kalka [paste] plant fiber with their extract were used, here plant fiber is naturally supplied excipient along with that some excipient was added to enhance. In Decoction heating procedure is involved to get maximum yield of extract. Here hard and dried materials are mostly taken. For those whose active principles are lost on boiling, for that Phant dosage form developed. Some bioenchancers along with some taste and flavouring agents are added in churna Kalpana. This are given with suitable vehicle. Without use of tail [oils], Sneha Kalpana cannot be done.

Here it acts as a carrier for both water and lipid soluble in the form of noisome and liposome. Here those surface which are resistible to absorption in deep tissues¹⁹, they act as carrier for that. For giving faster absorption and distribution Asavaarista was developed. It helpful to energize the bio system. Here Self-generated alcohol serves as hydro alcoholic milieu for continuous extraction and preservation of the extract and also play an important role in bio absorption, enhancing bioavailability and to increase shelf life of the formulation²⁰. In some formulations due to have low dose, it gets difficult to convert into unit dose so in that case diluent was used. Example Marich [Piper nigrum] used in Gauripasana. By using several types of excipient as preservative, self-generated alcohol [Sandhan Kalpana], Sugar [Avaleha], oils/lipids [Sneha Kalpana] etc. the stability period get enhanced. Now days as Gellan gum [microbial origin], Scleroglucan [marine origin] and chondroitin sulphate from animal origin have been used. For sustain released formulation Locust gum and xanthan gum are widely in used²¹. Ginger used as not only binder but also bioenhancer and also used with different antibiotics [azithromycin, erythromycin, cephalixin, cefadroxil, amoxicillin]²². Basically, Pharmaceutical processing depends on many important factors such as route of administration and shelf life of final product, nature of the raw material, required concentration of the dosage form, solubility and heat stability²³. Now a day, Ascorbic acid derivatives [ascorbyl glycoside] which used in Drug nanoparticle formulation act as carrier compound and also act as antioxidant²⁴. Natural polysaccharides are incorporated to those target delivery of the drug to a specific site in the gastro intestinal tract [GIT], but this can be overcome by using various mechanisms like coating granules, pellets, tablets with polysaccharides, which make

polysaccharides useful in the colon-targeted drug delivery systems²⁵. Classification of Excipients: Basically natural excipients are heterogeneous compounds and mainly divided into three categories 1) First category [approved excipients]. It is [generally recognized as safe: GRAS] and originating from the food industry. 2) Second one is the intermediate category [essentially new excipients] It is obtained by already approved excipients by getting the means of the structural modification of it. The third category covers totally new compounds, which never used before.²⁶

List of Excipients [27-36]

1) Diluents: If tablet is inadequate to produce the volume, Diluents are fillers used to make up the volume of tablet. It is used as disintegrates in dispersible and orally disintegrating tablet.

Example: Calcium sulphate dehydrate, Sorbitol, Lactose, Dibasic calcium phosphate dehydrate etc

2) Binders: Binders provides cohesive strength to powdered materials and can be added in both dry and wet form to form granules. It used as binding agent in the tablets.

Example: Gelatine, starch, Acacia glucose, Lactose, cellulose derivatives- Methyl cellulose, Ethyl cellulose, Hydroxy propyl cellulose, Sodium alginate, etc.

3) Lubricants: It help to avoid the friction between die wall and tablet, prevent adhesion of tablet to dies and punches. Thus, it also helps in easy ejection of tablets from die cavity. It mainly classified in to two types: -

Example: 1) Insoluble- Magnesium stearate, Paraffin, Talc, Calcium stearate.

2) Soluble- PEG 400, 600, 8000, Sodium benzoate etc.

4) Glidants: It minimize friction between particles and helps in free flowing of granules from hopper to die cavity.

Example: Cornstarch, Talc, Colloidal Silicon dioxide [Aerosil] etc.

5) Anti-adherents: Avoids sticking of tablet to punches dies. Example: Talc

6) Super-disintegrants: It breaks down in to small particles when it come in contact with water in oral cavity, Example: Starch, Sodium starch glycollate etc

Role of Super disintegrants in the manufacturing of tablets

Ideally an oral solid dosage form must be dispersing into the primary particles from which it was prepared. Traditionally, starch is widely used as disintegrant in tablet formulations. [37-46]

In tablet formulations as well as in in some hard -shell capsule, Disintegrating agents are used to promote moisture penetration and dispersion of the dosage form in dissolution fluids.

Characteristics of disintegrate

- It must have poor solubility as well as poor gel formation.
- Good compressibility as well as hydration capacity.
- Does not have capacity to form complexes with the drugs

Factors affecting action of disintegrants

- Percentage and combination of disintegrants present in the tablets.
- Types of substances present in the tablets.
- Screening and Mixing
- Hardness of the tablets.
- Presence of surfactants.
- Nature of Drug substances.

Even though excipients are the non-active ingredients, they are still plays an important in the successful production of liquids orals, parenteral⁴⁸, powders, tablets, semi solids in acceptable dosage form. For the compression of 1 mg dose tablet of potent drugs is quite challenging in such case excipients can add pharmaceutical products and thus it gives opportunities to introduce new dosage forms⁴⁹

The following are essential properties of excipient:

1. It must be Physical as well as chemical stability.
2. Does not affect on drug bioavailability.
3. Free from pathogenic microbial organisms.
4. It must be Cost effectiveness.

DISCUSSION AND CONCLUSION

Excipients is one of the important component of medicinal products, and have the major share in a formulation, by showing their unique pharmacokinetics and pharmacodynamics action to complete the target of medicine, so for safety and stability it must be must be evaluated first. Now a day, synthetic excipients were widely use but when the safety and cost was considered we have to look towards traditional concept of using excipients. In Ayurvedic pharmaceuticals natural excipients which are used, basically fulfil all the basic requirements like safety, efficacy quality, cost effectiveness. To assure safety and stability certain testing procedure were carried out where they have to subject extreme conditions of humidity, temperature and if the test is in favour then they are further tested for assuring safety. This safety assurance of excipients helps to design an effective and safe dosage form of formulation and thus we get optimal effect to cure the disease.

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