INTRODUCTION:

Orally disintegrating (dissolving) tablets (ODTs) are solid dosage forms that are placed in the mouth, rapidly disintegrate/dissolve when in contact with the saliva and then easily swallowed without the need for water. The fast disintegrating behavior of the ODT in the mouth limits the active ingredients that can be incorporated to drugs that exhibit good taste, stability in gastric conditions and have long half-life. Bitter tasting drugs can cause discomfort to patients and consequently reduce their compliance, whereas incorporating drugs that suffer from instability in gastric fluids reduces the efficacy of the dosage form (bioavailability). On the other hand, delivering active drugs that have short half-life in ODTs compromise the practicality of the dosage form as more frequent administration is required. To address these issues, a great deal of interest has been directed towards incorporating multiparticulate drug delivery system in ODT formulations. The multiparticulate drug delivery system comprises of drug particles encapsulated or coated by one or more layers of polymers that control the release of the drug. The polymer can be selected to provide extended, delayed or pulsed drug delivery, allowing the rate of release of the drug to be tailored as required. Moreover, they provide many advantages over single-unit dosage forms because of their multiplicity and small sizes including reduced risk of systemic toxicity, enhanced bioavailability, reduced risk of local irritation and reduced patient to patient variability as a result of their more predictable gastric emptying. Accordingly, the formulation of multiparticulate into ODTs can extend their application to more challenging drugs (e.g. acid sensitive) by overcoming restrictions imposed by the nature of these drugs and combine the benefits of ODTs and multiparticulate drug delivery system. The compression of multiparticulate into ODT formulations has attracted substantial attention in both academia and industry and resulted in many scientific publications and patent applications. However, to produce a tablet with good structural integrity, relatively high compression pressures are required. These high pressures can cause damage to the polymer layers of the multiparticulate system, and, as a result, compromise their release controlling properties.

Peroral controlled-release multiple unit dosage forms (e.g., pellets, granules or sustained release pellets, microcapsules, microparticles) are becoming more and more important on the pharmaceutical market, as they provide several advantages compared to single-unit dosage forms (e.g., tablets or capsules). A multi-unit controlled release tablet dosage form offers several advantages in comparison to capsules.
• Small size of the unit enabling the preparation to be swallowed easily (i.e. ease of esophageal transit as compared to large size capsules)
• Ability to administer a portion (dose division) of such multiple-unit tablets without compromising their controlled release properties.

• Ability to incorporate large dose of drug in controlled release form in comparison to capsules.

• Lesser cost of formulation and production as compared to capsules.

• Feasibility of using existing tabletting capacities in the manufacturing set up.

• Greater stability of drug and the formulation owing to small size and absence of gelatin shell.

• Ability to formulate such tablets in a dispersible base that can be reconstituted during use to form a suspension that can be easily swallowed and hence suitable for children and elderly.

• Lesser tendency for product tampering.

• Controlled-delivery or large doses of biologically active ingredient is also possible in this way and is thus advantageous in comparison to tablets and capsules, which owing to their size will be difficult to swallow and in comparison to chewable tablets, where chewing would result in loss of controlled release characteristics.