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Contents

Motto of this Journal
1. To provide scientific, technical and social welfare updates
2. To promote scientific drafting among staff and students
3. To circulate institutional updates
4. To build flat form to serve the community
5. To identify and appreciate potential achievements

Novel and co-processed excipients

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There has been a radical change in tablet manufacturing due to the introduction processes such as direct compression method and use of high speed machines due technology there has been an increased demand for exploiting the diverse functionalities of excipients that make use of their flow and compression properties. Due to the simplicity in terms of manufacturing and associated cost implied, direct compression method is highly preferable method of tablet production this in turn has led to an increased research and detailed study for developing newer excipients with better tableting properties. Various techniques along with substantial usage of particle and material sciences have been employed for the introduction of a new class called as co processed excipients. This has been written with aim of giving detailed information about the sources of new excipients, potential advantages of co processed excipients material characteristics required for co processing, various methods of preparing co processed for direct compression available in the market, description of some available co processed excipients, evaluation parameters for checking the functionality of co-processed excipients and their future developments.

An excipient is a natural or synthetic substance formulated alongside the active ingredient of a medication. significance of the excipients includes:

- Aids processing of the system during manufacture
- Protect, support, or enhance stability
- Assist in product identification
- Enhance any other attribute of the overall safety and effectiveness
- Bioavailability, or patient acceptability

Novel Excipients

Novel excipient is a new chemical entity, a new innovation that has not been used in any drug approved by regulatory authorities or it is a combination of excipients containing new chemical entity/entities (not in approved drugs) and excipients that are already in approved drugs in a mixed or co-processed scenario.

Considerations

- The Community provisions concerning additives in foodstuffs: any criteria which are based on the toxicological data, with cross-references to these data.
- The quality specifications which have been laid down in the directives are satisfactory as long as the routine control tests used are validated.
- The international specifications (FAO/WHO/JECFA), and other publications, such as the Food Chemical Codex.
- For medicinal products for cutaneous use, data on the ingredient used in cosmetic products.
- Data concerning the toxicology of the novel excipient according to the dosage form and the route of administration of the medicinal product

Development of novel excipients can be carried out in two different ways:

Modification of known excipients

This type of development is done by modification of already existing excipient by developing its derivative or successor. Chemical modification in structure of excipient is done by changing or introducing new functional groups to existing excipient. Classical example of it may be development of different cellulose derivatives, cyclodextrins etc.

Completely new excipients

This is the most challenging task that researchers have to face. It starts from thinking about base moiety for excipient. Once target is

identified, different chemical structure classes are screened and selected structure is optimized for particular characteristics. After that scale up and pilot scales batches were taken. At each step, quality control testing and characterization different parameters such as viscosity, rheology, spectroscopy testing etc. is done. Along with this, toxicological testing in animals is carried out which generally takes three years to complete. Subsequently, production scales batches are manufactured and drug master file (DMF) application is submitted. In all, novel excipient development takes 6-8 years to complete.

Functionality

Physicochemical

It involves assessment of physicochemical properties of excipients, impurities profiling, and stability assessment. This characterization involves spectroscopic, chromatographic, thermal methods of analysis. During this analysis, viscosity, rheology, melting point, specific gravity, refractive index, acid and ester values, loss on heating and drying, pH value, heavy metals, residual solvents and monomers were determined and noted and used to know there purity.

Safety

During this study, ICH M4S (R2) guideline is followed for generation of safety data. Chronic and sub-chronic toxicity, genotoxicity (including mutagenicity), reproductive toxicity, carcinogenicity, primary irritation and skin sensitization testing, bioavailability, pharmacokinetics (ADME) and characterization of impurities and their toxicity are done in this study domain.

Regulatory

Question arises in minds whether excipients are actually inert? Historically, Sulfanilamide tragedy 1937 happened due to lack of knowledge about excipients' use. This gave us regulatory reforms leading to development of regulatory guidelines regarding excipients. Currently, there is no special provision for approval of new excipients. Excipients are approved along with the dosage forms. Excipient is regarded as "approved" when the new drug formulation containing novel excipient received regulatory approval. Existing guidelines do not provide guidance on potentially useful excipients from food / beverage industries or for excipient with a new application such as changing dose route. But still pharmaceutical excipient companies are investing in evaluation of new materials and application of new uses for existing excipients.

For excipient(s) used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross references to supporting safety data (nonclinical and/or clinical) should be provided according to the drug substance format. Similarly European Medicines Agency has given following guidelines in Section 4.5 with following:

For novel excipients, a dossier should be established containing the same data as required for new active substances:

- A strict definition of the excipient, its function and its conditions of use. If the excipient is complex or is made of a mixture of compounds, the composition should be specified in qualitative and quantitative terms.
- For novel excipients and for excipients presented as a mixture of compounds the following should be taken into consideration:
- Any bibliographical data on the chemistry and on the toxicology and the field in which the product is already used.
- The community provisions concerning additives in foodstuffs: any criteria which are based on the toxicological data, with cross-references to these data.
- The quality specifications which have been laid down in the directives are satisfactory as long as the routine control tests used are validated.
- The international specifications (FAO/ WHO/ JECFA), and other publications such as the Food Chemical Codex.
- For medicinal products for cutaneous use, data on the starting material in cosmetic products.
- Data concerning the toxicology of the novel excipient should be presented according to the dosage form and the route of administration of the medicinal product (if applicable).
- Documentation on chemistry of excipients is required for all new excipients, taking as its basis the CPMP Guideline on the Chemistry of New Active Substances

- The origin of the excipient, including the name and address of manufacturer.
- A general outline of the synthesis (manufacture and purification).
- Structure.
- Physical, chemical properties, identification and purity tests.
- Validated methods of analysis with a presentation of batch results.
- Miscellaneous information (microbiological tests, etc).
- Contamination, presence of foreign substances, residual solvents etc.
- In the case of an excipient obtained from a mixture of several components, the quality of each component and the physiochemical tests for the mixture should be described.
- Stability data should be provided as required for the active substances in the ICH Q1A
- The routine test procedures and limits should be established on the basis of the documentation given in the dossier.

International Pharmaceutical Excipients Council (IPEC) is working for harmonization and setting up guidelines for novel excipients. IPEC has set up excipient master file guide for novel excipients as Type IV Drug master file (DMF). This guide has been divided into administrative information and technical document portion.

Sources of new excipients: Excipients with improved functionality can be obtained by developing new chemical excipients, new grades of existing materials, and new combinations of existing materials. Any new chemical excipient being developed as an excipient must undergo various stages of regulatory approval aimed at addressing issues of safety and toxicity, which is a lengthy and costly process. In addition, the excipient must undergo a phase of generic development, which shortens the market exclusivity period. The high risk and significant investment involved are not justified in view of the meager returns from the new excipients. A plausible solution is for excipient and pharmaceutical manufacturers to develop drug products jointly, during which a new excipient becomes part and parcel of the eventual new drug application. This type of arrangement already has been successfully applied in the intravenous delivery field, in which CYDex and Pfizer worked collaboratively to obtain the approval of a solubilizer. The combined expertise of pharmaceutical and excipient companies can lead to the development of tailor made innovative excipients. Developing new grades of existing excipients has been the most successful strategy for the development of new excipients in past three decades, a process that has been supported by the introduction of better performance grades of excipients such as pregelatinized starch, croscarmellose, and crospovidone.

However, functionality can be improved only to a certain extent because of the limited range of possible modifications. A new combination of existing excipients is an interesting option for improving excipient functionality because all formulations contain multiple excipients. Many possible combinations of existing excipients can be used to achieve the desired set of performance characteristics. However, the development of such combinations is a complex process because one excipient may interfere with the existing functionality of another excipient. Over the years, the development of single- bodied excipient combinations at a sub particle level, called co processed excipients, has gained importance. New physical grades of existing excipients and co processed excipients are discussed further in the following section of this article that explains particle engineering. Particle engineering is a broad- based concept that involves the manipulation of particle parameters such as shape, size, size distribution, and simultaneous minor changes that occur at the molecular level such as polytypic and polymorphic changes. All these parameters are translated into bulk level changes such as flow properties, compressibility, moisture sensitivity, and machinability.

Particle engineering as source of new excipients Solid substances are characterized by three levels of solid state: the molecular, particle, and bulk level. These levels are closely linked to one another, with the changes in one level reflecting in another level. The molecular level comprises the arrangement of individual molecules in the crystal lattice and includes phenomena such as polymorphism, pseudo polymorphism, and the amorphous state. Particle level comprises

Individual particle properties such as shape, size, surface area, and porosity. The bulk level is composed of an ensemble of particles and properties such as flowability, compressibility, and dilution potential, which are critical factors in the performance of excipients. The fundamental solid state properties of the particles such as morphology, particle size, shape, surface area, porosity, and density influence excipient functionalities such as flowability, compactability, dilution potential, disintegration potential, and lubricating potential.

Hence, the creation of a new excipient must begin with a particle design that is suited to deliver the desired functionalities. Varying the crystal lattice arrangement by playing with parameters such as the conditions of crystallization and drying can create particles with different parameters. It is also possible to engineer particles without affecting the proceeding molecular level. Avicel 101 and 102 (microcrystalline cellulose) and spray dried lactose are examples in which such an approach has been successfully applied. However, particle engineering of a single excipient can provide only a limited quantum of functionality improvement. A much broader platform for the manipulation of excipient functionality is provided by co-processing or particle engineering two or more existing excipients. Co-processing is based on the novel concept of two or more excipients interacting at the sub particle level, the objective of which is to provide a synergy of functionality improvements as well as masking the undesirable properties of individual excipients.

The availability of a large number of excipients for co-processing ensures numerous possibilities to produce tailor made “designer excipients” to address specific functionality requirements. Co-processed excipients are prepared by incorporating one excipient into the particle structure of another excipient using processes such as co-drying. Thus, they are simple physical mixtures of two or more existing excipients mixed at the particle level. Coprocessing was initially used by the food industry to improve stability, wettability, and solubility and to enhance the gelling properties of food ingredients such as co processed glucomannan and galactomannan.

Co-processing of Excipients in the pharmaceutical industry can be dated back to the late 1980s with the introduction of co processed microcrystalline cellulose and calcium carbonate, followed by Cellactose (Meggle Corp.,Wasserburg, Germany) in 1990, which is a co processed combination of cellulose and lactose. A similar principle was applied in developing silicified microcrystalline cellulose (SMCC), which is the most widely used co processed excipient. Co-processing excipients leads to the formation of excipient granulates with superior properties compared with physical mixtures of components or with individual components. They have been developed primarily to address the issues of flowability, compressibility, and disintegration potential, with filler–binder combinations being the most commonly tried.

The combination of excipients chosen should complement each other to mask the undesirable properties of individual excipients and, at the same time, retain or improve the desired properties of excipients. For example, if a substance used as a filler–binder has a low disintegration property, it can be co-processed with another excipient that has good wetting properties and high porosity because these attributes will increase the water intake, which will aid and increase the disintegration of the tablets.

Monograph: Once the excipient has been used in formulations and has been approved by regulatory authorities, monograph making process starts. Proposed monograph data package is sent to Pharmacopeia expert committee on excipients for review. If it is accepted, it is released for public comment. If no comments are received for monograph, it will be approved for inclusion which takes 60- 90 days. If comments are received, revision is made and again public consultation is done. In general, for an excipient monograph to get official status, 6 to 15 months are required.

Future trends: In short it can be said that challenges in formulation and drug delivery of active ingredients are impossible to solve with old excipients. Therefore, more research will be focused on development of novel excipients for efficient drug delivery at targeted site. Individual approval of excipient by separate registration process from finished product

registration will provide guide to pharma companies for effective use of novel excipient in safe dosage. Due to this, research on novel excipient will also foster leading to their use in different dosage forms and routes. All these activities will promote innovation in novel excipients by providing ease of market approach and penetration to excipient companies. Final outcome of this will be effective, safe and reliable medicine to patient leading to betterment of man kind

Co Processed Excipient: Co-processing excipient is an excipients mixture containing more than one excipient and not prepared by simple physical mixing. These materials are formulated with co-crystallization, co-grinding, co-precipitation, spray drying and common solvent evaporation techniques.

Need: The physical properties such as particle size, shape, density may differ from one excipient to another excipient and results segregation and non-uniformity. In case of co-processed excipients, the physical properties are well controlled. The time required for process validation can be reduced and process optimization is simplified. One of the excipient usually contributes major amount and the other component is incorporated in to the main component to attribute other beneficial properties. In certain cases both the components may have same functional activity (diluents). Co-processing excipients containing the combination of microcrystalline cellulose and mannitol imparts the desired compressibility and good mouth feel and rapid dissolution. The former property is due to micro crystalline cellulose and the later is attributed by mannitol. Other commercial example in the market is emdex which contains 93% dextrose and 7% maltodexrin. The ability to modulate the solubility, permeability, or stability of drug molecules. The growing performance expectations of excipients to address issues such as disintegration, dissolution, and bioavailability.

Advantages of co-processing

- Improved Flow Properties
- Compressibility
- Better dilution potential
- Fill weight variation
- Reduced lubricant sensitivity

Technologies used In Co-Processed Excipients

Roller compaction

Dry granulation process is a particle-bonding process. Miller described the theory of granule bond formation as

a. Particle rearrangement
b. Particle deformation
c. Particle fragmentation
d. Particle bonding

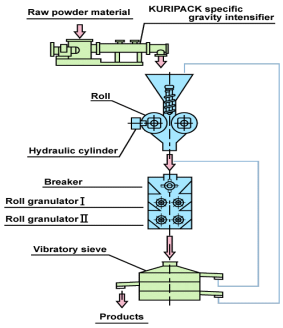
- In the roller compaction process, powder blends first pass a feeding zone, where most of the rearrangement occurs.
- The dense powders then go through a compaction zone, where increasing force is being exerted by two counter-rotating rolls.
- As the pressure goes up further into the compaction zone, the particles deform, fragment, and bond to form ribbons.

Advantages

1. Good control of process and cost-advantages compared to wet granulation.
2. As no liquid or drying is involved, this process is more suitable for water or heat sensitive drugs.
3. Compared to direct compression, roller compaction can handle high drug loading, improve flow and content uniformity, and prevent segregation

Disadvantages

1. Dissolution problem.
2. Loss of compatibility



Flow Chart for Roller Compact

Wet Granulation

Wet granulation is a process still widely used in the pharmaceutical industry. The advantages includes: It provides better control of drug content uniformity at low drug concentrations, as well as control of product bulk density and

ultimately compactibility (brittle fracture), even for high drug contents. Processing takes place in one of two types of closed granulating systems.

Fluid bed granulators:

- In fluid bed granulation, the powder mix is maintained as a fluidized bed by a flow of air injected upwards through the bottom screen of the granulator.
- The binding solution is sprayed above the powder bed, in a direction opposite to the air flow.
- Other spraying directions can be used on the same equipment for solids coating.
- The granules result from the adhesion of solid particles to the liquid droplets that hit the bed.
- Partial drying by the fluidizing air occurs continuously during granulation. The process continues until all the powder agglomerated, and it needs to be stabilized as far as moisture balance is concerned

High-shear granulation

- An impeller maintains the powder in agitation in a closed vessel, and here also a binder solution is sprayed from the top.
- As the liquid droplets disperse in the powder, they form the first nuclei o future granules. The agitation forces prevent the development of large agglomerates, because they would be too fragile to sustain the shear.
- However, as mixing and spraying proceed, the existing agglomerates undergo densification, whereby the internalized binder is squeezed out to the surface of the wet agglomerates. The process is stopped somewhere in this phase before an excess of liquid or excessive densification provokes a phase inversion, i.e. a slurry or uncontrollable growth ('balling' phenomenon).Then dries. This is denser than fluid bed.

Hot melt extrusion (HME)

- Hot melt extrusion is another thermal processing technique that has attached interest as a novel approach for the development of polymeric immediate, sustained release or transdermal/trans mucosal delivery system.
- This process is widely used in transferring and melting of polymer inside a barrel by a rotating screw.
- The polymer melt is then pressurized through the die and solidify into variety of shapes. Extrusion can be further processed into tablets or granules.
- HME is a continuous, simple and efficient process. No water or no solvent is required as the molten polymer can function as a thermal binder.
- The intense mixing and agitation during HME also disaggregates particles and improves the content uniformity of the extrudes.
- HME requires high temperature greater than 80°C. The excipient and the active ingredient need to be stable under those conditions.
- Plasticizers, antioxidants and other excipients can be included into the power blend to improve the processing condition and stability of each component during extrusion.

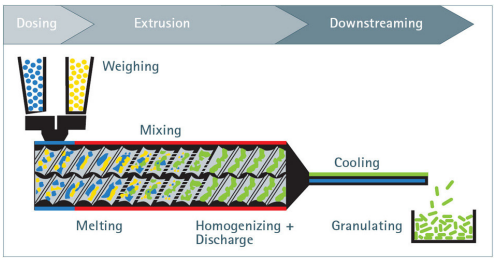


Figure: Hot melt extrusion

Spray drying

This technique enables the transformation of feed from a fluid state into dried particulate form by spraying the feed into a hot drying medium. It is a continuous particle processing drying operation. The feed can be a solution, suspension, dispersion or emulsion. The dried product can be in the form of powders, granules or agglomerates depending upon the physical and chemical properties of the feed, the dryer design and final powder properties desired. Spray drying process mainly involves five steps:

I .**Concentration**: feedstock is normally concentrated prior to introduction into the spray dryer.

ii. **Atomization**: This creates optimum condition for evaporation to a dried product.

iii. **Droplet-air contact:** Atomized liquid is brought into contact with hot gas, resulting in the evaporation of 95%+ of the water contained in the droplets in a matter of a few seconds.

iv. **Droplet drying:** Moisture evaporation takes place in two stages- The first stage, sufficient moisture in the drop to replace the liquid evaporated at the surface and evaporation takes place at a constant rate. The second stage begins when there is no longer enough moisture to maintain saturated conditions at the droplet surface, causing a dried shell to form at the surface. Evaporation then depends on diffusion of moisture through shell, which increases in thickness.

v. **Separation:** cyclones, bag filters, and electrostatic precipitators may be used for the final separation stage. Wet Scrubbers are often used to purify and cool the air so that it can be released to atmosphere

Excipients Used in Pharmaceutical Industry

Trade name	Composition and their percentage		
Ludipress	Lactose monohydrate 93.4%	Polyvinyl pyrrolidine 3.2%	Crospovidone 3.4%
Cellactose	Lactose monohydrate 75%	Cellulose 25%	
Pharmatose dcl 40	B-lactose 95%	Anhydrous lactitol 5%	
Prosolv	Microcrystalline 98%	Colloidal silicone dioxide 2%	
Star lac	Lactose monohydrate 50%	Maize starch 50%	
Directly compressible sucrose	Sucrose 95%	Sorbitol 5%	
Di-pac	Sucrose 95%	Modified dextrin 3%	
Starch 1500	Amylose 5%	Amylopectin 15%	Unmodified starch 80%

Evaluation parameters for co processed excipients

Particle size distribution- The particle size distribution can be calculated by statistical method such as frequency curve method. When the number, or weight, of particles lying within a certain size range is plotted against the size range or mean particle size, a so called frequency curve is obtained.

Carr's index- The bulk density is the quotient of the weight to the volume of sample. The tapped density was determined as the quotient of the weight of the sample to the volume after tapping a measuring cylinder 500 times from a height of 2inches. Carr's index (percentage compressibility) was calculated as one hundred times the ratio of the difference between the tapped density and bulk density to the tapped density.

$$C = 100\frac{V_B - V_T}{V_B}$$

Hausner Ratio- Hausner ratio is the ratio of bulk density to the tapped density.

$$H = \frac{\rho_T}{\rho_B}$$

Where ρ_B is the freely settled bulk density of the powder, and ρ_T is the tapped bulk density of the powder. The Hausner's ratio is not an absolute property of a material; its value can vary depending on the methodology used to determine it.

Angle of repose- The angle of repose is a relatively simple technique for estimating the flow properties of a powder. It can easily be determined by allowing a powder to flow through a funnel and fall freely onto a surface. The height and diameter of the resulting cone are measured and the angle of repose calculated from this equation:

$$\text{Angle of repose } (\theta) = \tan^{-1}\left(\frac{h}{r}\right)$$

Where, 'h' is the height of the powder cone and 'r' is the radius of the powder cone.

Future trends: The obvious advantages of solid dosage forms and changing technological requirements will keep alive the search for newer excipients. The newer excipients are required to be compatible not only with the latest technologies and production machineries, but also with the innovative active principles such as those originating from biotechnology. Developments in the field of excipients and manufacturing machinery have helped in establishing traditional inert excipients as functional components. A deeper understanding of their solid-state properties and its impact on excipient functionality is further going to fuel this trend. Functionalities, hitherto unavailable to the formulator, can now be incorporated into the product by judicious choice of high-functionality excipients. Further, a narrow pipeline of new chemical excipients, and an increasing preference for the direct compaction process, creates a significant opportunity for the development of high-functionality excipients. A greater synergy between excipient manufacturers and the pharmaceutical manufacturer in the future is going to help in the development of tailor-made designer excipients complying with safety, performance, and regulatory issues.

Conclusion: Technological advancements in tablet manufacturing, introduction of high-speed machineries, and a shift in tableting toward direct compaction have catalyzed the search for newer excipients meeting these requirements. Excipients are no more considered as inert ingredients of formulation, but have a well-defined functional role. Co-processed excipients are a result of this arduous innovation only, wherein two excipients are co-processed to provide products with improved functionality by retaining their favorable and avoiding the unfavorable properties. The success of these excipients depends on their quality, safety, and functionality. Although the first two parameters have remained constant, significant improvements in functionality provide wide opportunities for the increased use of co-processed excipients. The main obstacle in the success of co-processed excipients is the non-inclusion of their monographs in official pharmacopeias, which discourages their use by manufacturers. With recommendations from IPEC and the continual efforts of excipient manufacturers, these products could find their way into official monographs, either as mixtures or as single-bodied excipients.

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Bioceramics as Drug Delivery Systems

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Bioceramics arebiocompatible,and can be inert,bioactive and biodegradable in physiological environment that makes it an ideal biomaterial.Bioceramics have evolved to become an integral and vital segment of our modern health care, including novel drug delivery system.The incorporation of drugs to bioceramicmatrices is receiving great interest in the field of biomedical and pharmaceutical technology.Bioceramics have been used as drug delivery and targeting systems showing homogeneous and reproducible performances.The particle size, stability, and loading capacity of nanobioceramics can be easily modified by customizing the structures and physicochemical properties to ensure their effectiveness and safety for clinical applications.

Bioceramics are a class of advanced ceramics which are defined as ceramic products or components used for repair and replacement of diseased and damaged parts of the musculoskeletal system,employed in medical and dental applications,mainly as implants and replacements. They are biocompatible,and can be inert,bioactive and biodegradable in physiological environment that makes it an ideal biomaterial. However, it is brittle with poor tensile strength that makes it unsuitable for load bearing applications. Materials that are classified as bioceramics include alumina,zirconia,calciumphosphates,silica based glasses or glass ceramics and pyrolytic carbons.

Composite materials may be defined as those materials that consist of two or more fundamentally different components that are able to act synergistically to give properties superior to those provided by either component alone. Composites made of bioinert and bioactive ceramics are produced to achieve two important features, bioactivity and mechanical strength. Such composites were biologically evaluated by scientists through several animal tests. Alumina ceramic can form composites with hydroxyapatite that are bioactive. Animal experiments of HA/alumina composite reveal that it can form tight osteointegration with bone. It is bioactive with high strength.

TYPES OF BIOCERAMICS:

Depending on the function and characteristics, we can find different types of bioceramics. Bioceramics may be

Bioinert: alumina and Zirconia
BioResorbable: tricalcium phosphate
Bioactive: hydroxyapatite, bioactive glasses and glass ceramics

Porous for tissue ingrowth: hydroxyapatite-coated metals, alumina.

Bioceramics may be bioinert (alumina, zirconia), bioresorbableor biodegradable (tricalcium phosphate) and bioactive (hydroxyapatite, bioactive glasses, and glass-ceramics). Bioinertmaterials form a fibrous capsule around the implant. Bioactive materials on the other hand form an interfacial bond with the implant, whereas bioresorbable (biodegradable) materials are replaced with the new tissue as the implant dissolved.

Alumina and zirconia are chemically inert and hard. Therefore it is an ideal material for an articulating surface in hip and knee joints. Alumina is also used in dental crowns, cochlear implants, maxillo-facial applications and as a scaffold for bone the growth. Zirconia is used in artificial knee, bone screws and plates, and as femoral heads. Pyrolytic carbon (commonly called as pyrocarbon) is mainly used as an artificial heart valve material because of its good strength, wear resistance and durability, and most importantly, thromboresistance i.e. the ability to resist blood clotting.it is also used in orthopedics for small joints such as fingers and spinal inserts.

Calcium phosphates include tricalciumphosphates, hydroxyapatite and tetracalciumphosphates. Hydroxyapatite found in

bone is a poorly crystalline apatite,formed by nanosized needle like crystals. Unliketetracalcium phosphates and tricalciumphosphates,hydroxyapatite does not break down under physiological conditions. It is bioresorbable,thermodynamically stable at physiological pH and actively takes part in bone bonding,forming strong chemical bonds with surrounding bone. This property has been exploited for rapid bone repair after major trauma or surgery.

ADVANTAGES OF BIOCERAMICS:

1. Biocompatible and biodegradable.
2. Capable to act as cietvery systems for a large varietyofbiologically active molecules.
3. Wide particle size variation, from macro to nano range.
4. No disease transmission risk.
5. No immunogenicity/anaphylaxis.
6. Better stability prcge.
7. Easy to fabricate,.
8. Unlimited materia/ suppiy at low cost.

DISADVANTAGES OF BIOCERAMICS:

1. Mechanical failure under tensile stresses in presence of chemical environment.
2. limited range of elastic modulus of ceramics.
3. Rate and type of bioceramics to musculoskeletal system i.e, fixation of cement with bone.
4. Lack of data on effects on age,metabolicstates,diseased states etc on behaviour of bioceramics.

FUNCTIONS OF BIOCERAMICS:

Bioceramics satisfy needs as diverse as low co-efficients of friction for lubricating surfaces in joint prostheses, surfaces on heart valves that avoid blood clotting, materials that stimulate bone growth and those that can harness radioactive species for therapeutic treatments.

Bioceramics, such as calcium phosphate ceramics and cements and silica-based glasses, are widely used as components of implants for bone and teeth restoration. Nowadays, the advanced processing methods and new chemical strategies allow the incorporation of drugs within them or on their functionalized surfaces. In this regard, bioceramics act as local drug delivery systems to treat large bone defects, osteoporotic fractures, bone infections and bone tumours. The development of new mesoporous nanoceramics, suitable to be used as carriers for drug delivery, has also opened new perspectives for cancer therapies. Mesoporous silica nanoparticles can be prepared as vehicles able to release the drug within specific cancerous cells. When the pores are closed with molecular nanogates, stimuli-responsive systems can be obtained, thus allowing drug release at will by supplying external stimuli such as magnetic fields, ultrasound or light.

CONCLUSIONS:

Bioceramicmaterials including bioceramic nanoparticles (nanobiocerarnics) may effectively be utilized for the delivery of a multitude of drugs like antibiotics, antineoplastics, steroids, peptides and protein drugs, radioisotope delivery, DNA or gene delivery. However, the drug release rate profile, pharmacokinetic profile, bioavailability study, clinical study, biodegradation kinetics study, stability studies should thoroughly be performed to ascertain the longterm reliability of bioceramics as a safe, effective and affordable means for drug delivery and targeting in due course.

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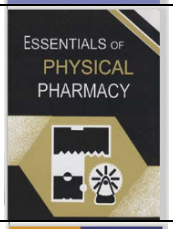
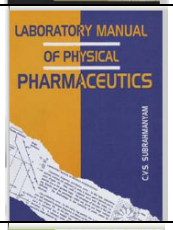
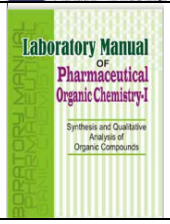
Ms .M. Yogitha, B. Pharm II year

Books published by GRCP faculty

	*Dr CVS Subrahmanyam, J. Thimmasetty, Industrial Pharmacy – Selected Topics, Vallabh Prakashan, Delhi, 1ST ed, 2013, ISBN: 978-81-85731-98-8*
	*Dr CVS Subrahmanyam, Essentials of physical pharmacy, Vallabh Prakashan, Delhi, 1st ed, 2014, ISBN: 81-85731-34-9*
	*Dr CVS Subrahmanyam, Laboratory manual of Physical Pharmaceutics, Vallabh Prakashan, Delhi, 2nd ed 2014, ISBN: 9788185731285*
	*Dr NM Raghavendra, Mr. Sayan Dutta Gupta. Laboratory manual of Pharmaceutical Organic Chemistry, Vallabh Prakashan, Delhi, 2013 ISBN: 9788185731810*

Industrial visits

The students of B. Pharm III year I semester were given onsite exposure to Centre for Aromatic and Medicinal Plants, Secunderabad on 26-07-2013. Our students gained knowledge regarding the cultivation and collection of various medicinal plants. Dr Sneha JA and Mrs Swapna A, accompanied our students and helped them to acquire knowledge regarding the medicinal plants.

Honours and achievements of staffs

	*Dr. N. M. Raghavendra is a visiting Scientist at Dept. of Applied Pharmacology, Fundacao Oswaldo Cruz, Rio de Janeiro, BRASIL. His credentials include several projects from different national bodies, DHR, DST, ICMR and AICTE sponsored projects.*
	*Mrs. Trapti Saxena has received best presentation award at Pharma Innovate-2k13.*
	*Dr. Induru Jagadesh has attended refresher course on "Manufacturing Strategies" at UGC-academic staff college, JNTU, Hyderabad, obtained certificate course in yoga and consciousness at AU, advanced international certificate course on IPR organized by WIPO.*