**Practicum 1: 20 points**

Location: Salk 402; Time 3.30 to 5.00 pm - All groups

So far, we have studied various oral dosage forms such as Tablets, Capsules and Modified release dosage forms. We have studied physicochemical properties of a drug that influence design of a particular dosage form. We have also focused on essential components (excipients) of each dosage from, brief manufacturing process, advantages, disadvantages and important considerations for dosage form design as well as important counseling points for patients. We have seen some representative case studies where choice of a particular dosage form has influenced final clinical outcome (bioavailability, pharmacokinetics, compliance, patient convenience etc).

During this group practicum, you will be given some essential information about a drug candidate including physicochemical properties, pharmacokinetics information and patient related factors such as disease condition (drug’s generic or trade name will NOT be given). As a group, you will apply the knowledge gained in the class to design 2 different dosage forms (one Immediate release dosage form and one Modified release dosage from) for the given drug based on the provided information.

In this group assignment, each group will be given important properties of a drug, patient compliance issues to be addressed, disease conditions involved or other pertinent information. This information will guide you in choosing an appropriate oral dosage form. As a group, you will use the given drug information to come up with creative formulation compositions for an **Immediate release** and a **Modified release** dosage form. Below, I provide examples of information that may be provided to you:

* Drug properties: Water solubility, partition coefficient, color, odor, taste, stability problems (if any), bioavailability, half-life etc. (Note: only some of these properties may be included for each drug)
* Dose of the drug & frequency of administration for immediate release dosage form (e.g. Acetaminophen 500 mg 4 times a day)
* Disease condition, side effects etc.
* Any other relevant information to guide dosage form choice.

During the group assignment, each group will answer following questions using the attached word document template (Answer template practicum 1).

1. Which immediate release dosage form should be used ( eg. tablet/capsule) including the appropriate strength & frequency of administration (e.g. CureAll Tablets, 500 mg 4 times a day) – 2 points
2. Essential and appropriate excipients to be added to the Immediate release dosage form and role of each excipient. – 4 points
3. Indicate if the drug is a good candidate for modified release dosage form or not. Justify your answer. – 2 points
4. Assume that the drug is suitable candidate for modified release dosage form and suggest an appropriate modified release dosage form and strength (e.g. CureAll Extended Release Tablets, 1000 mg). – 1 point
5. What will be the frequency of administration of modified release dosage form & its justification? (e.g twice daily. Daily dose is 2 g & each tablet will maintain blood levels for 12 h) – 2 points
6. What will be the type (singe unit / multiunit system) and release mechanism (membrane /matrix controlled) for dosage form. Justification for selecting that type (single / multiunit) and release mechanism (e.g. It will be a single unit (tablet) dosage form and drug release will be by Matrix controlled mechanism. Drug will be released from tablets by diffusion and erosion of matrix) – 3 points
7. Essential and appropriate excipients to be added to the modified release dosage form and their role – 3 points
8. Patient counseling points for Immediate release dosage form – 1 point
9. Patient counseling points for Modified release dosage form – 2 points

**Notes for group assignment:**

1. You will have access to class notes during group assignment. Please make sure that at least 1 group member has Laptop to submit the group assignment electronically.
2. Please submit your answers online in the attached word document template within **1 h30 min**.
3. There is **no right or wrong answer** to these questions. If the dosage form you have selected addresses the problems associated with drug / patient compliance issues / stability or aesthetic issues, and you can justify the choice of dosage form, excipients choice, release mechanism etc. the answer will be acceptable. So, use creative thinking and logic, and apply all your knowledge acquired to propose innovative dosage forms to solve specific problems.
4. Some representative examples where points could be deducted are given below (this is not an exclusive list):

|  |  |
| --- | --- |
| **Drug information provided to you** | **Problem with your proposed dosage forms**  |
| Drug is extremely bitter | Your formulation approach does not involve any kind of taste masking (e.g. film coating of tablet, absence of sweetener in liquid dosage form etc)  |
| Drug gets degraded in acidic environment | No protection to dosage form from stomach acid (e.g. enteric coating) |
| Drug has a very bad (unpleasant) color | You propose uncoated tablets or liquid form without any color |
|  | You miss essential excipient for the proposed dosage from |