OBJECTIVES OF STUDY

The main aim of this study is to develop new concept for the formulation of dispersible tablets using novel concepts such as taste masking of active, sub-layering, pH dependent coating of active to avoid any taste of formulation in saliva and or with oral administration, increase the release profile of active in vitro to make more bioavailability of active in vivo. The project will study the formulation of two classes of drugs that are potentially difficult to formulate as dispersible tablets: high dose, poorly compressible drugs and high dose, highly soluble drugs. Paracetamol and Na-p-aminosalicylate and Tolfenamic Acid and other combination will be used as models of each class respectively.

There are various dosage form of individual Paracetamol such as conventional tablets, dispersible tablets, effervescent tablets, etc available in the Indian and international market. Fixed dose combination such as Paracetamol and Ibuprofen, Paracetamol and Diclofenac Sodium, Paracetamol and Ketoprofen etc are also available in the market. The existing formulation with Ibuprofen, diclofenac sodium is having common side effect such as gastric irritation, nausea, and vomiting in some case. So the fixed dose combination / dispersible formulation of Paracetamol need to be develop to overcome these side effects. The basic drawback of Paracetamol dispersible tablets is the bitter taste of formulation instead of presence artificial sweetener in the formulation; this is basically due to property of Paracetamol.

So there is need to develop a formulation with effective taste masking of active such as Paracetamol and develop a new combination of fixed dose combination with no or less side effect as compare to available fixed dose combination in market. On the basis of literature and market survey it was observed that there is no any combination or very little combination is available for the fixed dose combination of Paracetamol with Tolfenamic Acid.

Tolfenamic acid (TA) is one of the class of non-steroidal anti-inflammatory drugs (NSAIDs). It is used to treat the symptoms of migraine. A study concludes, "Tolfenamic Acid was found significantly better than placebo in the subjective evaluation of drug efficacy (p<0.001) and in reducing the reported hangover symptoms in general (p < 0.01). In the Tolfenamic acid group,
significantly lower symptom scores were obtained for headache (p<0.01), and for nausea, vomiting, irritation, tremor, thirst and dryness of mouth (all p < 0.05).”

Hence the aim is to systematically study disintegrants combinations in a general Paracetamol formulation or formulation of fixed dose combination, with regard to rationalizing disintegrants choice intra- and extra granularly and in combination.