OBJECTIVE
Objective of the present work

In the last decade competition in Pharmaceutical arena has revolved around improving physiochemical properties of drug formulation to give patient a better product. In the present scenario, there is an ever-increasing demand for more patient compliant dosage forms. Depression is a condition that affects a person's mind and body. It impacts all aspects of everyday life including eating, sleeping, working, relationships, and how a person thinks about himself/herself. People who are clinically depressed cannot simply will themselves to feel better or just "snap out of it." If they do not receive appropriate treatment their symptoms can continue for weeks, months, or years. Depression not only causes suffering to those who are depressed, but it also causes great difficulty for their family and friends who often do not know how to help.

Around 50 % of Patients with depression do not fully comply with treatment and non compliance is linked to relapse, rehospitalization, poor outcome and high economic costs. At least half of the patients prescribed long term medication for chronic disease do not fully comply with treatment. Non compliance is particularly likely when the treatment goal is to prevent symptom recurrence or illness relapse. Depression is no exception to this pattern of treatment compliance.

Even though very effective treatments are available to help those who are depressed, only about one-third of those who are depressed actually receive treatment. Many people do not seek treatment for depression for a variety of reasons. Some believe that depression is the result of a personal weakness or character flaw. And some time the patient is not able to come to terms that he is suffering from depression and refuses to take medicines or even if he takes the medicine the fact that he is under medication for depression makes him more depressed. Thus it is a challenge to a formulation development scientist to formulate an antidepressant drugs in such a way that it can be administered to the patient without his knowledge and if the drug is bitter then the task is even more difficult.

Taste masking formulation development & stability assessment of antidepressant drug – Paroxetine Hydrochloride
Paroxetine hydrochloride is widely used antidepressant drug but it is very bitter and it poses challenge of being administered to depressed person without the patient knowing about it.

Thus, the primary aim of this work involves the masking of the bitter taste of Paroxetine hydrochloride.

I. Following techniques will be studied for masking the bitter taste of Paroxetine hydrochloride.

1) Complexation with cyclodextrin and its derivatives
2) Coating with water insoluble polymers
3) Complexation with resins
4) Incorporating in chocolate matrix
5) Use of gel forming agent, which lowers the diffusing out of drug in the oral cavity
6) Microencapsulation of drug in pellets

The taste masking efficiency of the above methods will be evaluated by both invitro and invivo methods of taste evaluation. The invitro method of evaluation will be carried out by physical methods such as dissolution technique. The invivo method will involve taste assessment by panel testing.

II. Once the taste masking is achieved the second target will be to formulate the taste masked drug in patient friendly dosage form. Patient friendly dosage form are the dosage forms which are easy to administer to patient. In case of categories of antidepressant drugs, the patient friendly dosage form is the form, which can be administered to the patient without his knowledge. So the drug will be formulated in the following dosage form for secret administration.

1) Solution dosage form
2) Orodispersible tablets
3) Fast dissolving/dispersible films in oral cavities
4) Controlled release dispersible tablets
5) Chocolate dosage forms

* Taste masking formulation development & stability assessment of antidepressant drug in Paroxetine Hydrochloride*
6) Gel dosage form

All the above formulations will be characterised as per the requirement of that dosage form. Apart from the routine characterisation all the dosage form will be characterised in terms of taste.

Stability studies of all the above dosage form will be carried out at both short term and long term studies. One important aspect of the stability studies will involve the taste assessment at all the conditions and at all the time interval in order to determine whether the formulation retains its palatability or not.

III Followed by the formulation of the above dosage form the next step will be the comparison between all the dosage form to determine which dosage form is more patient friendly.

IV The last and final aim of the above work will involve the administration of the dosage form to the actual patients with the aid of juices or other suitable aids. The aim of this study will be to determine whether the drug can be administered secretly to the patients or not.
Scheme of work

Paroxetine Hydrochloride

- Cyclodextrin complexation
  - Liquid Syrup
    - Taste evaluation
      - Administration & Evaluation in patients
        - Stability
          - Stable Taste masked Syrup
  - Fast dispersible Tablets
    - Taste evaluation
      - Administration & Evaluation in patients
        - Stability
          - Stable fast dispersible tablets
  - Fast dissolving film
    - Taste evaluation
      - Administration & Evaluation in patients
        - Stability
          - Stable fast dissolving films
- Resin complexation
  - Loading on Spheres
    - Coating with ethyl cellulose
      - Incorporation in chocolate matrix
        - Taste masked chocolate
          - Taste evaluation
            - Stability
              - Stable chocolate dosage form
  - Extrusion & Spheronisation
    - Coating with Eudragit S 100 and HPMCP
      - Evaluation of release control
        - Controlled release fast dispersible tablets
          - Invitro comparison with market formulation
            - Bioequivalent study
              - Actual patient acceptability studies
                - Stability
                  - Stable controlled release fast dispersible tablets
  - Dissolving in water
    - Gelling with hydrophilic polymer
      - Soft gel formulation
        - Taste evaluation
          - Stability
            - Stable Gel dosage form

Comparison of all the dosage forms for taste. Evaluation of Advantages and disadvantages of all the above dosage forms.