

## RESEARCH & REVIEW ON HOT MELT EXTRUSION: AN EMERGING DRUG DELIVERY TECHNOLOGY OF 21st CENTURY

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Hot melt extrusion (HME) is emerging technology which is gaining high importance in the pharmaceutical industry as a novel technique for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. It is a fast growing technology platform that is utilized to solve difficult formulation challenges, primarily in the area of solubilization. Due to fast processing, high degree of automation, absence of solvents, simple and continuous operation and ability to process poorly compactable material into tablet form are some of the main advantages offered over conventional processing by this emerging technique. Applications of HME in pharmaceutical industry continues to grow and recent success of this technique have made it a useful tool of consideration as a drug delivery solution.

The use of hot-melt extrusion (HME) within the pharmaceutical industry is steadily increasing, due to its proven ability to efficiently manufacture novel products. HME involves the application of heat, pressure and agitation through an extrusion channel to mix materials together, and subsequently forcing them out through a die. Twin-screw extruders are most popular in solid dosage form development as it imparts both dispersive and distributive mixing. It blends materials while also imparting high shear to break-up particles and disperse them. HME extrusion has been shown to molecularly disperse poorly soluble drugs in a polymer carrier, increasing dissolution rates and bioavailability.

There are two kinds of extruders: single and twin screw extruders (see Figure 2). Single screw extruders are fundamentally utilized for dissolving and passing on polymers to expel them into ceaseless shapes though twin screw extruders are utilized for softening blending polymers in with extra materials (shades, fillers, reinforcers, and APIs), and for devolatilization. In the creation of pharmaceutical definitions, which require homogeneous and reliable blending of numerous detailing fixings, a twin screw extruder is favored in light of the fact that the pivot of the between cross section screws gives better blending to deliver a homogeneous strong containing finely scattered API particles or a strong arrangement of API in polymer. Reliable liquefy blending by means of twin screw expulsion can improve the disintegration rate and bioavailability of inadequately water-dissolvable API plans. Consistently conveyed API is likewise an essential to create medicate eluting gadgets with intra-and between clump reproducibility of medication discharge energy.

Dissolving is cultivated by frictional warming inside the barrel. For twin-screw extruders, the materials experience shearing between the pivoting screws and between the screws and the mass of the barrel as they are passed on. The barrel can be warmed with barrel-mounted radiators on the or cooled with water. The barrel segment temperatures are normally streamlined with the goal that the material consistency is sufficiently low to permit legitimate blending and transport down the barrel, while additionally keeping temperatures sufficiently low to stay away from warm debasement.

The screws of a twin screw extruder are typically built to give various sorts of blending and passing on conditions at different zones in the barrel. During item improvement, secluded screws with various components (Figure 3) fitted on a typical shaft permit the fitting and advancement of the screw plan for every item. Segments of the screw can be intended to perform molecule size decrease, blending, and passing on capacities. The length of the screw comparable to the barrel width (the L/D proportion) is picked to enhance the level of blending and the quantity of zones required to accomplish the last item qualities. A case of a total particular screw is appear in Figure 4. Single piece creation screws might be worked to a similar plan as the improvement screws and are simpler to clean for cGMP consistence.

Revolution of the screws makes distributive and dispersive blending (Figure 5). Distributive blending boosts the division and recombination of the materials while limiting vitality contribution by blending in with low extensional and planar-shear impacts. This consistently mixes the materials however doesn't fundamentally lessen scattered material molecule size and yields negligible warm and shear corruption of delicate materials.

Dispersive blending applies extensional and planar shear fields to break the scattered materials to littler size, in a perfect world utilizing vitality at or somewhat over the edge level expected to separate them.

The utilization of various blending components permits the twin screw extruder to perform both molecule size decrease and blending with the goal that the APIs can be fused into the polymer in scattered structure or, if the API dissolvability in the

polymer is sufficiently high, in disintegrated structure. Since the extrudate cools quickly on leaving the extruder, any API that is disintegrated in the polymer at the blending temperature might be not able to recrystallize on cooling, prompting supersaturated strong arrangements. In such cases, security of the item should be firmly followed as recrystallization of the API over lengthy timespan scales is conceivable, particularly at raised capacity temperatures and high API loadings, which may affect the timeframe of realistic usability of the last item.

Various sorts of leave bites the dust are utilized to shape the extrudate to the ideal profile. These kicks the bucket incorporate sheet and film passes on utilized in transdermal film applications, strand bites the dust utilized for clinical tubing and some medication eluting gadgets, shape bites the dust utilized in blow embellishment, and co-expulsion bites the dust utilized in repository gadget plans. Distinctive downstream helper parts are additionally utilized in the completing procedure, including water showers and air blades for cooling, transport lines for moving the expelled item from the pass on to the furthest limit of the line, strand-cutters for cutting the extrudate into tubing or poles, and spoolers for extrudate assortment. Pelletizers are utilized for cutting the extrudate into littler pieces for direct container filling and, on account of certain gadgets, for infusion embellishment to frame the last item.

HME permits the API to be blended in with the polymer under the base of shear and warm anxieties and, thus, with the development of negligible procedure related API degradants. Cancer prevention agents are regularly included inside the plan, and the short living arrangement time in the barrel (normally on the request for minutes) additionally assists with limiting warm debasement, particularly contrasted with clump blending and other aggravating procedures.