COMPARATIVE DISSOLUTION STUDY OF COMMERCIALLY AVAILABLE-PARACETAMOL TABLETS

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ABSTRACT

Oral dosage form like tablets, capsules, suspensions etc is one of the most common method used for the administration of drug.. Among all, tablets are more widely used being tempered free, cost effective, and stable. In formulation systems, manufacturing process and raw materials used affects the quality of finished product. It is very much essential to determine the parameters of tablets to ensure the quality of the product. Quality is the most important issue in the pharmaceutical field due to the presence of a drug which is considered as safe and therapeutically active agent. In-vitro evaluation ensures their quality, bioavailability as well as optimum therapeutic activity. Paracetamol (acetaminophen) which are the active metabolites of phenacetin is commonly used for the relief of headaches and pains, and is a major ingredient in numerous cold and flu remedies. Paracetamols are available in different brands in Indian market. The main objective of the present study was to conduct the comparative in-vitro dissolution studies of various brands collected from the local market to determine whether all the formulations used were equivalent or significantly different. The calibration curve was constructed covering the concentration range of 1 to 10 mcg/ml at 268 nm by UV spectrophotometer (UV 2203 Double beam spectrophotometer, Shimadzu). Five different brands of Paracetamol of 500 mg conventional tablets from different manufacturers were selected in the study and dissolution testing in Phosphate buffer at pH 7.4 was conducted from each brands for 90 mins by using dissolution testing apparatus USP type-ll. The dissolution rate was subjected to various mathematical models like zero order, first order, Higuchi and Hixson-Crowell equations to elucidate the kinetic behavior of drug release from the test samples. Different release kinetics model of all the selected brands was assuring the quality standard of manufacturing.

Keyword : - *Physical Property ,Chemical Property, Solubility,Paracetamol,(NSAIDs)*

1. INTRODUCTION

Paracetamol (INN)) or acetaminophen (USAN) is a widely-used analgesic and antipyretic medication. Derived from coal tar, it is the active metabolite of phenacetin, but unlike phenacetin, paracetamol has not been shown to be carcinogenic in any way. Paracetamol generally is well tolerated, lacks many of the side-effects of aspirin, and is available over-the-counter. It is commonly used for the relief of fever, headaches, and other minor aches and pains. In combination with non-steroidal anti-inflammatory drugs (NSAIDs) or opioid analgesics, paracetamol is used also in the management of more severe pain.[2] Paracetamol is a major ingredient in numerous cold and fluremedies. While generally safe for human use at recommended doses, acute overdoses of paracetamol can cause potentially fatal liver damage and, in rare individuals, a normal dose can do the same. Paracetamol toxicity is the foremost cause of acute liver failure in the Western world, and accounts for most drug overdoses in the United States, the United Kingdom, Australia and New Zealand.[3][4][5][6] This risk is heightened by alcoholism. A 2008 study indicates that Paracetamol given to infants may also be linked to an increased risk of developing asthma in children.[7][8][9]

The words acetaminophen and paracetamol come from the chemical names for the compound: para-acetylaminophenol and para-acetylaminophenol. The brand name Tylenol also derives from this name: para-acetylaminophenol. In some contexts, it is shortened to APAP, for N-acetyl-para-aminophenol.

2. DRUG PROFILE:

Chemical IUPAC Name :
N-(4-hydroxyphenyl)acetamide
Chemical Formula
C8H9NO2
Chemical Structure
| Chemical data:
o Formula: C8H9NO2
o Mol. mass: 151.169 g/mol
o SMILES: eMolecules & PubChem
| Physical data:
o Density: 1.263 g/cm³
o Melt. point: 169 °C (336 °F)
o Solubility in water : 14 mg/mL @ 25C [1] mg/mL (20 °C)
| Pharmacokinetic data:
o Bioavailability almost 100%
o Metabolism 90 to 95% Hepatic
o Half life 1–4 hours
o Excretion Renal
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| Therapeutic considerations
o Licence data:
| Routes
o Oral, rectal, intravenous
MOLECULAR WEIGHT:- 151.16
DESCRIPTION:- white crystalline powder.
SOLUBILITY :- Freely soluble in ethanol (95%) & in acetone, sparingly soluble in water, very slightly soluble in dichloro ethane & in ether.
WORKING:- The drug acts by blocking the production of chemicals, known as prostaglandins, which are responsible for pain transmission. Unlike aspirin and other non steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, paracetamol acts in the brain, blocking an enzyme involved in the transmission of pain.
CATEGORY:-Analgesic and antipyretic.
DOSAGE :- 0.5 - 1 gm upto 4 gm daily in divided doses.
STORAGE :- Store in well closed, light- resistant container.
SIDE EFFECTS:-The drug has certain side effects, that can affect individuals in different ways. The following are some of the side effects, that are often associated with the drug:
• Nausea
• Rashes
CHEMICAL PROPERTIES
Preparation Of Paracetamol
Paracetamol is a commonly used analgesic. Aspirin and ibuprofen are the two other most common analgesics. The chemical name for paracetamol is N-(4-hydroxyphenyl)ethanamide.
It may be prepared in the laboratory by reacting 4-aminophenol with ethanoic anhydride.

3. RESULTS

- Calculate the percentage yield of recrystallized paracetamol.
- Record the melting point of the recrystallized paracetamol.
- Sketch a diagram of the chromatogram obtained (or put the chromatogram in a transparent plastic bag and stick it in your notebook)
- Compare your results with other members of your group and explain any
- differences.
- Look at this scheme for making paracetamol from phenol:
- Using the data shown together with the percentage yield you estimated for the conversion of 4-aminophenol to paracetamol, calculate the yield of paracetamol that might be obtained from 50 g of phenol.

4. CONCLUSIONS

Evaluation studies have a significant part to play in anticipating formulation problems and identifying logical path in both liquid and solid dosage form technology. The need for adequate drug solubility cannot be overemphasized. The most appropriate salt for development. Stability studies in solution will indicate the feasibility of parental or other liquid dosage form and can identify methods of stabilization. In parallel solid-state stability by DSC, TLC and HPLC in the presence of tablet and capsule excipient will indicate the most acceptable vehicles for solid dosage form. Bioavailability and absorption of drug is dependent on dissolution profile. A dissolution study gives an idea about the amount of drug available for absorption after oral administration. In the present study, the release of paracetamol from all tablets, specially F – C batch (Crocin 500) was followed sustained release; though the drug release in 60 mints were almost about 60% which meets BP Specifications.

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