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PHARMACEUTICAL EXCIPIENTS AND THEIR ELABORATIVE APPROACH

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ABSTRACT: Drug delivery refers to administering pharmacological substances for therapeutic purposes. The pharmaceutical sector is rapidly evolving, exploring various dosage and administration methods, including targeted immunotherapies, which often require innovative excipients. The choice of excipients significantly affects drug characteristics like onset of action, bioavailability, and stability. This review focuses on diversifying pharmaceutical excipients, particularly highlighting multifunctional excipients derived from natural sources, including marine and animal origins, due to their non-toxic, biocompatible, and cost-effective properties. In light of the complexity of drug formulations, it emphasises the growing need for innovative excipients. Additionally, covered in the review are excipient classifications, their functions in drug delivery systems, safety profiles, regulatory concerns, potential interactions, new market entrants, and selection criteria. In conclusion, a thorough review of excipients in drug delivery systems is given in this work.

INTRODUCTION: The Latin "excipere," from which the word "excipient" is derived, implies "to except" or "other than." Everything other than the active pharmaceutical ingredient is referred to as a pharmaceutical excipient. The pharmaceutical sector is essential to the world since medications are essential for curing illnesses. Repeatable dosage, quality, efficacy, safety, stability, and patient compliance are all guaranteed by pharmaceutical dosage forms ¹. Due to the risks and costs of pharmaceutical research, many believe

medications should be developed to meet all human needs and distributed based on necessity. The pharmaceutical industry is vital for global economic progress by creating new medicines and improving patient lives. Common dosage forms include pills, syrups, inhalers, injections, and herbal products. Excipients, which are inactive compounds, are added to pharmaceutical formulations to aid in production, stability, bioavailability, and patient acceptance.

In addition to improving stability, maintaining pH and osmolarity, and acting as antioxidants, emulsifying agents, and tablet binders, they can also affect the solubility and efficacy of active ingredients (APIs). Excipients are essential to the production and safety of drugs, according to research ^{1, 2}.

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Up to 90% of a medication's mass or volume might be made up of pharmaceutical excipients, which frequently surpass the amount of the active pharmaceutical ingredient (API) ^{3, 4}. Natural excipients have gained interest for their varied pharmaceutical applications. Natural polysaccharide polymers enhance drug stability, bioavailability, patient acceptability, and product identification. The term 'multifunctional excipients' refers to ingredients that perform various roles in dosage forms, while 'high functionality excipients' refer to individual excipients that boost the effectiveness of new drug delivery systems at lower costs ⁵. The main goal of using multifunctional excipients is to enhance desired features while masking undesirable ones. A key example is silicified microcrystalline cellulose,

which combines colloidal silicon dioxide and microcrystalline cellulose ^{6, 7}. Agar, alginates, starch, and guar gum are examples of plant-based pharmaceutical excipients that are frequently utilised in the industry as coating materials, thickening agents, binders, and stabilisers ⁸. The major goal is to draw attention to different kinds of excipients, safety difficulties, and regulatory considerations. In the pharmaceutical sector, excipients can come from a variety of sources, which does not necessarily ensure quality and calls for meticulous testing. Unique excipients in new medicine delivery and manufacturing enhance patient compliance, offer different delivery routes, improve safety profiles, and enable access to new medical advances, addressing gaps in healthcare.

Main Requirements of Excipients:



FIG. 1: MAIN REQUIREMENTS OF EXCIPIENTS

Roles of Excipients:

1. Assist in drug delivery system production.
2. Improve bioavailability and patient acceptability.
3. Assist with product safety and identification.
4. Enhance drug efficacy.
5. Maintain drug integrity during storage.

Need for developing new Excipients: Excipients are essential to the pharmaceutical sector. In an effort to standardise purity and functioning testing requirements, the International Pharmaceutical Excipients Council (IPEC) represents the United States, Europe, and Japan. Up until now, the emphasis has been on creating novel excipients in

response to consumer demand rather than through marketing tactics, and this field has seen little action for a number of years ^{8,9}.

But the elements influencing the hunt for novel excipients are:

- A. The need for an optimal filler-binder that can replace two or more excipients and the increasing acceptance of the direct compression technique
- B. Tableting technology is expanding its speed capabilities, requiring excipients to retain acceptable compressibility and low weight fluctuation even at short dwell durations.
- C. Current excipients include poor die filling due to agglomeration, high moisture sensitivity, and

loss of compaction of microcrystalline cellulose (MCC) during wet granulation.

Ideal Excipient Properties:

- ❖ The product should be stable and reproducible.
- ❖ It must not interact adversely with drugs.
- ❖ It should be pharmacologically inactive.
- ❖ It needs to fulfil the desired functionality.
- ❖ Additionally, it should be low-cost.

Excipients Play Various Roles in a Formulation. here are Some of their Main Functions:

- Manufacturing of drug delivery system enhancing the bioavailability, stability and patient acceptability
- Support product identification and safety.
- Improve drug effectiveness and delivery.
- Maintain drug integrity during storage.

New (Novel) Excipients: The FDA's database of inactive ingredients frequently does not include chemically changed excipients that produce new or novel agents. The terms "new" and "novel" are difficult to define for excipients¹⁰. If an excipient is not in the current list, it is regarded as new. Database of FDA Inactive Ingredients:

As if any minor modification any change in the chemical composition of an excipient creates a new excipient. Mixtures of excipients can also result in a novel excipient if they are used in a dosage form not previously utilized for those excipients. Physical modifications, like micronizing, do not typically create a new excipient.

Novel Excipients Include:

- Chemically modified excipients and new chemical entities (NCEs)
- New applications for already-existing excipients
- New grades within excipient families that already exist

- Distinct quantities, grades, or administration methods from those previously examined, co-processed excipients that were previously utilized in products that were approved.

Requirements for New Excipients: Although a monograph is not legally required for the commercialisation of an excipient, suppliers should abide by it in order to meet regulatory requirements. Major pharmacopoeias (USP-NF, Ph. Eur., and JP) are superseded by national pharmacopoeias, which establish quality standards for excipients. Excipients should be presented by suppliers with a monograph or other pertinent documentation.

Multifunctional Excipients: There is increasing interest among formulation pharmacists and pharmaceutical companies in developing excipients with enhanced physico-mechanical properties of products¹¹.

Excipient Monograph Includes:

- Monograph Name: Primary name in compendia.
- Official Title: Name commonly used in industry.
- Definition: Assay acceptance criteria as a percentage range.
- Packaging and Storage: Specific conditions for protection.
- Labelling: Requirements to differentiate grades (e.g., by molecular weight).
- Description: Characterization of chemical structure, molecular weight, physical form, and solubility.
- Identification: Tests confirming identity.
- Composition: Tests for concomitant components, organic/inorganic content, and residual solvents.
- Assay: Test for quantifying excipient content.
- Other Tests: Additional tests for pH, preservative content, or endotoxin as needed.

Excipient Grades: Pharmaceutical excipients come in various grades, differentiated by their physical and chemical properties. They serve several functions in tablet formulation, including:

- ✚ Essential manufacturing functions (binders, glidants, lubricants)
- ✚ Enhancing patient acceptance (flavours, colourants)
- ✚ Aiding product identification (colourants)
- ✚ Optimizing the release of drug drug by changing the amount of hydrophilic polymers, disintegrants, biodegradable polymers, wetting agents)
- ✚ Improving stability (antioxidants, UV absorbers)

Grouping of Excipients according to the US National Formulary ^{12, 14}:

- The pH of formulations can be adjusted and maintained with the use of acidifying or alkalising agents.
- In the gastrointestinal tract, disintegrates help tablets or capsules break up. Expulsion of the formulation from pressurised containers is made possible using aerosol propellants.
- Immiscible compounds can be mixed with the help of emulsifying or solubilizing agents.
- Antifoaming chemicals stop or lessen the production of foam in formulations.
- Glidants enhance powder combinations' flow characteristics.

- Antimicrobial preservatives prolong the shelf life of products by preventing bacteria development.
- Humectants keep formulations moist and stop them from drying out.
- Antioxidants stop the active substances from degrading oxidative.
- When compressing tablets, lubricants lessen friction between the constituents.
- In solid dosage forms, binder aids in keeping the components together.
- A semi-solid foundation for drug distribution through the skin is offered by ointments.
- Plasticizers improve coatings' flexibility and film-forming characteristics.
- Bulking agents increase bulk to formulations while maintaining medication efficacy.
- Co-solvents increase the solubility of poorly soluble medicines.
- Coloring compounds enhance the look of medicinal compositions.
- Sweetening compounds enhance the flavour of oral drugs.
- Coating agents protect tablets and regulate medication release.
- Suspending agents contribute to the uniform dispersion of insoluble particles in liquid compositions.

TABLE 1: EXCIPIENTS' IMPACT ON MEDICINE TREATMENT OUTCOME

Excipient	Indication	API	Excipient's Role
Nanoparticles (Albumin)	Bladder, Breast and other cancers, Pancreatic	PXT {Paclitaxel}	Used as Drug (Carrier) of drug ¹⁵
Chitosan, different oil excipients, lecithin	Rheumatoid Arthritis	Statins	high payloadneed for Drug Carrier ¹⁶
Leucine, trehalose	human papilloma virus (HPV)	Virus like particles for HPV	vaccines need for cold storage ¹⁵
Dextrose and Mannitol	Alzheimer's , Parkinson's	A range of growth factor therapies	Mainly Used as (Carrier) of drug ^{17, 18}
Adeno-associated virus			

Natural Excipients: Nature offers a variety of materials, known as natural excipients, which enhance the health of living things. Recent interest in these excipients has grown due to their diverse

pharmaceutical applications. Derived from plants, animals, and minerals, natural excipients improve stability, bioavailability, and patient acceptability. They are favored for their abundance, safety, compatibility, cost-effectiveness, and eco-friendliness compared to synthetic alternatives.

Additionally, plant-based excipients are renewable and sustainably sourced, contributing to their increased demand¹⁹. The wide use of excipients is based on their qualities and molecular weight, with natural polymers being a primary focus in medication production research²⁰.

TABLE 2: CLASSIFICATION OF NATURAL GUMS BASED ON THE CHEMICAL STRUCTURE

Chemical Structure	Examples
Glucomannans	Konjac glucomannan ²²
Tetrahetero glycans	Psyllium seed Gum, Gum Arabic ²⁵
Penta-heteroglycans	Gum ghatti, tragacanth ²⁶
Tri-heteroglycans	Gellan gum, Arabinoxylans ²⁴
Galactomannans	Fenugreek gum, guar gum, cassia gum, tara gum ²¹
Uronic acid conjugating systems	Xanthum gum ²³
Based on shape	
Shape	Examples
Linear shape	Cellulose, pectin, Algins, amylase ²⁷
Branched type, Branch on branch, Short branches	Tragacanth, gum arabic, Amylopectin ²⁸
	Xanthan, Xylan
Based on charge	
Category	Examples
Gums (Anionic)	Arabicgum, kayagum, tragacanth, gellan gum, agar, algin, Carrageenan ³⁰
Gums (non-ionic)	arabinans, cellulose Guargum, locust bean gum, , Xanthan gum amylase, and Galacto mannans ²⁹
Gums (Cataionic)	Chitosan ³¹
Based on gelation behaviour	
Gels	Examples
Re-entrant gels in this galactose residues are removed	Xyloglucan ³⁴
In Cold set gels form gels on cooling the solution	Gellan gum, flexed gum, Gelatine ³²
Heat set gels form gels on heating any formulation	Konjac glucomannan ³³
Based on origin	
Origin	Examples
From Plant extracts	Pectin, larch gum. ³⁷
Seaweeds like	Alginic acid, sodium alginate, agar-agar, carrageenan ⁴⁰ .
Exudates from Microbial	Gellangum, taragum, xanthan gum, dextran, spruce gum ³⁹ .
Plant exudates	karaya gum, locust bean gum, Arabic gum, acacia gum, tragacanth, gumgathi, chicle gum, and Konjac glucomannan ³⁶ .
From Animal origin	Chitin, chitosan, chondroitin sulfate, hyaluronic acid ⁴¹ .
From Seed gums	Guar gum, tamarind gum, ipomea, locust bean gum, karaya gum ³⁵ .
Roots and Plant tuber	Potato starch ³⁸ .

TABLE 3: NATURAL PRODUCTS INCLUDE NATURALLY OCCURRING POLYMERS AND DERIVATIVES⁴²⁻⁴⁵

Name	Use
Sperminea bile acid	Used as a DNA transfixion agent
De-acylated saponin	Surfactant
Spermidine	lipid peroxidation Inhibitor
Phytic acid	Protein stabilizer
Sialic acid	Avoiding RES drug delivery
poly galacturonic acid Galacturonicacid	Used as a Contrast medium in MRI
GalactosylatedHistoneH1	Liver gene delivery
Biopolymer	Protective coating for liposome
Cyclodextrins	Solubilizer for hydrophobic molecules
Phospholipids	Liposomes
Fibronectin	Protein stabilizes
Enoxaparin, heparin	Protein stabilizer
Squalene, squalane	Vaccine adjuvant
Phosvitin	Protein stabilizer

Transferrin Phosvitin – galactomannan conjugate	Ligand inreceptor-mediated gene delivery Emulsifier
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Synthetic Polymer or Modification^{46, 52}:

- ❖ Tyloxapol improves dendrimer-mediated drug delivery, whereas hydroxypropyl methacrylamide is employed for targeted drug delivery.
 - ❖ Histidylpoly (lysine) promotes endosomal egress and increases transfection efficiency.
 - ❖ Poly-fumaric and poly-sebacic acids improve the bioadhesive characteristics of polymers. Steryl poly (lysine) is used for nonviral DNA transfer in complex formation.
 - ❖ PLA-POE block copolymers regulate medication release and inhibit protein adsorption.
- ❖ PEG-poly (lysine) or polyaspartic acid block copolymers serve as polymeric micellar drug carriers. PLGA is commonly utilised for long-term medication delivery.
 - ❖ Poly-aspartic acid and poly-glutamic acid are hydrophilic analogues for hydrophobic compounds, while
 - ❖ POE-poly (-benzyl L-glutamate) is used in nanoparticle-based hydrophobic medication delivery.
 - ❖ Poly (amidoamine) dendrimers serve as vaccination adjuvants, facilitating drug entrapment and increasing transfection.

TABLE 4: THE USE OF SYNTHETIC POLYMERS TO MODIFY NATURAL PRODUCTS^{57, 60}

Name	Use
Galactosylatedpoly (lysine)	For vector as a Gene delivery
Carboxy phenoxy propane: sebacic acid copolymer	In the Implantable drug-delivery system
Polyrotaxanes	Various Drug delivery
Galactosylated Poly (ethyleneimine)	Lectin-mediated gene transfer to hepatocytes
Polyoxy ethylated derivative of castor oil	Emulsifier and also Surfactant
Tocopherol–PEG–succinate hepatocytes	Antioxidant or solubilizer in formulation
SP-B:poly(lysine)	Vector in Gene delivery
Alpha-2-Macroglobulin: poly (lysine)	Gene delivery vector

Modification of Natural Commodities or Polymers Using Small Molecules:

- Di-galactosyl glycerol is a key component in liposome formulations, whereas chlorogenic acid-chitosan is water soluble at basic ph.
 - Proteinoids, or acylated amino acid polymers, make oral protein administration easier. DOSPA, when combined with histamine- or protamine-derived peptides, increases lipid-mediated gene transfection. Acylcarnitine reduces adverse effects, but palmitoyl glycol
- chitosan is used in controlled drug delivery design.

 - N-octyl-glucoside is used in proteoliposome production by detergent-mediated dialysis.
 - Sulfolipocyclodextrin derivatives and cyclodextrin sulfobutyl ethers serve as solubilizers, vaccination adjuvants, and anti-hemolytic drugs. 3-[(3-cholamidopropyl)-dimethylammonio]-1-propane sulfonate is an efficient solubilising substance.

TABLE 5: ENGINEERING OF SYNTHETIC POLYMERS WITH POLYMERS^{66, 70}

Name	Uses
Polypeptides, DTPA	Delivery of drug
Long-chain alkyl amine substituted polyacrylic acid	As a Solubilizer
ethyl acrylic acid and propyl acrylic acid	pH-dependent membrane lysis

Advantages of Natural Excipients: Natural excipients are safe, biodegradable, and environmentally benign because they are made from natural resources. They are non-toxic because they are primarily carbohydrates chemically. They are typically cheaper and have lower manufacturing

costs than synthetic excipients, and they do not cause adverse effects in humans. Additionally, they are widely available from various natural sources.

Advantages of Natural Excipients Include:

Biodegradable: They are produced by living organisms and pose no environmental harm.

Biocompatible and Nontoxic: As carbohydrates, they consist of non-toxic monosaccharide units.

Economic: Generally cheaper with lower production costs.

Safe: Their natural origin ensures they have no side effects.

Easily Available: Commonly produced in many countries. However, a disadvantage is the potential for microbial contamination during production due to exposure to the environment.

Variation: Synthetic manufacturing involves controlled processes with fixed ingredient quantities, while natural polymer production varies due to environmental factors. The hydration rate is inconsistent due to differences in material collection related to region, species, and climate, leading to variations in chemical composition. Additionally, the reliance on environmental conditions results in a slow production rate for natural polymers⁷¹.

Marine-Original Pharmaceutical Excipients:

Numerous polymers derived from microbes and marine sources are valuable as pharmaceutical excipients because of their significant biological characteristics, such as biocompatibility and biodegradability.

Marine and animal-derived chemicals are more affordable, chemically inert, biodegradable, ecologically benign, and easily accessible than synthetic polymers¹⁸. Prion infections are among the safety issues with excipients originating from animals, which prompts more research and refining to reduce pollutants. Certain animal products may also be prohibited by religious convictions⁷².

Agar: A major source of polysaccharides, seaweeds are a particular type of multicellular marine algae. The three groups are brown, green, and red, with the latter also being separated.

The development of marine algae that reach and settle in coastal regions has resulted in the widespread usage of marine compounds in the manufacture of a variety of products, including cosmetics, food supplements, and emulsifiers. *Gelidium cartilagineum* and *Gracilaria conchoides* may be found in the seas around Japan, New Zealand, South Africa, Southern California, Mexico, Chile, Morocco, and Portugal. Agar is made up of two primary polysaccharides: heterogeneous agarose and linear agarose^{73, 74}. Agar is used as a surgical lubricant, pill disintegrant, gelling agent in suppositories, emulsifying agent, suspending agent, and bacterial culture medium⁷⁵.

Carrageenan: Made up of galactose and 3,6-anhydro galactose units, carrageenan is a high molecular weight sulfated polymer found in marine environments. Red algae belonging to the *Eucheuma* and *Kappaphycus* genera are used to make it. For cell encapsulation, hydrogels based on carrageenan and other marine-derived polymers have also shown promise⁷⁶. Research has indicated that carrageenan is a viable excipient for use in preparations involving controlled release. Carrageenans are classed based on the degree of sulfation they contain: if they include one, two, or three sulphate groups, they are called kappa (κ), iota (ι), or lambda (λ). The simple extraction method involves immersing⁷⁷.

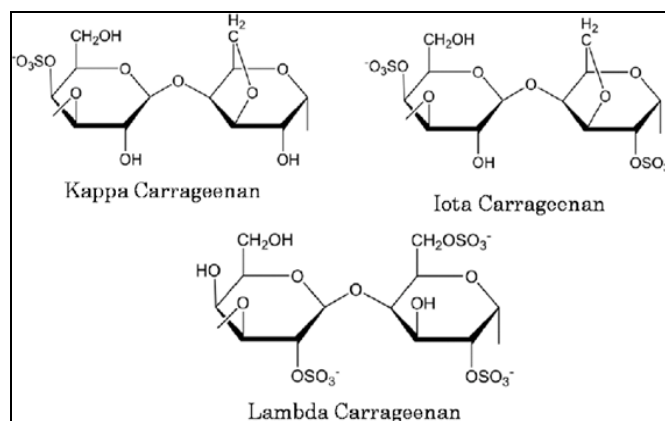


FIG. 2: STRUCTURE OF DIFFERENT CARRAGEENAN

Fucoidan: Brown macroalgae contain a polymer called fucoidan. When Kylin initially isolated the polysaccharide from maritime brown algae in 1913, it was called "fucoidin." According to IUPAC regulations, it is now known as "fucoidan,"

however some people still call it "sulfated fucan," "fucan," or "fucosan." Fucoidan's excipient properties have been demonstrated to include emulsifying, anti-aging, viscosity-enhancing, and skin-protective properties. A diverse class of carbohydrates, fucoidan is made up of uronic acid, galactose, mannose, xylose, sulphated, and acetyl groups⁷⁸. Drug carriers based on fucoidan, including hydrogels, microparticles, and nanoparticles, have been effectively created⁷⁹.

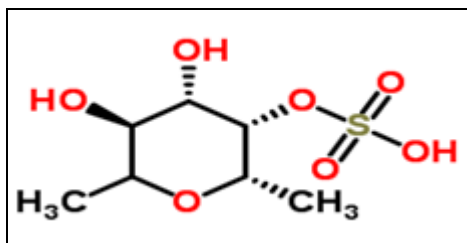


FIG. 3: FUCOIDAN STRUCTURE

Animal-Based Pharmaceutical Excipients:

Carminic Acid: In order to make carmine dye, which is used in the pharmaceutical industry to colour pills

and ointments, carminic acid a substance that is present in high concentrations in cochineal insects and that discourages other insects from preying on them is extracted from the insect's body and eggs and mixed with salts of ammonium, potassium, sodium, or calcium. Carmine is a recognised food additive that is utilised in a variety of meals and medications⁸⁰.

Shellac: An insect of the Coccidae family, *Laccifer-lacca*, excretes shellac, a resinous natural polymer. India, Assam, and Burma manufacture it⁸¹. With E number E904, the European Union (EU) has approved shellac, a refined lac product, as a food additive. The U.S. FDA has similarly granted it GRAS (Generally Recognised as Safe) designation^{82, 83}. Shellac is regarded as natural plastic because of its chemical resemblance to manufactured polymers. Its ability to form films and withstand acid makes it a common ingredient in the food and pharmaceutical industries.

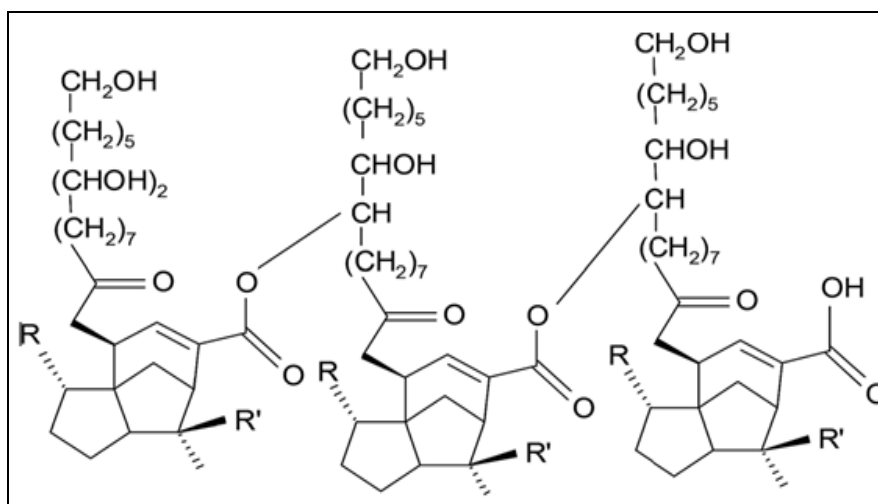
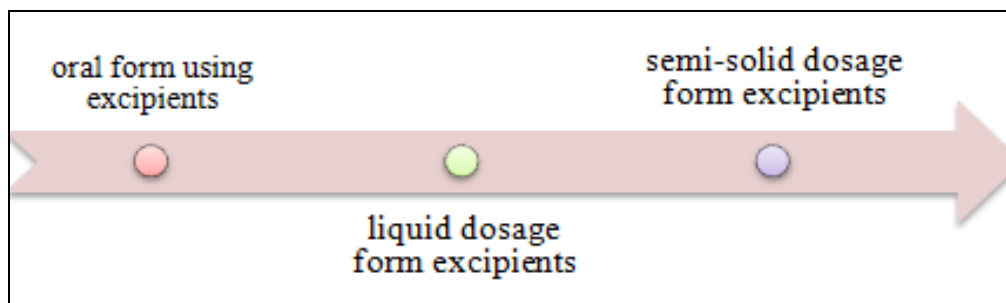


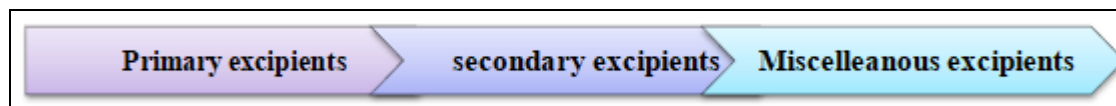
FIG. 4: STRUCTURE OF SHELLAC

During the development phase, the excipients and API are combined for a variety of purposes in order to create a dosage form that is ready for the intended usage.

Excipient Classification: The following are examples of excipients: a. oral dosage form; b. parenteral; c. topical medication delivery; and d. intranasal delivery mechanism.



Classification of Excipients:



Primary Excipients:

- ❖ Diluents
- ❖ Binders
- ❖ Disintegrants
- ❖ Lubricants
- ❖ Antiadhesives

Secondary Excipients:

- ❖ Flavours

- ❖ Sweeteners
- ❖ Coating agents
- ❖ Plasticisers
- ❖ Wetting agents

Miscellaneous Excipients:

- ❖ Buffers
- ❖ Adsorbents
- ❖ Wax

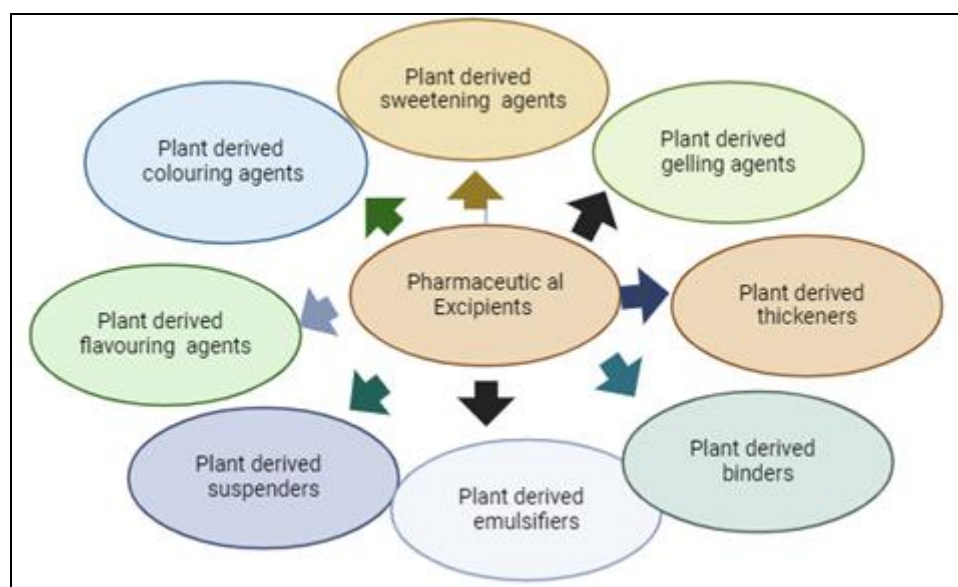


FIG. 5: DIFFERENT SOURCES OF EXCIPIENTS

Diluents: In order to give the pill a manageable size for compression and handling, diluent adds weight. A filler is added to a low dose of a potent drug to enhance the bulk volume of the powder and, consequently, the size of the tablet, since tablets typically weigh at least 50 mg. Hydrolysed starches, partially pre-gelatinized starches, and starches are examples of natural diluents. Diluents provide tablets greater qualities, including increased cohesiveness or flow. It should be possible for diluents to grind into small sizes as necessary^{84, 85}. The diluent ranges from 5 to 80% and API doses as -20µg. Maintained the tablet size should be more than 2-3mm and weight is -50mg.

All tablet excipients, including diluents, must adhere to specific formulation requirements.

1. They have to be nontoxic.
2. They must be offered for sale in a suitable grade.
3. They must have a reasonably low cost.
4. They must not be prohibited due to a component (like salt) or by themselves (like sugar).
5. They have to be inactive biologically.

6. Both by themselves and in conjunction with the medication or medications and other tablet ingredients, they must be chemically and physically stable.
7. They must be devoid of any undesirable "load" of microbes.
8. They must not create an off-color look and be color-compatible.
9. The diluent and additional excipients must be authorised direct food additives if the medication product (such as some vitamin preparations) is also categorised as a food.

Selection of Diluents: The appropriate diluent could be selected based on the manufacturer's experience, the diluent's cost, and how well it works with the other ingredients in the tablet. a) Calcium salts cannot be used as fillers for tetracycline products because calcium prevents tetracycline from being absorbed from the GIT. Water-soluble diluents should be employed when medications exhibit low water solubility in order to prevent potential bioavailability issues.

Classification of Diluents:

Diluents are categorised According to Their Solubility and Chemical Makeup:

Natural Diluents:

Starch: Hydrolysed starch (Emdex, Celutab), native starch (Pharm Gel, Starcap 1500, Sta-RX 1500), and partially pregelatinized starch (soybean powder).

Organic Diluents:

Lactose: In the production of pharmaceutical tablets and capsules, lactose is frequently utilised as a filler or filler-binder due to its general properties as an excipient. Lactose's general qualities, which include its low hygroscopicity, cost effectiveness, availability, bland taste, compatibility with other

excipients and active ingredients, excellent physical and chemical stability, and water solubility, are what make it a popular excipient.

α -Lactose monohydrate (trade names: Pharmatose, Respitose):

- ❖ Spray-dried lactose (Spray Process 315)
- ❖ Anhydrous Lactose (Pharmatose DCL-21)

Sucrose:

- Xylitol Erythritol
- Mannitol and Sorbitol
- Sugar tab, Di-Pac, Nu-tab.
- powdered cellulose (Elcema G-250)
- Microcrystalline Cellulose (Avicel, pH - 101.102.103)

Inorganic Diluents:

- Dibasic calcium phosphate dehydrates (Di-tab, Emcompress).
- Dibasic calcium phosphate anhydrate (A-Tab, fujicalin).
- Tribasic calcium phosphate (Tri-Tab)

Co-processed Diluents (Excipients): The co-processing approach is a revolutionary concept in which many excipients interact at the sub-particle level, masking the unwanted qualities of a single excipient. Co-processed diluents are created by combining two or more diluents using a suitable procedure. Co-processed excipients have been developed largely to address flowability, compressibility, and disintegration potential, with filler-binder combinations being the most often tested, such as Sugartab and Emdex.

TABLE 6: AN EXPLANATION OF CO-PROCESSED EXCIPIENTS AND THEIR USES ^{86, 91}

Grade	Description	Applications
Ludiflash	have a cooling impact on the lips and a little sweet taste. possess low hygroscopicity and exceptional flow ability. does not entirely dissolve in organic solvents or water.	Excellent excipient for direct compression of solid oral dosage forms that dissolve quickly for quick release.
F-melt	Spherically dense particles that are highly flowable, disintegrate in 30 seconds, save time and money, and have little sticking or capping.	Ideal for producing fast-dissolving oral tablets with lubricants and APIs by direct compression
Pharmaburst	Easy-to-use quick dissolving delivery platform, it is smooth and creamy and is very compatible.	Provides freedom to design robust "Quick Dissolve" formulations in-house, at a

Modified chitosan with silicon dioxide	Water wicking and swelling properties with improved flow and compact ion properties.	reasonable cost.
Mannogem EZ	free-flowing as a result of rapid dissolving, rapid dispersion, and less tiny particles.	Acts as super-disintegrant and filler
Glucidex IT	free-flowing as a result of rapid dissolving, rapid dispersion, and less tiny particles.	Application that dissolves quickly and is a great way to transport active ingredients that are hydrolysis-sensitive utilised as a diluent for tablets, capsules, spray drying carriers, and direct compression maltodextrin, which is utilised in the production of vitamins and supplement tablets that are directly compressible.

All coprocessed and modified excipients play an important role in the production of simple dosage forms that are resistant to air⁹².

- ❖ Co-processed excipients are being developed due to the growing adoption of direct compression and the need for a filler-binder to replace many excipients. They also can adjust solubility, permeability, and stability.
- ❖ To improve flowability, compressibility, and disintegration potential.
- ❖ Optimal filler binders that can replace many excipients are becoming increasingly popular.
- ❖ Appreciating new uses for economical excipients is a cost-effective and time-saving approach compared to completely new development.
- ❖ The number of excipients with suitable qualities for certain formulations.
- ❖ The compatibility of new medications with current excipients.

TABLE 7: DIFFERENT TYPES OF DILUENTS^{93, 94}

Soluble Diluents		
Sucrose	Lactose	Mannitol
Insoluble diluents		
Microcrystalline cellulose	Starch	Powdered Cellulose

Different Types of Diluents and its Compositions^{95, 98}.

- Amorphous lactose and crystalline α -lactose monohydrate make up Fast Flo Lactose.
- Lactose makes up 75% of microcells, while microcrystalline cellulose (MCC) makes up 25%.

- Ludipress has 3.5% polyvinylpyrrolidone (PVP) and 93% α -lactose monohydrate.
- The composition of Nu-Tab is 95–97% sucrose.
- Di-Pac is made up of 3% modified dextrans and 97% sucrose.
- 90–93% sucrose and 7–10% invert sugar are present in Sugar Tab.
- Emdex is made out of 7% vegetable gum and 93–99% dextrose.
- 93% calcium sulphate and 5% maltodextrins make up Cal-Tab.
- Calcium 90 has 9–10% starch and 90–91% calcium carbonate.

Binder: In order to improve granules and cohesiveness during direct compression and give tablets more mechanical strength, wet granulation uses binder, which are dry powders or liquids.

Based on where they come from, they are categorised as either natural polymers like starch or manufactured ones like PVC, HPMC, methylcellulose, ethyl cellulose, and PEG.

Solution binders, which dissolve in a solvent, and dry binders, which are added to the powder blend after a wet granulation process or as part of a direct powder compression technique, are two kinds of binders. Chemical structure and solubility are two criteria that can be used to classify binders. Examples include cellulose ethers, starches, natural gums, gelatin, saccharides, disaccharides, polysaccharides, and the synthetic polymer PVP.

Disintegrant: Including a disintegrant in the product's recipe. The disintegrant addition process

may impact a formulation's efficacy. Addition of disintegrants is possible:

Disintegrants can be introduced at both the intragranular and extra granular phases. Intragranular disintegrant is added prior to the granulation process. Extra granular disintegrant is applied following granulation but prior to the compression process.

Classification of Disintegrant:

There are two categories for disintegrants:

1. Conventional disintegrants, such as sodium alginate, starch, and microcrystalline cellulose.
2. Super Disintegrants: sodium starch glycolate (cross-linked starch) and croscarmellose sodium (cross-linked cellulose), among others. Currently, the most popular disintegrants in pharmaceutical preparations are these three super disintegrants. Most remarkably, super disintegrants can swell ten times in just thirty seconds.

Super-disintegrants are super-absorbing substances that have the ability to swell. These substances quickly expand after absorbing water or other fluids. For the disintegrable solid dose forms, they serve as a structural weakener. In the solid dosage form, they are normally used at a low level, usually 1–10% by weight in relation to the dosage unit's total weight. In the solid dosage form, they are usually employed at a modest level, usually 1% to 10% by weight in relation to the dosage unit's total weight¹⁰⁰.

Selection of Super Disintegrants: In addition to its swelling capabilities, super disintegrants must fulfil other requirements because they are used as excipients in tablet formulation.

1. Poor solubility is one of the best characteristics of disintegrants.
2. Inadequate gel production.
3. Good ability to stay hydrated.
4. Good flow and molding qualities.
5. No propensity to combine with the medications in complexes.

6. A pleasant mouthfeel.
7. It should also have favourable tableting qualities and work well with the other excipients.

Super-disintegrants' Mechanism:

- Swelling
- Capillary action and porosity (Wicking)
- Wetting heat
- The acid-base chemical reaction
- Repulsive forces of particles
- Recovery after deformation
- The enzymatic process

Advantages of Synthetic Super Disintegrants:

- Less of an impact on flow ability and compressibility.
- More efficient at the intragranular level.
- More hygroscopic (may cause issues with medications that are sensitive to moisture)
- Some are anionic and may slightly bind to cationic medications *in-vitro* (not an issue *in-vivo*).
- After wet granulation formulation, the amount of swelling in Primojel1 (sodium starch glycolate) and Polyplasdone XL101 (crospovidone) is reduced. Lastly, it was discovered that the medium ionic strength negatively impacted the croscarmellose ability to swell.

Lubricants:

- Tablet ejection from die-cavity with smoothness
- Prevent powder from adhering to punch faces.
- Lower the friction between particles when compressing

- Enhance the granule and powder blend flow in the die cavity.

According to Functionality:

Glidant: Enhance the powder's flow characteristics.

Anti-adherent: Reduce the likelihood that the punch will be adhered to

Die wall Lubricant: Facilitate easy ejection by lowering friction between the tablet surface and the die wall both before and after compaction.

According to Solubility:

Classification According to THEIR Solubility^{101,102}.

Hydrophilic:

- Boric acid is one example of a hydrophilic substance.
- The chloride of sodium is hydrophilic.
- A hydrophile is DL-leucine.
- 6000 and 4000 Carbowax are hydrophilic.
- Sulfate of sodium lauryl (SLS) is hydrophilic.

Hydrophobic Materials:

- Magnesium chloride is a hydrophobic substance.
- Stearic acid does not dissolve in water.
- It is hydrophobic to use Sterotex. Sterowet has no water repulsion.
- It's hydrophobic, Aerocil.

TABLE 8: ACCORDING TO CATEGORIES^{103, 104}

Categories	Concentrations
Glidant	
Aerosil	1 to 3
Native starch	1 to 10
Fumed silico -dioxide	0.1 to 0.5
Talc	1 to 5
Ant adherent	
Cab-O-sil.	0.1 to 0.5
Corn-starch	3 to 10
Talc.	1 to 5
DL-Leucine.	3 to 10
Fluid Lubricants	
Glycerol behenate	2 to 5
Vegetable oils	2 to 5
Mineral oil (Light)	1 to 3
Boundary Lubricants	
PEG (Polyethylene Glycol)	2 to 19
SLS (Sodium stearyl fumarate)	0.5 to 2.0
Metallic stearate	0.2 to 20

Coloring Agent: In tablet preparation, colors are typically used to identify similar-looking items, lower the chance of confusion, and enhance visual beauty.



FIG. 6: COLOUR WHEEL

The following Colourants are frequently used in P.I:

- The first is beta-carotene: (E160a) Color Index Numbers: CI 40800- (synthetic) and CI 75130- (natural).
- Indigo Carmine: soluble IndiGo blue, E132, FD & Cblue#2, sodium Indigo Sulfonate, Indigotin No. of Colour Index: CI 73015
- FD & Cyellow#6, Sunset Yellow FCF: (YelloworangeS., E110) CI15985 is the colour index number.
- Tartrazine: (FD & Cyellow#5, E102, Hydrazineyellow)
- BrilliantBlueFCF: (Erioskyblue, PatentBlue AR, E133, XyleneBlueVSG, Erioglaucine) CI42090 is ColorIndexNo.
- The colour index number for brookite titanium dioxide is CI77891.
- Quinoline Yellow SS: (Quinoline YellowA; YellowNo.204; Solvent Yellow33; FD & CYellow#11) (CI 47000 is the color index number.)
- AlluraRedAC: (FoodRed17; E129: FD & C, Red40; AlluraRed) CI16035 is the colour index number.
- QuinizarineGreen SS: (OilGreenG; D&C Green#6; SolventGreen3) No. of Colour Index: CI 61565

Excipients used in Natural Colorants¹⁰⁶: Carotenoids:

- The orange-red colour of capsanthin is found in capsicum.

- Crocin, a substance found in *Crocus sativus*, gives the plant its yellow-orange hue.
- Bixin, which gives *Bixa Orellana* its yellow-orange hue, is present in the plant.

Derivatives of Indole:

- Tyrian purple is produced by bromoindigotin, which is found in *Murex brandaris*.
- Indigotin, which gives indigo tinctorial its blue hue, is present in indigo.

Glycosides of Oxindole:

- Betanin, found in *Beta vulgaris* (beetroot root), is what gives it its red hue.

Diarylheptanoids

- Curcumin, which gives turmeric its yellow hue, is found in *Curcuma longa*.

Benzopyrones:

- Haematin, which gives logwood its black hue, is present in hematoxylon.

Anthraquinones:

- Alizarin, an ingredient in rubiatinctorium, gives it its red hue
- Kermesic acid, found in *Kermes ilicis*, is what gives it its scarlet hue.

Naphthoquinones:

- Shikonin, which gives *Lithospermum erythrorhizon* its violet hue, is present in the plant.

TABLE 9: LIQUID DOSAGE FORMS EXCIPIENTS^{107, 110}

Category of excipients	Formulation function	Working principle	Example.
Diluent.	Filler	Make up the bulk of solid unit dosage forms when the drug itself is inadequate to produce the bulk.	Directly compressible starches, lactose, Microcrystalline cellulose, dehydrated dibasic calcium phosphate, sorbitol, and dextrose.
Binders and Adhesives	Improve cohesive qualities of powder.	Improves free-flowing property.	Acacia, gelatine, starch paste, glucose, carboxymethyl cellulose, polyvinylpyrrolidone, and

Disintegrants	after administration make the particle to a smaller size when compared to Traditional disintegrants	Its Function is to draw water into the tablet, swelling it, and causing it to burst apart.	povidone. Starches, Clays, Cellulose, Cross-linked polymers, and Modified starches such as Primo gel and Exploitable and Vee gum HV.
super disintegrants	Improved disintegrant efficacy resulting in decreased use levels		Cross carmalose, Cross Povidone, Sodium starch glycolate.
Glidants	Improve powder mixture flow character	Added in the dry state prior to compression, it reduces friction between particles.	arches like Asbestos-free starch and corn starch, and also Colloidal Silicone dioxide (Carbosil)
Lubricants	Minimise inter-particle friction and stop tablet material from sticking to die and punch surfaces. enhance the flow rate of tablet granulation and make it easier for tablets to be ejected from the cavity.	place a low-shear-strength layer between the die wall and the tablet's tin bulk.	Polyethylene glycol, vegetable oil, talc, stearic acid, magnesium stearate, calcium stearate, and surfactants.
Coloring agents	Impart aesthetic appearance dosage form, disguising of colour drugs, product identification.		FD and C, D and C dyes and lakes.
(These must be approved and certified by F.D.A)			
Flavours	It is Limited to chewable tablets/ tablets intended.	Mask unpleasant taste of the formulation	Spray dried and other flavours, and syrups.
Sweeteners	Use is limited to chewable tablets. Impart sweet taste to the formulation		Saccharin. Mannitol, etc
Sorbents	Moisture proofing	liquid sorbing, taking up of liquid or gas either by adsorption or absorption in the dry state is on a limited basis	Silica gel, activated carbon, clay etc
Coating materials	helps to swallow unpleasant tasting tablets Protect tablet ingredients from deterioration by moisture,		Polysaccharides, Capsules coated by Gelatine, Povidone, and Ethyl cellulose. Hydroxypropyl methylcellulose (HPMC), Synthetic polymers, Shellac, Corn protein Zein, Polyethylene glycol, Polypropylene glycol, Triacetin. Castor oil, Diacetylated Monoglycerides,
Plasticizers	gelatine-based suppositories, film-coated tablets For soft gelatine capsule preparation etc	provide softness and resilience to suppositories, ascertain the hardness of the capsule shell in the event of soft gelatine capsules, and produce elasticity and flexibility to the coating materials in the case of tablets.	

Solvents and Cosolvents:

Function: Dissolve solute/Active medicinal component.

Working Principle:

- Reduce the effective charge on ions and break bonds to make the solution more soluble in solvents.
- Increase the strength of the solute-solvent interactions relative to the solute-solute and solvent-solvent interactions.

- Lessen the tension that exists between hydrophobic solutes and watery solutions.
- Water, alcohol, sorbitol, glycerin, propylene glycol, acetic acid, acetone, ethyl acetate, syrups, and ethanol are a few examples.

Buffers:

Function: Preserve the formulation's pH.

Working Principle: To preserve stability, donate hydrogen ions in bases and bind hydrogen ions in acids.

Examples include citric acid phosphate buffers, phosphate buffers, and acetate buffers.

Preservatives that are Antimicrobial:

Function: Stop microbiological development in formulations.

Working Principle: Prevent the growth of microorganisms by demonstrating bacteriostatic effect.

Examples include phenol, thiomersal, butylparaben, and benzoyl alcohol.

Antioxidants:

Function: Control oxidation Mechanism is preferred oxidation. Preserve the active pharmaceutical component by preventing oxidative chain reactions.

Examples include tocopherols, butylated hydroxytoluene (BHT), thiourea, sodium bisulfite, and ascorbic acid.

Agents for Wetting:

Function:

- Facilitate the dispersion and wetting of hydrophobic active compounds in pharmaceuticals.
- Reducing the interfacial tension between liquids and solids in suspensions is the working principle.

Examples include lecithins, Tween 80, Spans, and sodium lauryl sulphate (SLS).

Agents that Prevent Foaming:

Function: Prevent steady foam development. The liquid phase's cohesive binding and reduced surface tension are the working principles.

Examples include alcohols, paraffin oils, stearates, glycols, simethicone, and organic phosphates.

Thickening agents: Work by altering viscosity and preventing settling or sedimentation.

Working Principle: Increase viscosity by trapping solid particles.

Examples include microcrystalline cellulose, hydroxyethyl cellulose, and methylcellulose.

Humectants: Prevent aqueous vehicles from evaporating out of dosage forms.

Working Principle: Prevents solvent evaporation by being hygroscopic.

Glycerol, polyethylene glycol, and propylene glycol are a few examples. Chelating agents is to shield medications from catalysts that quicken oxidative processes.

Working Principle: In oxidation reactions, form complexes with metal ions to deactivate their catalytic activity.

Examples include citric acid, tartaric acid, dihydroxyethylglycine, and disodium EDTA.

Emulsifying agents: Work by preventing scattered globules in emulsions from coalescing.

Working Principle: Stabilise the emulsion by forming barriers at the interface and lowering interfacial tension.

Examples include cetrimide, sorbitan esters, macrogol esters, and sodium lauryl sulphate.

Flocculating agents: is to keep suspensions from caking.

Working Principle: By lowering the zeta potential of scattered particles, the addition of an electrolyte facilitates regulated flocculation.

Examples include carbomer, sodium alginate, and starch.

Sweetening Agents: They give recipes a sweet taste.

Examples include aspartame, sucrose, sorbitol, saccharin, and sucralose.

Colouring Agents: They provide compositions colour.

Examples include tartrazine, erythrosin, eosin, and amaranth.

Flavouring Substances:**Function:** Give formulas flavour.**Examples** include syrups and aromatic waters.**Propellants for Aerosols****Function:** Increase the container's pressure to force the product out.

Dichlorodifluoromethane and trichloromono-fluoromethane are two examples.

The Semisolid Dosage form of Excipients^{111, 114}:

- Oxidation is prevented by antioxidants. Butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), and ascorbic acid are a few examples.
- Solubilizers improve the active pharmaceutical ingredient's (API) solubility. Lanolin and cholesterol are two examples.
- Gels are created using gelling agents. Carbomer 934, Pemulen®, hydroxypropylcellulose, carboxymethylcellulose, and xanthan gum are a few examples.
- Emollients promote permeation by altering the skin or vehicle. Glycerin, mineral oil, petrolatum, and isopropyl palmitate are a few examples.
- To create a base for disintegration, suppository bases are utilised. Cocoa butter, glycerin, coconut oil, gelatin, and hydrogenated vegetable oil are a few examples.
- Excipients that create structures aid in the formation of a gel-like structure. Cetostearyl alcohol, sorbitan, hydrophilic surfactants, and fluid hydrocarbons such as mineral oil are a few examples.
- The formulation is preserved by the use of preservatives. Benzyl alcohol, propylparaben, methylparaben, imidazolidinyl urea, chlorocresol, and sodium benzoate are a few examples.

TABLE 10: POTENTIAL INGREDIENTS IN AYURVEDIC MEDICINE^{115,117}

Dose Form	Excipients correlates with guidelines of IPEC
Kalka	Prakshepdravya
Swarasa	Prakshepdravya
Kwath	Anupama and Prakshepdravya
Churna	supporting component for flavour and taste, Sahapana, Anupana
Avaleha	<i>In-situ</i> constituents of herbal, mineral and animal origin, Sugar, prakshepdravya, ghee, tail
Vati	Smoothing agent like ghee and some <i>in-situ</i> constituents of herbal, mineral and animal origin, Bhavnadravya, sometimes enhancer, binder
Ari or asava	Self-generated Alcohol during pharmaceutical procedure and some herbal constituents, water
Snehadravya	Some herbal constituents, water entrapped micelles, Tail, Ghee (Lipid content)

The Function and mode of Action of Natural Ayurvedic Pharmaceutical Excipients^{118, 122}:

- Water, or jala, is used as a binding agent.
- Trimethylated chitosan improves absorption.
- Acacia, potato starch, and ginger all serve as binders and bioenhancers.
- One uses coriander as a flavouring.
- As an excipient, andrographolide is employed.
- Cellulose and alginic acid function as binders, thickeners, and disintegrants.
- Amra and guggulu are utilised as adhesive and binding agents.
- Sugar, or sita, serves as a sweetener.
- As aromatic agents (Sugandhitdravyas), Ela, Dalchini, and Karpura are used.
- The purpose of raktavargadravyas is to colour.
- As a bioenhancer, piperine (Marich/Pippali) improves efficacy and bioavailability.
- Tankan is an antidotal medication.

TABLE 11: THE CHEMICAL ROLES OF EXCIPIENTS IN TRADITIONAL AND AYURVEDIC PHARMACEUTICS^{123, 125}

Sl. no.	Function	Example
1	Modulation of pH	pH Benzoic acid, citric acid, and tartaric acid
2	Water-soluble organic	Polyethylene glycol 300 & 400, Ethanol, Propylene glycol, Glycerin, N-methyl 2-pyrrolidone, Dimethyl acetamide
3	Water insoluble organic	Beeswax, D-α tocopherol, Oleic acid, Mono & di glycerides
4	Nonionic surfactants	Cremphor, Tween 20, Sorbitan monooleate, Peppermint oil, Polysorbate 20 & 80
5	hydrophobic lipids	Peanut oil, Sesame oil, olive oil and cotton seed
6	Phospholipids	DMPC, Choline, Glycerol, DSPG,

Aspects of Pharmaceutical Excipient

Regulation: Regulatory bodies are concerned with the efficacy, safety, and quality of excipients and are passing new laws mandating that pharmaceutical companies guarantee the calibre of their components. Therefore, the International Pharmaceutical Excipients Council (IPEC), a regulatory organisation, is necessary to oversee the functioning, safety, and quality of all pharmaceutical excipients. The biggest producer of pharmaceuticals is India. Controlling the excipients' quality and safety in India is therefore crucial. The primary reason for the emphasis on excipients is the history of patient deaths brought on by tainted excipients used by pharmaceutical corporations¹²⁶.

Safety Issue in Excipient: Aspects of pharmaceutical excipient regulation: regulatory bodies are concerned with the efficacy, safety, and quality of excipients. They are passing new laws mandating that pharmaceutical companies guarantee the caliber of their components. Therefore, the International Pharmaceutical Excipients Council (IPEC), a regulatory organization, is necessary to oversee the functioning, safety, and quality of all pharmaceutical excipients. The biggest producer of pharmaceuticals is India. Controlling the excipients' quality and safety in India is therefore crucial. The primary reason for the emphasis on excipients is the history of patient deaths brought on by tainted excipients used by pharmaceutical corporations¹²⁷.

Storage Condition of Pharmaceutical Excipients

¹²⁸: The general case is a long-term study with a minimum data submission duration of 12 months and storage conditions of 25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH. Intermediate study: Minimum data submission duration of 6 months, storage conditions of 30°C ± 2°C/65% RH ± 5% RH. Accelerated study: Data must be submitted within a minimum of six

months, and storage conditions must be 40°C ± 2°C/75% RH ± 5% RH.

Substances Associated with Drugs Meant to Be Stored in a Refrigerator:

Long-term Research: A minimum data submission time of 12 months is required, and storage conditions are 5°C ± 3°C.

Accelerated Study: Minimum data submission duration of 6 months, storage conditions of 25°C ± 2°C/60% RH ± 5% RH.

Substances Associated with Drugs Meant to Be Stored in a Refrigerator:

Long-term Research: A minimum data submission time of 12 months is required, and storage conditions are 5°C ± 3°C.

Accelerated Study: Minimum data submission duration of 6 months, storage conditions of 25°C ± 2°C/60% RH ± 5% RH.

CONCLUSION: Understanding the contents in pharmaceutical dosage forms, making informed decisions and adjustments depending on the unique properties of the substances, and putting out great effort to maximise the excipients' overall benefits are all part of the process. Success stories can ultimately be found in many areas of the drug products, such as their excellent formulation and manufacturing process, their market-share dominance in their therapeutic areas, their regulatory acceptability, and their seamless scale-up and process validation. Regulatory difficulties are a crucial first step to the effective outcome of drug goods because the success of a dosage formula.

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REFERENCES:

1. Elder DP, Kuentz M and Holm R: Pharmaceutical excipients Quality, regulatory and biopharmaceutical considerations. *Eur J Pharm Sci* 2016; 87: 88–99. doi: 10.1016/j.ejps.2015.12.018. [PubMed] [CrossRef] [Google Scholar]
2. Anderson OE: Pioneer Statute: The Pure Food and Drugs Act of 1906. *J Pub Law* 1964; 13: 189–196.
3. Abrantes CG, Duarte D and Reis CP: An Overview of Pharmaceutical Excipients: Safe or Not Safe. *J Pharm Sci* 2016; 105: 2019–2026. doi: 10.1016/j.xphs.2016.03.019. [PubMed] [CrossRef] [Google Scholar]
4. Haywood A and Glass BD: Pharmaceutical excipients—Where do we begin? *Aust. Pr Hescr* 2011; 34: 112–114. oi: 10.18773/austprescr.2011.060. [CrossRef] [Google Scholar]
5. Kanojia N, Kaur L, Nagpal M and Bala R: Modified excipients in novel drug delivery: need of the day. *J Pharm Technol Res Anag* 2013; 1: 81–107. doi: 10.15415/jptm.2013.11006. [CrossRef] [Google Scholar]
6. Onyekweli AO, Kunle O and Okoye E: Application of an newly developed multifunctional excipients in tablet formulation. *Res J Pharm Technol* 2013; 6(10): 19–31.
7. Grimling B, Karolewicz B, Nawrot U, Włodarczyk K and Górniak A: Physicochemical and Antifungal properties of clotrimazole in combination with high molecular weight chitosan as a multifunctional excipient. *Drugs* 2020; 18(12): 591.
8. Aulton ME: *The Science of Dosage forms Design*. second ed. London: Churchill Livignston 2002.
9. Steinberg M, Blecher L and Mercill A: From inactive ingredients to pharmaceutical excipients. *Pharm Technol* 2001; 25(7): 62-64.
10. Desai U, Chavan R, Mhatre P and Chinchole R: A review: Coprocessed excipients. *International JI of Pharmaceutical Sciences Review and Research* 2012; 12(2): 93-105.
11. Block LH, Moreton RC, Apte SP, Wendt RH, Munson EJ and Creekmore JR: Co-processed excipients. *Pharmacopeial Forum* 2009; 35(4): 1026-8.
12. Lachman L, Liberman L and Schwartz J: *Pharmaceutical Dosage Forms: Tablets*, CRC Press, 2nd edition 1 1989.
13. Remington J: *Remington. The Science and Practice of Pharmacy*, 9th Edition 1945; 2: 1615-1641.
14. Banker G and Rhodes C: *Drug and Pharmaceutical Sciences: Modern Pharmaceutics*, Marcel Dekker Inc, New York, 3rd Edition 1999; 72; 333-394.
15. Martin E: *Dispensing of Medication*, Mack Publishing Co, 7th Edition 2006; 740-741.
16. Perepelkin KE: Polymeric materials of the future based on renewable plant resources and biotechnologies; *Fibers, films, plastics. Fiber Chem* 2005; 37: 417- 430
17. Bhardwaj TR, Kanwar M and Gupta A: Natural gums and modified natural gums as sustained-release carriers. *Drug Dev Ind Pharm* 2000; 26: 1025-1038.
18. Ogaji IJ, Nep EI and Audu-peter JD: Advances in natural polymers as pharmaceutical excipients. *Pharmaceutica Analytica Acta* 2012; 3(1): 1–16.
19. Eriksson A, Burcharth J and Rosenberg J: Animal derived products may conflict with religious patients' beliefs. *BMC Medical Ethics* 2013; 14(1): 1–5.
20. Varshosaz J, Zaki MR, Minaian M and Banoozadeh J: Preparation, optimization, and screening of the effect of processing variables on agar nanospheres loaded with bupropion HCl by a D-optimal design. *Biomed Res Int* 2015; 1-13.
21. Izdorczyk M: *Understanding the chemistry of food carbohydrates*. Taylor and Francis, Boca Raton, FL, USA 2006.
22. Luna SM, Gomes ME, Mano JF and Reis RL: Development of a novel cell encapsulation system based on natural origin polymers for tissue engineering applications. *J Bioact Compat Polym* 2010; 25: 341–359.
23. Gasperini L, Mano JF and Reis RL: Natural polymers for the microencapsulation of cells. *J R Soc Interface* 2014; 11: 1–1.
24. Rinaudo M: Main properties and current applications of some polysaccharides as biomaterials. *Polym Int* 2008; 57: 397–430. [Google Scholar] [CrossRef]
25. Beratto-Ramos A, Agurto-Muñoz C, Pablo Vargas-Montalba J, Castillo R and del P: Fourier-transform infrared imaging and multivariate analysis for direct identification of principal polysaccharides in brown seaweeds. *Carbohydr Polym* 2022; 230.
26. Chakraborty R, Sanyal S, Dutta S, Raja Shaikh U, Kumar Dubey P and Das P: An ethnobotanical study of medicinal plants used by the ethnic group of people of the district of north 24 Parganas, Howrah, Kolkata, West Bengal, India. in: *practice and re-emergence of herbal medicine*. Bentham Science Publishers 2023; 175–87.
27. Reyes-Salas O, Juárez-Espino M, Manzanilla-Cano J, Barceló-Quintal M, Reyes-Salas A and Rendón-Orsorio R: Titrimetric and Polarographic Determination of Carminic acid and its Quantification in Cochineal (*Dactylopius coccus*) Extracts. *J Mex Chem Soc* 2011; 55(2): 89-93.
28. Patel AR, Schatteman D, De Vos WH, Lesaffer A and Dewettinck K: Preparation and rheological characterization of shellac oleogels and oleogel-based emulsions. *Journal of Colloid and Interface Science* 2013; 411: 114–21.
29. Wang J, Chen L and He Y: Preparation of environmental friendly coatings based on natural shellac modified by diamine and its applications for copper protection. *Progress in Organic Coatings* 2008; 62: 307–12.
30. Srivastava S and Thombare N: Safety assessment of shellac as food additive through long term toxicity study, *Trends Biosci* 2017; 10: 733–740.
31. Steinberg M, Blecher L and Mercill A: From inactive ingredients to pharmaceutical excipients *Pharm Technol* 2001; 25 (7): 62-4.
32. Chaudhari PD, Phatak AA and Desai U: A review: Coprocessed excipients—An alternative to novel chemical entities. *International Journal of Pharmaceutical and Chemical Sciences* 2012; 1(4): 1480-1498.
33. Awen BZ, Chandu BR, Katakam P, Dasari V and Peraman R: Exploitation of gum olibanum as novel natural binding agent in the deigning of oral furosemide formulation. *J Chem Pharma Sci* 2010; 3: 71-4.
34. Kunjwani HK, Manikrao AM, Rajesh KS, Sable VP and Indurwade NH: Natural gums as matrix and coating material for colon specific drug delivery. *Research J Pharm and Tech* 2009; 2(4): 705-709.
35. Jackson K, Young D and Pant S: Drug/Excipients Interactions & their effect on absorption. *Pharmaceutical Science and Technology Today* 2000; 10: 336-345.
36. The International Pharmaceutical Excipients Council of the Americas- Excipients Master File Guide 2004; 1-24.

37. Belet MH and Derle DV: Analysis of patents pertaining to superdisintegrants used in tablet manufacturing. *Journal of Intellectual Property Rights* 2008; 13: 601-604.
38. Camarco W, Ray D and Druffner A: Selecting superdisintegrants for orally disintegrating tablet formulations. *Pharmaceutical Technology Supplement* 2006.
39. Patel R, Barker J & ElShaer A: Pharmaceutical excipients and drug metabolism: a mini-review. *International Journal of Molecular Sciences* 2020; 21(21): 8224.
40. Pockle RD, Masareddy RS, Patil AS & Patil PD: A comprehensive review on pharmaceutical excipients. *Therapeutic Delivery* 2023; 14(7): 443-458.
41. Sanchez-Ballester NM, Bataille B & Soulairol I: Sodium alginate and alginic acid as pharmaceutical excipients for tablet formulation: Structure-function relationship. *Carbohydrate Polymers* 2021; 270: 118399.
42. Sanchez-Ballester NM, Bataille B & Soulairol I: Sodium alginate and alginic acid as pharmaceutical excipients for tablet formulation: Structure-function relationship. *Carbohydrate Polymers* 2021; 270: 118399.
43. Alaiya MA & Odeniyi MA: Utilisation of *Mangifera indica* plant extracts and parts in antimicrobial formulations and as a pharmaceutical excipient: a review. *Future Journal of Pharmaceutical Sciences* 2023; 9(1): 29.
44. Patel R, Barker J & ElShaer A: Pharmaceutical excipients and drug metabolism: a mini-review. *International Journal of Molecular Sciences* 2020; 21(21): 8224.
45. Santos A, Veiga F & Figueiras A: Dendrimers as pharmaceutical excipients: synthesis, properties, toxicity and biomedical applications. *Materials* 2019; 13(1): 65.
46. Flanagan T: Potential for pharmaceutical excipients to impact absorption: A mechanistic review for BCS Class 1 and 3 drugs. *European Journal of Pharmaceutics and Biopharmaceutics* 2019; 141: 130-138.
47. Sanchez-Ballester NM, Bataille B & Soulairol I: Sodium alginate and alginic acid as pharmaceutical excipients for tablet formulation: Structure-function relationship. *Carbohydrate Polymers* 2021; 270: 118399.
48. Jörgensen AM, Wibel R & Bernkop-Schnürch A: Biodegradable cationic and ionizable cationic lipids: A roadmap for safer pharmaceutical excipients. *Small* 2023; 19(17): 2206968.
49. Si Y, Luo H, Zhou F, Bai X, Han L, Sun H & Cha R: Advances in polysaccharide nanocrystals as pharmaceutical excipients. *Carbohydrate Polymers* 2021; 262: 117922.
50. Alaiya MA & Odeniyi MA: Utilisation of *Mangifera indica* plant extracts and parts in antimicrobial formulations and as a pharmaceutical excipient: a review. *Future Journal of Pharmaceutical Sciences* 2023; 9(1): 29.
51. Lambros M, Tran T, Fei Q & Nicolaou M: Citric acid: A multifunctional pharmaceutical excipient. *Pharmaceutics* 2022; 14(5): 972.
52. Wang B, Sun X, Xiang J, Guo X, Cheng Z, Liu W & Tan S: A critical review on granulation of pharmaceuticals and excipients: Principle, analysis and typical applications. *Powder Technology* 2022; 401:117329.
53. Jadach B, Świetlik W & Froelich A: Sodium alginate as a pharmaceutical excipient: novel applications of a well-known polymer. *Journal of Pharmaceutical Sciences* 2022; 111(5): 1250-1261.
54. Shah H, Jain A, Laghate G & Prabhudesai D: Pharmaceutical excipients. In *Remington* 2021; 633-643.
55. Wasilewska K & Winnicka K: Ethylcellulose—a pharmaceutical excipient with multidirectional application in drug dosage forms development. *Materials* 2019; 12(20): 3386.
56. Rao VA, Kim JJ, Patel DS, Rains K & Estoll CR: A comprehensive scientific survey of excipients used in currently marketed, therapeutic biological drug products. *Pharmaceutical Research* 2020; 37: 1-12.
57. Dash RP, Srinivas NR & Babu RJ: Use of sorbitol as pharmaceutical excipient in the present day formulations—issues and challenges for drug absorption and bioavailability. *Drug Development and Industrial Pharmacy* 2019; 45(9): 1421-1429.
58. Shokoya MM, Benkő BM, Süvegh K, Zelkó R & Sebe I: Positron annihilation lifetime spectroscopy as a special technique for the solid-state characterization of pharmaceutical excipients, drug delivery systems, and medical devices—a systematic review. *Pharmaceutics* 2023; 16(2): 252.
59. Pawar SB, Ahirrao SP, Kshirsagar SJ, City BK & Knowledge B: Review on novel pharmaceutical co-processed excipients. *Pharm. Reson* 2019; 2: 14-20.
60. Gupta KR, Pounikar AR & Umeekar MJ: Drug excipient compatibility testing protocols and characterization: a review. *Asian J Chem Sci* 2019; 6(3): 1-22.
61. Guru PR, Kar RK, Nayak AK & Mohapatra S: A comprehensive review on pharmaceutical uses of plant-derived biopolysaccharides. *International Journal of Biological Macromolecules* 2023; 233: 123454.
62. Van der Merwe J, Steenekamp J, Steyn D & Hamman J: The role of functional excipients in solid oral dosage forms to overcome poor drug dissolution and bioavailability. *Pharmaceutics* 2020; 12(5): 393.
63. Gu A & Wheate NJ: Macrocycles as drug-enhancing excipients in pharmaceutical formulations. *Journal of Inclusion Phenomena and Macrocyclic Chemistry* 2021; 100(1): 55-69.
64. Binab KA, Gaurav A & Mandal UK: A review on co-processed excipients: current and future trend of excipient technology. *Int J Pharm Pharm Sci* 2019; 11(1): 1-9.
65. Dahlgren D, Sjöblom M & Lennernäs H: Intestinal absorption-modifying excipients: A current update on preclinical *in-vivo* evaluations. *European Journal of Pharmaceutics and Biopharmaceutics* 2019; 142: 411-420.
66. Caballero ML & Quirce S: Delayed hypersensitivity reactions caused by drug excipients: a literature review. *J Investig Allergol Clin Immunol* 2020; 30(6): 400-408.
67. Caballero ML & Quirce S: Immediate hypersensitivity reactions caused by drug excipients: a literature review. *J Investig Allergol Clin Immunol* 2020; 30(2): 86-100.
68. Reagan KR & Jonans T: Comparison of Starch from Locally Grown Food Crops as a Pharmaceutical Excipient: A Systematic Review 2024.
69. Puga AM, Lopez-Oliva S, Trives C, Partearroyo T & Varela-Moreiras G: Effects of drugs and excipients on hydration status. *Nutrients* 2019; 11(3): 669.
70. Nakama KA, Dos Santos RB, Serpa P, Maciel TR & Haas SE: Organoleptic excipients used in pediatric antibiotics. *Archives de Pédiatrie* 2019; 26(7): 431-436.
71. Bhatia V, Dhingra A, Chopra B & Guarve K: Co-processed excipients: Recent advances and future perspective. *Journal of Drug Delivery Science and Technology* 2022; 71: 103316.
72. Veeravalli V, Cheruvu HS, Srivastava P & Madgula LMV: Three-dimensional aspects of formulation excipients in drug discovery: a critical assessment on orphan excipients, matrix effects and drug interactions. *Journal of Pharmaceutical Analysis* 2020; 10(6): 522-531.

73. Rassu G, Sorrenti M, Catenacci L, Pavan B, Ferraro L, Gavini E & Dalpiaz A: Versatile nasal application of cyclodextrins: Excipients and/or actives?. *Pharmaceutics* 2021; 13(8): 1180.
74. Bawuah P & Zeitler JA: Advances in terahertz time-domain spectroscopy of pharmaceutical solids: A review. *TrAC Trends in Analytical Chemistry* 2021; 139: 116272.
75. Kandar CC, Hasnain MS & Nayak AK: Natural polymers as useful pharmaceutical excipients. In *Advances and Challenges in Pharmaceutical Technology* 2021; 1-44. Academic Press.
76. Zaid AN: A comprehensive review on pharmaceutical film coating: past, present, and future. *Drug Design, Development and Therapy* 2020; 4613-4623.
77. Garcia MAVT, Garcia CF & Faraco AAG: Pharmaceutical and biomedical applications of native and modified starch: a review. *Starch-Stärke* 2020; 72(7-8): 1900270.
78. Bjelošević M, Pobirk AZ, Planinšek O & Grabnar PA: Excipients in freeze-dried biopharmaceuticals: Contributions toward formulation stability and lyophilisation cycle optimisation. *International Journal of Pharmaceutics* 2020; 576: 119029.
79. Kurakula M & Rao GK: Pharmaceutical assessment of polyvinylpyrrolidone (PVP): As excipient from conventional to controlled delivery systems with a spotlight on COVID-19 inhibition. *Journal of Drug Delivery Science and Technology* 2020; 60: 102046.
80. Parezanović GŠ, Lalic-Popovic M, Golcorbin-Kon S, Vasovic V, Milijašević B, Al-Salami H & Mikov M: Environmental transformation of pharmaceutical formulations: a scientific review. *Archives of Environmental Contamination and Toxicology* 2019; 77: 155-161.
81. Charoo NA: Critical excipient attributes relevant to solid dosage formulation manufacturing. *Journal of Pharmaceutical Innovation* 2020; 15: 163-181.
82. Belayneh A, Tadese E & Molla F: Safety and biopharmaceutical challenges of excipients in off-label pediatric formulations. *International Journal of General Medicine* 2020; 1051-1066.
83. Nakmode D, Bhavana V, Thakor P, Madan J, Singh PK, Singh SB & Mehra NK: Fundamental aspects of lipid-based excipients in lipid-based product development. *Pharmaceutics* 2022; 14(4): 831.
84. Adeleye OA, Bamiro OA, Albalawi DA, Alotaibi AS, Iqbal H, Sanyaolu S & Mena F: Characterizations of alpha-cellulose and microcrystalline cellulose isolated from cocoa pod husk as a potential pharmaceutical excipient. *Materials* 2022; 15(17): 5992.
85. Attia MS, Elsebaey MT, Yahya G, Chopra H, Marzouk MA, Yahya A & Abdelkhalek AS: Pharmaceutical polymers and P-glycoprotein: current trends and possible outcomes in drug delivery. *Materials Today Communications* 2023; 34: 105318.
86. Laux A, Gouws C & Hamman JH: Aloe vera gel and whole leaf extract: functional and versatile excipients for drug delivery?. *Expert Opinion on Drug Delivery* 2019; 16(12): 1283-1285.
87. Badwaik HR, Kumari L, Maiti S, Sakure K, Nakhate KT, Tiwari V & Giri TK: A review on challenges and issues with carboxymethylation of natural gums: The widely used excipients for conventional and novel dosage forms. *Inter J of Biological Macromolecules* 2022; 209: 2197-2212.
88. Parmar PK, Rao SG & Bansal AK: Co-processing of small molecule excipients with polymers to improve functionality. *Expert Opinion on Drug Delivery* 2021; 18(7): 907-928.
89. Ionova Y & Wilson L: Biologic excipients: Importance of clinical awareness of inactive ingredients. *PLoS One* 2020; 15(6): 0235076.
90. Sawangrat K, Yamashita S, Tanaka A, Morishita M, Kusamori K, Katsumi H & Yamamoto A: Modulation of intestinal transport and absorption of topotecan, a BCRP substrate, by various pharmaceutical excipients and their inhibitory mechanisms of BCRP transporter. *Journal of Pharmaceutical Sciences* 2019; 108(3): 1315-1325.
91. Chen G, Xu Y, Kwok PCL & Kang L: Pharmaceutical applications of 3D printing. *Additive Manufacturing* 2020; 34: 101209.
92. Harrer D, Armengol ES, Friedl JD, Jalil A, Jelkmann M, Lechner C & Laffleur F: Is hyaluronic acid the perfect excipient for the pharmaceutical need?. *International Journal of Pharmaceutics* 2021; 601: 120589.
93. Nan N, Hu W & Wang J: Lignin-based porous biomaterials for medical and pharmaceutical applications. *Biomedicine* 2022; 10(4): 747.
94. Dong J, Cheng Z, Tan S & Zhu Q: Clay nanoparticles as pharmaceutical carriers in drug delivery systems. *Expert Opinion on Drug Delivery* 2021; 18(6): 695-714.
95. Zhao H, Zhao L, Lin X & Shen L: An update on microcrystalline cellulose in direct compression: Functionality, critical material attributes, and co-processed excipients. *Carbohydrate Polymers* 2022; 278: 118968.
96. Abdelhak MJ: A review: Application of biopolymers in the pharmaceutical formulation. *J Adv Bio-Pharm Pharmacovigil* 2019; 1(1): 15-25.
97. Li M, Xu W & Su Y: Solid-state NMR spectroscopy in pharmaceutical sciences. *TrAC Trends in Analytical Chemistry* 2021; 135: 116152.
98. Chen Z, Ye SY & Zhu RG: The extraordinary transformation of traditional Chinese medicine: processing with liquid excipients. *Pharmaceutical Biology* 2020; 58(1): 561-573.
99. Lachowicz M, Stańczak A & Kołodziejczyk M: Characteristic of Cyclodextrins: Their role and use in the pharmaceutical technology. *Current Drug Targets* 2020; 21(14): 1495-1510.
100. Siepmann J, Faham A, Clas SD, Boyd BJ, Jannin V, Bernkop-Schnürch A & Leroux JC: Lipids and polymers in pharmaceutical technology: Lifelong companions. *International Journal of Pharmaceutics* 2019; 558: 128-142.
101. Aanisah N, Wardhana YW, Chaerunisaa AY & Budiman A: Review on modification of glucomannan as an excipient in solid dosage forms. *Polymers* 2022; 14(13): 2550.
102. Blynskaya EV, Tishkov SV, Vinogradov VP, Alekseev KV, Marakhova AI & Vetcher AA: Polymeric excipients in the technology of floating drug delivery systems. *Pharmaceutics* 2022; 14(12): 2779.
103. Al-Zoubi N, Gharaibeh S, Aljaberi A & Nikolakakis I: Spray drying for direct compression of pharmaceuticals. *Processes* 2021; 9(2): 267.
104. Waghule T, Saha RN, Alexander A & Singhvi G: Tailoring the multi-functional properties of phospholipids for simple to complex self-assemblies. *Journal of Controlled Release* 2022; 349: 460-474.
105. Qing PCZ, Janakiraman AK, Mohamed SAK, Rahman EH & Bin LK: An overview of Cocoa Butter: Novel excipients for oral tablets. *Int J Pharm Res* 2021; 13(1).
106. Kumar A, Bhatt P & Mishra N: Irritable bowel Syndrome with reference of Alosetron Hydrochloride and Excipient profile used in the manufacturing of Alosetron tablet-A review. *J Chem Pharm Sci* 2019; 12(03):71-78.

107. Martinez MN, Sinko B, Wu F, Flanagan T, Borbás E, Tsakalozou E & Giacomini KM: A critical overview of the biological effects of excipients (Part I): impact on gastrointestinal absorption. *The AAPS J* 2022; 24(3): 60.
108. Azad MA, Olawuni D, Kimbell G, Badruddoza AZM, Hossain MS & Sultana T: Polymers for extrusion-based 3D printing of pharmaceuticals: A holistic materials–process perspective. *Pharmaceutics* 2020; 12(2): 124.
109. Tekade AR & Yadav JN: A review on solid dispersion and carriers used therein for solubility enhancement of poorly water soluble drugs. *Advanced Pharmaceutical Bulletin* 2020; 10(3): 359.
110. van Hoogevest P, Tiemessen H, Metselaar JM, Drescher S & Fahr A: The use of phospholipids to make pharmaceutical form line extensions. *European Journal of Lipid Science and Technology* 2021; 123(4): 2000297.
111. Castañeda Ruiz AJ, Shetab Boushehri MA, Phan T, Carle S, Garidel P, Buske J & Lamprecht A: Alternative excipients for protein stabilization in protein therapeutics: overcoming the limitations of polysorbates. *Pharmaceutics* 2022; 14(12): 2575.
112. Santos A, Veiga F & Figueiras A: Dendrimers as pharmaceutical excipients: synthesis, properties, toxicity and biomedical applications. *Materials* 2019; 13(1): 65.
113. Wasilewska K & Winnicka K: Ethylcellulose—a pharmaceutical excipient with multidirectional application in drug dosage forms development. *Materials* 2019; 12(20): 3386.
114. Tian P, Yang F, Yu LP, Lin MM, Lin W, Lin QF & Chen YZ: Applications of excipients in the field of 3D printed pharmaceuticals. *Drug Development and Industrial Pharmacy* 2019; 45(6): 905-913.
115. Singh P, Mishra G & Dinda SC: Natural excipients in pharmaceutical formulations. *Evidence Based Validation of Traditional Medicines: A comprehensive Approach* 2021; 829-869.
116. Aminu N, Chan SY, Mumuni MA, Umar NM, Tanko N, Zauro SA & Toh SM: Physicochemical compatibility studies of triclosan and flurbiprofen with excipients of pharmaceutical formulation using binary, ternary, and multi-combination approach. *Future Journal of Pharmaceutical Sciences* 2021; 7: 1-16.
117. Aanisah N, Wardhana YW, Chaerunisaa AY & Budiman A: Review on modification of glucomannan as an excipient in solid dosage forms. *Polymers* 2022; 14(13): 2550.
118. Yadav H & Karthikeyan C: Natural polysaccharides: Structural features and properties. In *Polysaccharide Carriers for Drug Delivery* 2019; 1-17. Woodhead Publishing.
119. Lamichhane S, Bashyal S, Keum T, Noh G, Seo JE, Bastola R & Lee S: Complex formulations, simple techniques: Can 3D printing technology be the Midas touch in pharmaceutical industry?. *Asian Journal of Pharmaceutical Sciences* 2019; 14(5): 465-479.
120. Ozkan CK, Esim O, Savaser A & Ozkan Y: An overview of excipients classification and their use in pharmaceuticals. *Current Pharmaceutical Analysis* 2021; 17(3): 360-374.
121. Elder DP, Kuentz M & Holm R: Pharmaceutical excipients quality, regulatory and biopharmaceutical considerations. *European Journal of Pharmaceutical Sciences* 2016; 87: 88-99.
122. Kalasz H & Antal I: Drug excipients. *Current Medicinal Chemistry* 2006; 13(21): 2535-2563.
123. Abrantes CG, Duarte D & Reis CP: An overview of pharmaceutical excipients: safe or not safe?. *Journal of Pharmaceutical Sciences* 2016; 105(7): 2019-2026.
124. Pifferi G & Restani P: The safety of pharmaceutical excipients. *Il Farmaco* 2003; 58(8): 541-550.
125. Hancock BC & Goldfarb DJ: Excipient taxonomy for the 21st century. *Journal of Pharmaceutical Sciences* 2023; 112(3): 626-633.
126. Avdeef A, Bendels S, Tsinman O, Tsinman K & Kansy M: Solubility-excipient classification gradient maps. *Pharmaceutical Research* 2007; 24: 530-545.
127. Dureja H & Kumar D: Pharmaceutical Excipients: Global Regulatory issues. *Indonesian Journal of Pharmacy* 2013; 215-221.
128. Faustino C, Bettencourt AF, Alfaia A & Pinheiro L: Introducing students to rheological classification of foods, cosmetics, and pharmaceutical excipients using common viscous materials. *Journal of Chemical Education* 2015; 92(5): 936-939.
129. Loftsson T: Excipient pharmacokinetics and profiling. *International Journal of Pharmaceutics* 2015; 480(1-2): 48-54.

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