INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

To Formulate and Evaluate Paracetamol Tablet

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ARTICLE INFO

Published: 05 Jun. 2025
Keywords:
Paracetamol, Tablet formulation, pharmaceutical evaluation, Drug release
DOI:
10.5281/zenodo.15597495

ABSTRACT

The present study aims to formulate and evaluate paracetamol tablets to ensure optimal therapeutic efficacy, safety, and patient compliance. Paracetamol, a widely used analgesic and antipyretic agent, was selected due to its well-established pharmacological profile and extensive clinical use. Tablets were prepared using the direct compression method with various excipients to enhance compressibility, disintegration, and dissolution profiles. The formulated tablets were evaluated for key quality parameters including hardness, friability, weight variation, disintegration time, and in vitro drug release. The results indicated that the optimized formulation met pharmacopeial standards and exhibited.

INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used to manage the pain and Inflammation (swelling and redness) associated with some types of arthritis (such as Rheumatoid arthritis) and other musculoskeletal disorders. NSAIDs are also used to treat non-Inflammatory conditions such as migraine, period pain and postoperative pain, and to reduce Fever.

- How NSAIDs Reduce Pain and Inflammation
- Prostaglandins are substances in the body that act like hormones. They trigger Inflammation, pain, and fever by increasing body temperature and widening blood Vessels, which leads to redness and swelling where they're released.
- NSAIDs work by blocking an enzyme called cyclooxygenase (COX), which is needed

To make prostaglandins. By lowering prostaglandin levels, NSAIDs help ease pain, Bring down fever, and reduce swelling.

Paracetamol:

Paracetamol (PCT), a compound derived from an acetylated aromatic amide group, was first

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Introduced by Von Mering in 1893. It is one of the most commonly used medications for Reducing fever (antipyretic) and relieving pain (analgesic), and it is available in various Formulations and dosages. Although paracetamol possesses both antipyretic and analgesic Properties, it does not exhibit any anti-inflammatory activity.In modern medical practice, paracetamol is considered a safe substitute for acetoacetic acid And phenacetin. Given its widespread use, it is essential to accurately determine the Concentration of paracetamol in pharmaceutical products, as excessive intake can lead to Serious health risks such as fulminant liver necrosis and other toxic reactions.One of the metabolites formed during paracetamol metabolism is 4-aminophenol (also Referred to as p-aminophenol or AP), which is known to have harmful effects on the kidneys (nephrotoxic) and may cause birth defects (teratogenic). Consequently, the British Pharmacopoeia specifies that the amount of 4-aminophenol in the active ingredient of Paracetamol must not exceed 0.005% . However, its presence in finished paracetamol Products may vary. According to the British Pharmacopoeia monograph, the permissible limit

For 4-aminophenol in paracetamol tablets is set at 0.1%.

Uses of Paracetamol:

Pain relief

i. Headaches and Migranes
ii. Toothaches
iii. Muscle and Joint pain

Fever reduction

i. Infections
ii. Flu and Cold

Tablet:

Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by Compressing a drug or a mixture of drugs, with or without diluents. Tablets are solid Medicines that are usually round and flat or slightly curved. They are one of the most Common ways to take medicine—about 70% of all medicines are given as tablets. Most drugs Can be made into tablets, except when it's hard to do or not suitable for the patient. Tablets Are made by either pressing the ingredients together (compression) or shaping them in molds. Along with the main drug, tablets also contain other helpful ingredients. These can include Fillers to add size, binders to hold the tablet together, substances to help the powder flow and Not stick, ingredients that help the tablet break apart in the stomach, sweeteners or flavors to Improve taste, and colors to make them look nice.

Tablets

Among oral solid dosage forms, tablets are the most economical, convenient to transport, And widely accepted by patients. Tablets are compacted solid units formed by compressing Properly prepared granules using a tablet press. The clinical effectiveness of a tablet depends On factors such as the labeled dose and the drug's absorption within the body. The main Objective of an oral tablet is to deliver a precise amount of medication through the Gastrointestinal system to achieve the desired therapeutic outcome.

Properties of Tablet :-

1. Should be elegant product having its own identity while being free of defects such as Chips, cracks, discoloration and contamination.
2. Should have strength to withstand the rigors of shocks encountered in its production, Packaging, shipping and dispensing.
3. Should have the physical stability to maintain its physical attributes over time.
4. Must be able to release the medicament agent(s) in the body in a predictable and Reproducible manner.
5. Must have a suitable chemical stability over time so as not to allow alteration of the Medicinal agent

Type of tablet :-

Oral Tablets for Ingestion:-

a. Standard Compressed Tablets
b. Multiple Compressed Tablets Compression Coated Tablets
   i. Sugar coated
   ii. Film coated tablets
   iii. Gelatin coated tablets
   iv. Enteric coated tablets

Layered tablet

Inlay tablet

a. Targeted Tablets
   i. Floating Tablet
   ii. Colon Targeting Tablet
b. Chewable tablets
c. Dispersible tablets

Tablets used in the Oral Cavity :-

a. Lozenges and troches
b. Sublingual tables
c. Buccal tablet
d. Dental cones Mouth dissolved / rapidly dissolving tablets

Tablets used to prepare Solution:-

a. Effervescent tablets
b. Molded tablets Hypodermic tablet Dispensing /soluble tablet
c. Tablet Triturate

Structure Wise :-

a. Divisible Tablets
b. Aperture Tablet
c. Concave Convex Tablets
d. Core Tablet

Advantages of Tablet:-

-Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for The greatest dose precision and the least content variability.

-They are easiest and cheapest to package and strip.

-Low in cost.

-Lighter and compact.

-Having greatest chemical and microbial stability over all oral dosage forms

-Suitable for large scale production.

-Easy to swallow with least tendency for hang-up.

-Objectionable odour and bitter taste can be masked by coating technique.

-Sustained release product is possible by enteric coating.

-Easy to handling.

AIM AND OBJECTIVES

Aim

-To formulate and evaluate paracetamol tablet.

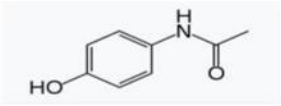
Objective:

A. To formulate paracetamol tablet
B. To evaluate paracetamol tablet
C. The objective of medicinal formulation development project is to deliver drug to the patient in the required amount, at the required rate, consistently a batch, from batch to batch, and over the product shelf life.
D. To study the comparative quality evaluation of paracetamol tablet with marketed paracetamol tablet to select the best formulation .
E. To analyse formulation ingredients in the tablet dosage form.
F. To formulate paracetamol tablet by using direct compression method.

DRUG & EXCIPIENT PROFILE

Appearance	White
Indications	For the treatment of fever, head headache, pain
Protein Binding	Plasma protein binding occure at paracetamol conc. Greater than 60 µg ml-1. The extent of protein binding at a plasma conc. Of 280 µg ml-1 of the drug is between 15 & 21 % for both pig and man.
Half Life	1.5-2.5 hours
Excretion	85 to 95% of therapeutic dose if excerted in the urine within 24 hours with about 4,55,30,4 and 4% appearing as a unchanged paracetamol and its glucuronide, sulphate, mercapturic acid & cysteine conjugates, respectively

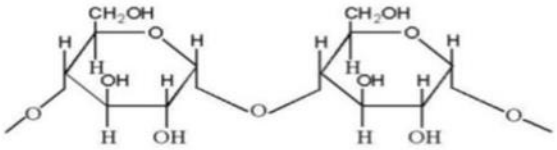
- **Active pharmaceutical ingredient Paracetamol** Structural Formula:



Molecular formula	C8H9NO2
Molecular weight	155.19 g/mol
IUPAC name	N-(2,3,5,6,-trtradeuterio-4-hydroxyphenyl) acetamide
Brand name	Calpol
Synonyms	Acetaminophen-d4
Solubility	Water
Melting Point	169°C
Category	Analgesic & Antipyretic
Use	As a painkiller
Mechanism of action	Paracetamol has a center analgesic effect that is mediated through acitivation of a descending serotonergic pathway. Debate exists about its primary site of action, which may be inhibition of prostaglandin (PG) synthesis or through an active metabolite influencing cannabinoid receptors
Route of administration	Oral or intravenous administration
Route of elimination	Urine

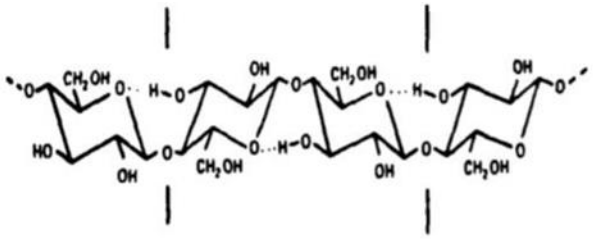
Drug excipients – Structural formula –

Lactose



Molecular formula	C12H22O1
Molecular weight	242.30mg\mol
IUPAC name	(2R,3S,4S,5R,6R)-2-(hydroxymethyl)-6-[(2R,3S,4R,5R,6S)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxy-oxane-3,4,5-triol
Description	An odourless ,tasteless white substance occurring widely in plant tissue and optained chiefly from cereals and potatoes .it is a polysaccharide which function as a carbohydrates store and is important constituent of human diet
Use	Disintegrating agent
Solubilty	polar solvent
Melting point	256-258° C
Category	Rapidly digestible starch slowly and resistant starch depending upon its digestion profile

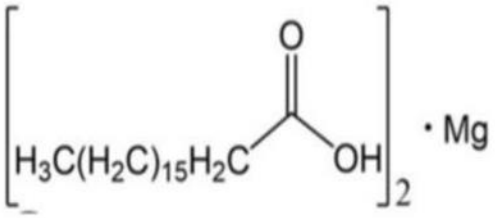
1. Cellulose :- Structural formula:-



Molecular formula	(C6H10O5) n
Molecular weight	266.25g\mol
IUPAC name	acetic acid ;2,3,4,5,6-pentahydroxyhexanal
Description	Cellulose is a molecule , consisting of hundreds – and sometimes even thousands – of carbon , hydrogen and oxygen atoms
Use	Binder
Solubility	strong acidic or alkaline
Melting point	260-270 ° C
Category	Organic compound

Magnesium stearate :-

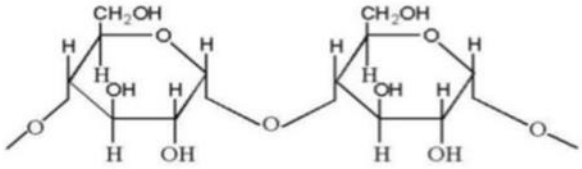
Structural formula ;



Molecular formula	C36H70MgO4
Molecular weight	591.2g\mol
IUPAC name	Magnesium ; octadecanoate
Description	White , water – insoluble powder
Use	As a lubricant
Solubility	Slightly soluble in benzene
Melting point	88.5° C
Category	Flow agent

4.Starch : -

Structural formula :



Molecular formula	C12H22O1
Molecular weight	242.30mg\mol
IUPAC name	(2R,3S,4S,5R,6R)-2-(hydroxymethyl)-6-[(2R,3S,4R,5R,6S)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxy-oxane-3,4,5-triol
Description	An odourless ,tasteless white substance occurring widely in plant tissue and optained chiefly from cereals and potatoes .it is a polysaccharide which function as a carbohydrates store and is important constituent of human diet
Use	Disintegrating agent
Solubilty	polar solvent
Melting point	256-258° C
Category	Rapidly digestible starch slowly and resistant starch depending upon its digestion profile

METHOD

Direct compression

The direct compression method is considered the simplest and most cost-efficient technique for manufacturing orally disintegrating tablets (ODTs). One of its main advantages is that it can be carried out using standard tablet production and packaging equipment, which eliminates the need for specialized machinery or major modifications in the manufacturing process. This significantly reduces production costs and setup time.

Furthermore, the efficiency of this method has been enhanced by the development and availability of modern tableting excipients. These include substances with superior flow properties, better compressibility, and rapid disintegration characteristics, all of which are critical for the successful formulation of ODTs. Key excipients that contribute to these improved functionalities include superdisintegrants (which help the tablet break apart quickly in the mouth), effervescent agents (which promote disintegration through the release of gas upon contact with saliva), and sugar-based excipients (which not only aid in disintegration but also improve taste and mouthfeel). Overall, the combination of conventional equipment and advanced excipients makes direct compression a highly favorable method for ODT production, especially from a commercial and practical standpoint. All material used in the present work where commercial sanple. Paracetamol, lactose, cellulose, magnesium stearate and starch. All the reagent used where of analytical grade. Freshly prepared distilled water was used in work.

Different stages of Compression process

1. **Filling**

This procedure of tablet compression machine involves the transfer of granules into position For tablet compression. The ultimate product is then blended into homogeneous blend.

2. **Metering**

The metering procedure for the tablet compression procedure involves removal of excess Granules from the compression machine at this stage; the required weight of granules to be Compressed into tablets is controlled by the height of the lower punch in the die.

3. **Compression**

During compression stage the top and bottom punch come together by pressure within the die To form the tablet. As the punches enter into the compression stage, the top and bottom Punches move between two large wheels called compression roles.

4. **Ejection**

The ejection procedure for tablet compression process involves removal of the tablet from the Lower punch-die station. In this stage, the upper punch retracts from the die cavity and rises Above the turret table. Then the lower punch rises in the die, which turn pushes the tablet Upward to the top surface of the die tablet and out of the die cavity. Then the tablet is Collected in the container

CONCLUSION: -

The formulation and evaluation of paracetamol tablets were successfully carried out using appropriate excipients and direct compression techniques. The prepared tablets met standard pharmacopeial requirements, including acceptable weight variation, hardness, friability, disintegration time, and drug content uniformity. In-vitro dissolution studies confirmed that the tablets released the drug effectively within the prescribed time, indicating good bioavailability. Overall, the formulated paracetamol tablets demonstrated satisfactory physical and chemical properties, making them suitable for therapeutic use.

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HOW TO CITE: Vishal Dake*, Akash Chavan, Prathamesh Sangave, Rajashree Dahale, Amruta Ladane, Kolse H. S., Dr. Ramesh Ingole, To Formulate and Evaluate Paracetamol Tablet, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 6, 780-787. https://doi.org/10.5281/zenodo.15597495