INTRODUCTION

Large proportions of new drug candidates have poor water solubility. To overcome this problem, various formulation strategies were reported in the literature including complexation with cyclodextrins, solid dispersions, and coprecipitates. In recent years, however, much attention has been focused on lipid based formulations with particular emphasis on selfemulsifying drug delivery systems \(^1,2\).

Self-emulsifying drug delivery systems (SEDDS) are mixtures of oils and surfactants, ideally isotropic, and sometimes containing cosolvents, which emulsify spontaneously to produce fine oil-in-water emulsions when introduced into aqueous phase under gentle agitation. Recently, SEDDS have been formulated using medium chain triglyceride oils and nonionic surfactants, the latter being less toxic. Upon peroral administration, these systems form fine emulsions (or microemulsions) in gastro-intestinal tract (GIT) with mild agitation provided by gastric mobility. Potential advantages of these systems include enhanced oral bioavailability enabling reduction in dose, more consistent temporal profiles of drug absorption, selective targeting of drug(s) toward specific absorption window in GIT, and protection of drug(s) from the hostile environment in gut \(^3,4,5\).

Many workers have claimed various rational applications of SEF for enhancing bioavailability and site-specific targeting of highly lipophilic drugs (eg, WIN 54954, 1 N 4472, 2 idebenone, 3coenzyme Q10, 4 halofantrine, 5 cyclosporin A6).

In recent years, much attention has been focused on lipidbased formulations for delivering Biopharmaceutic Classification System (BCS) class II (low solubility, high permeability) drugs, which suffer limited oral bioavailability, high intra- and intersubject variability and lack of dose proportionality.\(^1\) Self-emulsifying system (SES) is one of the most popular and commercially viable approaches for the delivery of such solubility problem drugs that exhibit dissolution-rate-limited absorption. SES is ideally an isotropic mixture of oils and surfactants and sometimes cosolvents, which emulsifies spontaneously to produce fine oil-in-water emulsion when introduced into aqueous phase under gentle agitation. Upon peroral administration, these systems form fine (micro) emulsions in the gastrointestinal tract (GIT) with mild agitation provided by gastric mobility.\(^2-4\) Conventionally, SES is contained in hard or soft gelatin capsules for ease of administration. However, certain problems such as
leaking, leaching of components from the capsule shell, and interaction of SES with capsule shell components are often observed for such liquid-filled capsules 6–8.

Advantages 9–13:

1. Enhance solubility, dissolution and oral absorption of lipophilic drugs.
2. Enhance oral bioavailability of poorly absorbed drug.
3. Protection of drug from hostile effect of gastro intestinal tract.
4. Ease of formulation in regarding of commercial application.
5. Enhanced solvent capacity, increased stability and the potential to administer the final product as an oral soft gelatin capsule.

Disadvantages 14–18:

- Drug released in a short period of time (burst released), leading to a sudden concentration of drug in blood, may cause toxicity.

Developmental problems:

- Development of a drug delivery system is a time consuming process, because requiring the matching of the appropriate delivery system component and their relative level to drug substance to obtain the desired absorption characteristics.

- In vitro and In vivo study is not well correlated with absorption studies, as the complex interactions, which arise between the lipid based formulation (the digestive system) and the co-administered drug.