Aim & Objectives
1. AIM AND OBJECTIVES

Most of the APIs are crystalline solids at room temperature and also exhibit different crystal habits, which ultimately affect the formulation.

Tablets are the ruling dosage form, which requires an economical process for production. Wet granulation is the widely used technique for tablet production, especially for the drugs which are either of high dose or having poor micromeric and mechanical properties. Wet granulation process is always associated with mixing of ingredients, selection of granulating solution, binder selection, wet screening, drying sifting, etc, which is costly in terms of time required, expensive equipments and labor. Direct compression is the process by which, tablets are compressed directly from a simple blending of APIs and excipients. This technique can cut down cost of expensive equipments, labor and manufacturing steps, which is a current need of pharmaceutical industries.

Flow and compactibility of particles or powder are the most important considerations in direct compression as blending, transfer of materials, compaction and fluidization depends on good flow properties. The other fundamental properties which are essential in solids for dosage form are particle size distribution, shape, melting point, solubility, dissolution, etc.

Surface area and real area of contact will lead to cohesion and adhesion properties of particle surface and imparts poor flow property. Particle size enlargement has become an important tool in modifying the flow property of pharmaceuticals.

Improvement in efficiency of manufacturing and high degree of particle functionality can be achieved by various techniques like co-crystallization, pelletization, crystallo-co-agglomeration, spherical crystallization, melt solidification, etc.

Apart from this, poorly water soluble drugs often requires high dose in order to reach therapeutic plasma concentration through oral administration. Improvement in rate and extent of dissolution is highly desirable for such compounds. Various techniques are employed to enhance the rate and extent of dissolution like cogrinding with excipient(s), cosolvency, solid dispersion, complexation, etc.
In the present investigation, two drugs 1) Metformin HCl (freely water soluble) and 2) Chlorzoxazone (poorly water soluble) are selected for study. Both the drugs have high cohesiveness, very poor flow property and compressibility, hence wet granulation is the only option for manufacturing of conventional tablets.

Here, by applying particle engineering techniques like co-crystallization, crystallo-co-agglomeration (CCA) and pelletization, the drugs has been converted to a form of excellent flowability and direct compressibility to tablets with improved dissolution profile. Moreover, cogrinding in presence and absence of polymer(s)/excipient(s) is employed to bring amorphization in drug which can drastically improve the dissolution kinetics of drug.

Coformer(s) /polymer(s) /excipient(s) /carrier(s) used in the above processes are the range of hydrophobic to hydrophilic type like, SLS, span-80, tween – 20, PEG 400, PVP K30, HPMC, HPC, NaCl, lactose, mannitol, ethyl cellulose, neusilin US2, kaolin, talc, etc.

**The objectives of present investigation are,**

1. To study the effect of solvents and polymers on the crystallization behavior of active pharmaceutical ingredients.
2. To optimize the experimental conditions for obtaining crystal morphs of active pharmaceutical ingredients.
3. To study mechanical properties of the crystals morphs.
4. To characterize the crystals of active pharmaceutical ingredients.
5. To study the solubility and manufacturability of these crystals morphs.
6. To study dissolution behavior and improve pharmacokinetic properties of these crystals morphs.