Review on Hot Melt Extrusion Technique

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Abstract

Various approaches have been adopted to address this including preparation of solid dispersions and solid solutions. Hot-melt extrusion is an efficient technology for producing solid molecular dispersions with considerable advantages over solvent-based processes such as spray drying and co-precipitation. Hot-melt extrusion has been demonstrated to provide sustained, modified, and targeted drug delivery. Hot-melt extrusion (HME) is an established process that has been used since the early 1930s, predominately in the plastics manufacturing industry, but also in the food processing industry. Currently, more than half of all plastic products, including bags, sheets, and pipes, are manufactured using HME. Since the advent of plastics production, polymers have been
Melted and formed to different shapes for a variety of industrial and domestic applications. HME is the process of embedding drug in a polymeric carrier. Today this technology has found its place in the array of pharmaceutical manufacturing operations. Melt extrusion process are currently applied in the pharmaceutical field for the manufacture of a variety of dosage forms and formulations such as granules, pellets, tablets, suppositories, implants, stents, transdermal systems and ophthalmic inserts. This is relevant for poorly-soluble pharmaceutically active substances, frequently encountered among novel drugs.

Introduction

Hot-melt extrusion is one of the most widely applied processing technologies in the plastic, rubber and food industry. Melt extrusion process are currently applied in the pharmaceutical field for the manufacture of a variety of dosage forms and formulations such as granules, pellets, tablets, suppositories, implants, stents, transdermal systems and ophthalmic inserts. Industrial application of the extrusion process dates back to 1930's [1]. Hot-melt extrusion is one of the most widely applied processing technologies in the plastic, rubber and food industry. Currently, more than half of all plastic products, including plastic bags, sheets and pipes are manufactured by this process [2].
Recently melt extrusion has found its place in the array of the pharmaceutical manufacturing operations. Several research groups have evaluated this technology to achieve enhancement in dissolution rates for poorly water soluble drugs, to modify drug release and transdermal passage of the drug. Extrusion is the process of converting a raw material into a product of uniform shape and density by forcing it through a die under controlled conditions [1]. Extrusion can be operated as a continuous process, which is capable of consistent product flow at relatively high throughput rates. An extruder consists of two distinct parts: the conveying system which transports the material and imparts a degree of distributive and dispersive mixing, and the die system which forms the material into the required shape. Extrusion may be broadly classified into a molten system under temperature control or a semisolid viscous system. In molten extrusion, heat is applied to the material in order to control its viscosity and enable it to flow through the die. Whereas, semisolid systems are multiphase concentrated dispersions containing a high proportion of solid mixed with liquid phase [3].

Methodology

THERMOPLASTIC

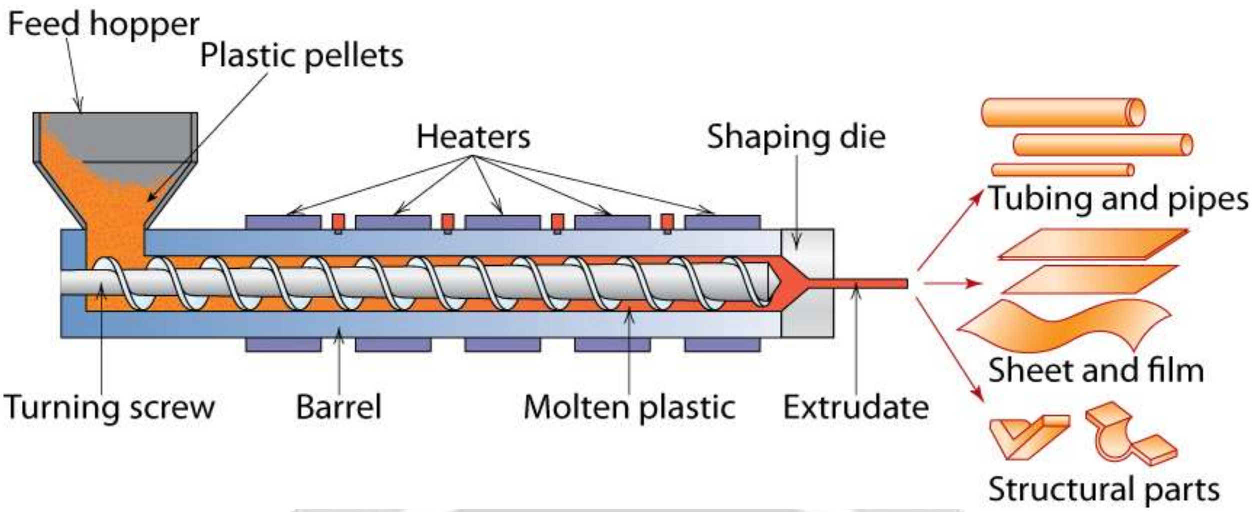
A **thermoplastic**, or **thermo softening plastic**, is a plastic polymer material that becomes pliable or mouldable at a certain elevated temperature and solidifies upon cooling [6]

Most thermoplastics have a high molecular weight. Thermoplastics differ from thermosetting polymers which form irreversible chemical bonds during the curing process. Thermosets do not melt when heated, but typically decompose and do not reform upon cooling.

Before these techniques were employed, plastic automobile parts would often crack when exposed to cold temperatures. These are linear or slightly branched long chain molecules capable of repeatedly softening on heating and hardening on cooling

HOT MELT EXTRUSION PROCESS

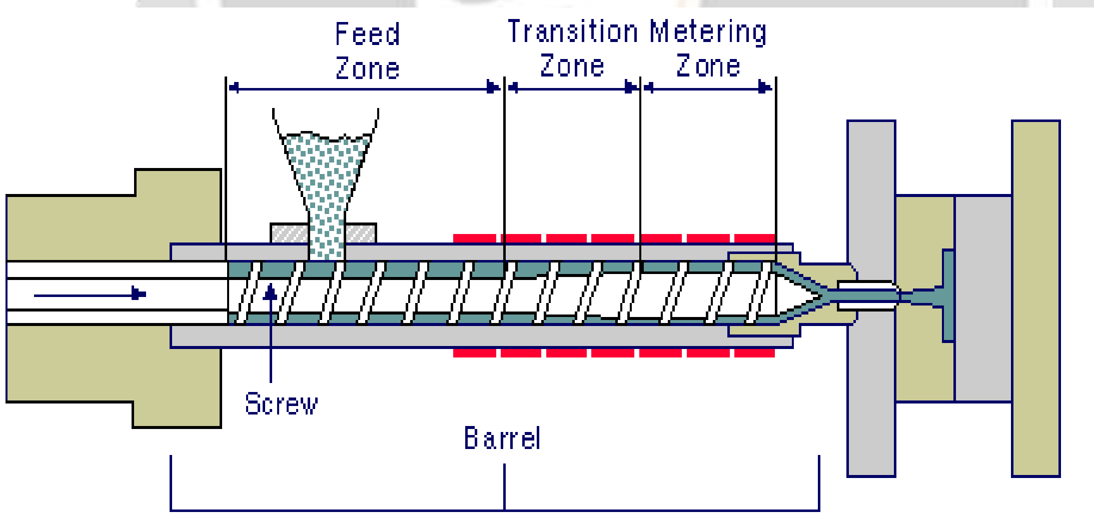
Hot-melt extrusion equipment consists of an extruder, auxiliary equipment for the extruder, downstream processing equipment, and other monitoring tools used for performance and product quality evaluation (8). The extruder is typically composed of a feeding hopper, barrels, single or twin screws, and the die and screw driving unit .The auxiliary equipment for the extruder mainly consists of a heating/cooling device for the barrels, a conveyer belt to cool down the product and a solvent delivery pump. The monitoring devices on the equipment include temperature gauges, a screw-speed controller, an extrusion torque monitor and pressure gauges. The theoretical approach to understanding the melt extrusion process is therefore, generally presented by dividing the process of flow into four sections (4):
1) Feeding of the extruder.
2) Conveying of mass (mixing and reduction of particle size).
3) Flow through the die.
4) Exit from the die and down-stream processing.
Generally, the extruder consists of one or two rotating screw inside a stationary cylindrical barrel. The barrel is often manufactured in sections, which are bolted or clamped together. An end-plate die, connected to the end of the barrel, determines the shape of the extruded product.



The heat required to melt or fuse the material is supplied by the heat generated by friction as the material is sheared between the rotating screws and the wall of the barrel in combination with electric or liquid heaters mounted on the barrels[9]. Most commercial extruders have a modular design, providing a choice of screws or interchangeable sections which alter the configuration of the feed, transition, and metering zones. This makes it possible to modify the process to meet particular requirements.

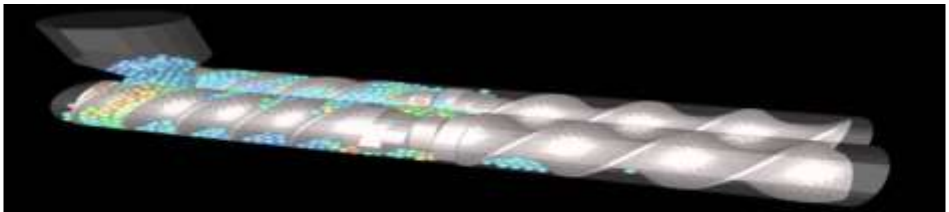
Different temperature zones

The extrusion channel is conventionally divided into three sections: feed zone, transition zone, and metering zone. The starting material is fed from a hopper directly in to the feed section, which has deeper flights or flights of greater pitch. This geometry enables the feed material to fall easily into the screw for conveying along the barrel. The space between screw diameter and width of the barrel is normally in the range of 0.1-0.2 mm.



4.2. There are two types of extruders:

Single-screw and twin-screw extruders. The single-screw extruder has been the most widely used. Twin-screw extruders use two side-by-side screws either co-rotating or counter-rotating there are several advantages of twin-screw extruders over single-screw extruders such as easier material feeding and dispersion capacities, less tendency to over-heat and shorter transit times. However, single-screw extruders are more simple and cheaper.. Example of twin-screw design: co-rotating (top) and counter-rotating (bottom) twin-screws



CONCLUSION

Today melt extrusion technology represents an efficient pathway for manufacture of drug delivery systems. Resulting products are mainly found among semi-solid and solid preparations. The potential of the technology is reflected in the wide scope of different dosage forms including oral dosage forms, implants, bio adhesive ophthalmic inserts, topical films, and effervescent tablets. In addition, the physical state of the drug in an extrudate can be modified with help of process engineering and the use of various polymers .Twin screw extruder is preferred instead of single screw because of its better mixing capability, higher productivity. Work on optimum utilization of energy in extruder has a greater scope. Extrusion process is effectively utilized in recycling of plastic.

Drawbacks of the technology are often related to high energy input mainly related to shear forces and temperature. This is where process engineering becomes significant. The design of screw assemblies and extruder dies are two major areas, which have significant impact on product quality and degradation of drug and polymers.

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