Available Online at

http://www.ijcpa.in

April-June 2017

International Journal of CHEMICAL AND PHARMACEUTICAL ANALYSIS

eISSN: 2348-0726 ; pISSN : 2395-2466

DOI : http://dx.doi.org/10.21276/ijcpa

Review Article | Volume-4 | Issue-3 | Article ID: 1317

HOT MELT TECHNOLOGY: AN OVERVIEW

Bhansali Sarika Rameshlal, Patil Pravin B., Kalkotwar R.S.

Affiliation: S.N.D. College of Pharmacy, Babhulgaon, Yeole, Nashik-423401, Maharashtra

***Corresponding Author:** Email: pprashant32@yahoo.com*

Received: 10 April 2017 / Revised: 11 May 2017 / Accepted: 13 May 2017 / Available online : 29 May 2017

ABSTRACT

Hot-melt technology is a process in which molten excipient(s) and/or drug are either layered on substrate, congealed alone or with excipient(s) using different technologies. Hot-melt technology is used to design various dosage forms and drug delivery systems which fulfil the therapeutic needs of the patient, which are cost-effective and manufactured by eco-friendly process. Hot-melt technology is used to enhance the bioavailability of poorly water soluble and lipophilic drugs, taste masking of bitter drugs, fabrication of extended release multiparticulates and designing of micropellets for compaction. This paper reviews the innumerable benefits of hot melt technology, based on a holistic perspective of the equipment, processing technologies to the materials, novel formulation design and developments, and its varied applications in oral drug delivery systems.

Keywords *– Hot melt; Excipients; Technology*

1. INTRODUCTION

A dosage form is a drug delivery systems designed to deliver the active ingredient(s) to the body. It must produce the same therapeutic response each time it is administered. The most common and popular route for administration of a dosage form or drug delivery system is oral. Amongst the various drug formulations or delivery systems for oral administration, the solid dosage forms are most widely used and produced. Tablets and capsules are the two most predominant solid oral dosage forms.

Hot-melt technology is used to design variety of oral dosages forms such as tablets with improved bioavailability of poorly water soluble drugs, taste masking and preparation of orodispersible tablets and multiple unit formulations.

Hot-melt technology is used to design different dosages forms and drug delivery systems which fulfil the therapeutic needs of the patient, which are cost-effective and manufactured by eco-friendly process. Hot-melt technology is used to enhance the bioavailability of poorly water soluble and lipophilic drugs, taste masking of bitter drugs, fabrication of extended release multiparticulates and designing of micropellets for compaction.[1-4]

2. ADVANTAGES OF HOT MELT TECHNOLOGIES

The various advantages of hot-melt technology in drug delivery are listed below:

1. Neither solvent(s) nor water is used in the process.

2. Fewer processing steps are needed, thus shorter processing times.
3. Fewer processing steps, thus less critical process parameters.
4. Good stability at varying pH and moisture levels.
5. Used for improved drug delivery.
6. Overall low production cost.
7. Since organic solvents are avoided, the process is environment friendly as well as safe for personnel and facility where processing is done.

3. LIMITATIONS OF HOT MELT TECHNOLOGIES

The various demerits of hot-melt technology in formulation design are as under:

i. Requires high energy input.
ii. Cannot be applied to heat-sensitive materials.
iii. Specially designed equipments are required.
iv. Limited lipidic excipients and thus limitations in formulation design.

4. TECHNIQUES USED IN HOT MELT TECHNOLOGY

Hot-melt technology is a process in which molten excipient(s) and/or drug are either layered on substrate, congealed alone or with excipient(s) using one of the following processes to design improved drug delivery systems –

a) Hot-melt coating
b) Spray congealing
c) Hot-melt extrusion and spheronization
d) Hot-melt extrusion
e) Hot-melt granulation.

a) Hot-melt coating: Hot-melt coating involves spraying of molten excipient(s) or mixture of molten excipient(s) and drug either in suspended or dissolved form onto a substrate during fluidization in a fluid-bed coating device. The lipid solidifies on the substrate upon cooling and forms a thin homogenous film.[5]

***b) Spray congealing*:** Spray congealing is a method of converting molten excipient(s) with drug into dry powder, granules or spheroids by spraying through suitable pneumatic nozzles in a stream of co-current or counter-current cold fluidized air.[6]

***c) Hot-melt extrusion and spheronization**:* Hot extrusion spheronization is a multiple step process. The process involves hot-melt extrusion of low melting point excipient(s) with drug followed by hot-melt spheronization and gradual cooling during spheronization to produce uniform size spherical congealed particles, called as spheroids, pellets, beads or matrix pellets.

d) Hot-melt extrusion: Hot-melt extrusion is the process of converting a uniform mixture of excipient(s) and drug into a product of uniform shape and density by forcing it through a die under controlled conditions of temperature to convert the molten clear mass into solid mass.[7]

***e) Hot-melt granulation**:* Hot-melt granulation is the process of formation of agglomerates of mixture of excipient(s) and active pharmaceutical ingredient(s) using molten mass as binder under high shear mixing.

5. CONCLUSION

Over the last three decades industrial adaptability has allowed hot-melt technology to gain wide acceptance and has already established its place in the broad spectrum of manufacturing operations and pharmaceutical research developments. Hot-melt technology has proven to be a robust method of producing numerous drug delivery systems and therefore it has been found to be useful in the pharmaceutical industry enlarging the scope to include a range of polymers and APIs that can be processed with or without plasticizers. It is a solvent-free, robust, quick, and economy-favoured manufacturing process for the production of a large variety of pharmaceutical dosage forms.

6. CONFLICT OF INTERESTS

The authors declare that there is no conflict of interests regarding the publication of this paper.

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