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FORMULATION, EVALUATION & COMPARISON STUDIES OF PARACETAMOL TABLET MANUFACTURED BY USING DIFFERENT BINDER

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ABSTRACT

This study investigates the impact of different binder types on the formulation and quality of paracetamol tablets. Paracetamol, a widely used analgesic, is commonly formulated as a tablet. Binder selection significantly influences tablet properties like disintegration time, hardness, and friability, ultimately affecting drug release and patient outcomes. This research involved formulating paracetamol tablets using various binders like starch, PVP, and HPMC. Each formulation was evaluated for its physical properties (e.g., disintegration time, hardness, friability) and drug release characteristics. The data was then analyzed to compare the performance of each binder and identify the most effective option.

The study highlights the influence of binder choice on tablet quality, demonstrating that each binder impacts the formulation differently. Findings suggest that [Insert specific findings from the study, e.g., starch yielded the fastest disintegration time, PVP led to the highest tablet hardness, HPMC provided the most sustained drug release] This information can be valuable for pharmaceutical manufacturers and researchers seeking to optimize paracetamol tablet formulations for improved patient outcomes and enhanced drug delivery. The study concludes with recommendations for future research directions, including exploring the impact of binder concentration and the development of novel binder systems for enhanced tablet properties.

I. INTRODUCTION

Paracetamol has analgesic and antipyretics properties but it has no useful anti-inflammatory properties. Paracetamol is readily absorbed from the gastrointestinal tract. Paracetamol is categorized under BCS classification II.

Tablets are solid dosage forms containing one or more drugs with or without excipients, prepared by compression. It provides greatest dose precision and least. Natural content variability. Inert materials employed in addition to active ingredients are collectively called tablet additive.

They include:

1. DILUENTS: It are fillers designed to make up the required weight of the tablet.

Ex: Lactose, inorganic dicalcium salts, microcrystalline cellulose.

2. BINDING AGENTS: It are added in dry or in liquid form to obtain cohesive mass for direct compression.

Ex: Cellulose derivatives, gelatin solution, glucose syrup, tragacanth, a mucilage, etc.

3. DISINTEGRATING AGENTS: It are added to facilitate breakup of the tablet when in contact with gastrointestinal fluids.

Ex: Dry starch, starch derivatives, clays, cellulose derivatives, alginate.

4. ADSORBENTS: It included when formulation contains liquids, volatile oils, etc.

5. ANTIFRICTIONAL AGENTS: It enhance flow properties.

Ex: Talc, corn starch, silica derivatives, etc.

Many dosage forms formulated today are complex system containing many other components along with the active pharmaceutical ingredient (API), these compounds are generally added along with the active pharmaceutical ingredients in order to protect, support or enhance stability of the formulation. Drug products contain both drug substance (commonly referred to as active pharmaceutical ingredient or API) and excipients.

Binder excipients hold the ingredients of a formulation together, for example in a tablet. Binders ensure that tablets, powders, granules and others can be formed with the required mechanical strength. Moreover, they

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give volume to low active dose tablets. The role of the binder excipient is to act as a binder to bind powder, granules and other dry ingredients together to give the product the necessary mechanical strength. They can also give low-dose pills. Usually used for wet granulation, adding a binder to create more effective and predictable particle formation. These excipients can agglomerate powders into granules in a process called granulation, and also affect their properties, such as compaction, drug release, flow, solubility, and strength. Binder excipients are used in the process of drug or drug preparation to improve the disintegration, volume, bioavailability and dissolution of the drug.

Examples of Binders are:

Methyl cellulose, Gelatin, Sodium alginate, starch, tragacanth.

Types of Binder:

A. Classification on the basis of their source:

1) Natural polymer:

Ex: Starch , pregelatinized starch ,gelatin , acacia , tragacanth , sodium alginate and gums.

2) Synthetic polymer:

Ex: PVC , HPMC , methyl cellulose, ethyl cellulose, PEG.

3) Sugar:

Ex: Glucose, Sucrose, Sorbitol.

B. Classification on the basis of their application:

1) Solution binder:

These are dissolved in a solvent.

Ex: Gelatin , cellulose, cellulose derivatives, polyvinyl pyrrolidine, starch, sucrose and polyethylene glycol.

2) Dry binder:

These are added to the powder blend, either after a wet granulation step or as part of a direct powder compression formula.

Ex: Cellulose , methyl cellulose .

Properties of binder:

1. To act as a bulking agent or filling material.
2. To improve the flow of granules from the hopper to the die cavity to ensure uniform fill for each tablet .
3. To facilitate the breakup of a tablet in the gastrointestinal tract .
4. To minimize the problem of picking .
5. To improve the taste of chewable tablets

Natural binder	Synthetic binder
1. Natural binder are found naturally in our environment.	1. Synthetic binder are produced artificially by humans in lab.
2. They occur naturally.	2. Do not occur naturally.
3. It is produced from biological processes.	3. It is produced from chemical processes.
4. Most binder are easily degradable by biological processes.	4. Most binder are hard to degrade by natural processes.

Binder:

Sodium alginate

Alginates obtained from different algae species, season and place of harvesting will differ significantly in their chemical composition (mannuronic /guluronic (M/G) ratio), structural/block organization, and physicochemical properties (molecular weight, rheological characteristics, moisture content, particle size distribution, purity, etc.). The extraction method and process parameters (temperature, time of extraction, alkali concentration and pre-treatment) have also shown an impact on the properties of the produced alginate

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(Vauchel et al. 2008; Chee et al. 2011) .In view of this, limits not to be exceeded are recommended in the European Pharmacopeia for sodium alginate (NaA) and alginic acid (AA) (European Pharmacopeia 2017). With this aim, the different analytical methods used for the determination of the composition, primary structure and MW of alginates, major factors affecting the behavior of alginates in direct compression, are exposed, followed by the different compaction studies carried out that relate the structure of alginates to their mechanical and dissolution performances. The analyzed information will provide a clear prospect of the additional studies that will still be needed to fully exploit the capabilities of alginates as pharmaceutical excipients for direct compression. Due to advances in drug delivery technology, it exist the interest of finding excipients which can be included in novel dosage forms to fulfil specific functions and in some cases even influence directly or indirectly the extent and/or rate of drug release and absorption. Hence, even if other pharmaceutical excipients such as hydroxypropylmethylcellulose (HPMC) can find similar applications than sodium alginate as hydrophilic matrices for drug delivery, their different structure can has an effect on their mechanical and biopharmaceutical properties. For example, alginates have been described as more appropriate for tableting pressure sensitive materials than more plastic cellulose derivative materials as less damage on the pellets was observed using elastic alginates. (Schmid, 2009) Also, more plastic polymers were proven to be more sensitive to lubricant which can lead to a loss of compressibility. Sodium alginate has also been extensively used in the preparation of oral sustained release formulations, as it can delay the dissolution of the active ingredient from tablets, capsules and aqueous suspensions or used as taste masker and as elastically deforming excipient in soft tableting. The tableting properties of NaA has been described to be mainly affected by its inherent deformation behavior tightly related to its primary structure/composition and by physical factors such as its particle shape, size, porosity, density and surface roughness. Sodium alginate tablets with high guluronic acid content (65-75%) showed higher elastic recovery than low G content alginates (35-45%) after ten days of storage. Differences in the shape of the alginate particles can also affect the hardness of tablets prepared by direct compression (Moreton 2009). For example, alginates presenting a fibrous form have been described to provide tablets possessing superior hardness due to the potential mechanical interlocking of fibrous and irregularly shaped particles, as previously described in the literature for the case of hydroxypropyl methylcellulose particles. The dissolution of NaA tablets has been reported to be controlled by external factors such as the pH of the medium; and intrinsic factors such as alginate's viscosity, composition/primary structure, concentration and particle size .Viscosities of alginates solutions are mainly controlled by their concentration, MW, composition and the arrangement of the mannuronic and guluronic monomer units in the alginate chain. A correlation between the solubility of the alginate under acidic conditions and their composition was found by Haug et al. when studying the high solubility. The release properties of alginate-containing matrix tablets have been found not only to be affected by the chemical composition but also by the particle size of the powders and the compaction pressure used for their preparation.

II. LITERATURE REVIEW

Tripathi 2004.

Paracetamol belong to non- steroidal anti-inflammatory drug (NSAID) and it is prescribed most frequently for pain relieve. It is also used as antipyretics agent with analgesic and in the relief of headache, fever and other aches. While it has analgesic and antipyretics properties comparable to those of aspirin or other NSAIDs its peripheral anti-inflammatory activity is usually limited by several factors, one of which is high level of peroxide present in inflammatory lesion.

Sarg et al.., 2007.

Paracetamol is generally safe for human use at the recommended doses while generally safe for use at a recommended dose, toxicity of paracetamol is the foremost cause of acute gastro intestinal problem.

Daly et al., 2008.

Paracetamol is considered to be inhibitor of cyclooxygenase (COX), and recent findings suggest that it is highly selective for COX-2 . Overdose of paracetamol cause fatal liver damage and rare individuals, normal dose can do the same.

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Yogananda et al., 2009.

The safety and efficacy of a pharmaceutical dosage form depend on its quality. The efficacy of pharmaceutical dosage form generally depends on their formulation properties, and manufacturing method, hence it is likely that the quality of dosage form may vary.

Llorent- Martinez et al., 2007

The fluorimetric methods were developed either by oxidation of acetaminophen with alkaline hexacyanoferrate or hydrolysis followed by reaction with benzylamine.

Mot et al., 2010

For determination of paracetamol in multicomponent pharmaceutical preparations computer-controlled instrumentation and multivariate calibration methods are playing a very important role.

Cekic et al., 2005 ; Shrestha and Pradhananga., 2009

The majority of published spectrophotometric method are based on the preliminary hydrolysis of paracetamol to p-aminophenol and coupling of the latter with various phenolic reagents.

Sellappan Velmurugan et al., 2013

The formulated mucoadhesive tablets of losartan potassium using polymers such as Caropol 940P , pectin and sodium alginate in alone and in combination as release retarding agent to prolong the drug release and to avoid first pass metabolism by direct compression method.

Mandal et al. 2009; Holte et al. 312 2003; Veski et al. 1994; Sanchez-Ballester et al. 2019

Sodium alginate has also been extensively used in the preparation of oral sustained release formulations, as it can delay the dissolution of the active ingredient from tablets, capsules and aqueous suspensions .

Stender et al. 2018; Nazemi et al. 2020

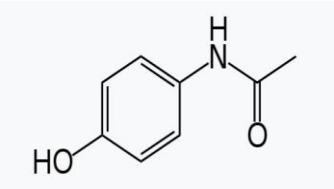
Alginate matrices have been also used for the encapsulation of proteins and amorphous drugs improving their physicochemical properties.

Drug profile

Ingredients:

Paracetamol (Acetaminophen)

Structure:



Chemical Formula: C8H9NO2

Molar mass:151.163 g/mol

Uses:

Paracetamol is a commonly used medicine that can help treat pain and reduce a high temperature . It's typically used to relieve mild or moderate pain, such as headaches , toothache and reduce fever caused by illnesses such as colds and flu.

Lactose:

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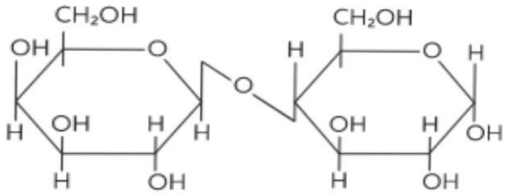
Structure:



Chemical Formula: C12H22O11

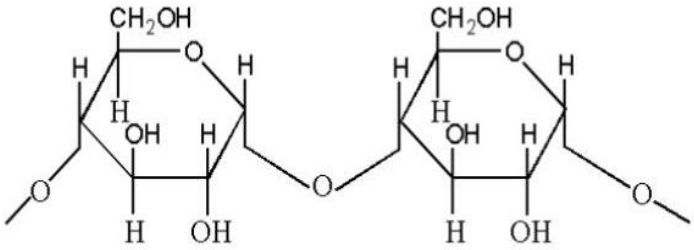
Molar mass: 360.31g/mol

Uses:

Lactose is a natural sugar that's found in milk .It is a carbohydrate and it is made up of two sugars: glucose and galactose . Lactose used as Diluent.

Starch:

Structure:



Chemical Formula: (C6H10O5)n

Molar mass: 359.33 g/mol

Uses:

It possesses both absorbent and demulcent properties. It is used in the formulation of tablets and pills as a vital disintegration agent and a binder. It is employed as a diluent (or filler) and lubricant in the preparation of capsules and tablets.

Magnesium Stearate:

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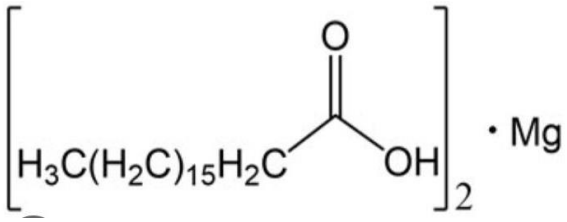
Structure:



Chemical Formula: Mg(C18H35O2)2

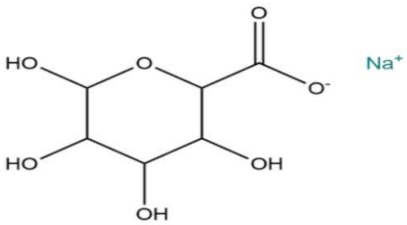
Molar mass: 591.24 g/mol

Uses:

Magnesium stearate is the magnesium salt of the fatty acid, stearic acid It has been widely used for many decades in the food industry as an emulsifier, binder and thickener, as well as an anticaking, lubricant, release, and antifoaming agent magnesium stearate used as Lubricant .

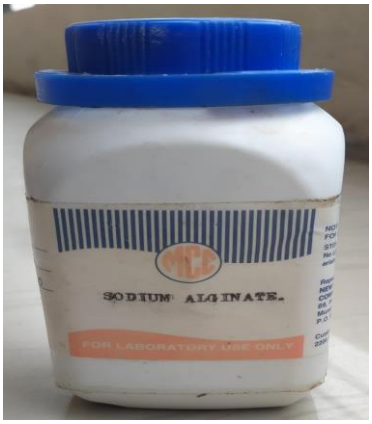
Sodium alginate:

Structure:



Chemical Formula: (C6H7NaO6)n

Molar mass: 428.23 g/mol



Uses:

Sodium alginate is used as a emulsifier and thickening agent It is used in the formulation of antacid .It is used as a gel in pharmaceutical preparations .It is used as a binding agent or binder in the preparation of tablet.

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III. AIM AND OBJECTIVES

Aim: Formulation, evaluation and comparative studies of paracetamol tablets by using different binder.

Objective:

1. The objective of a medicinal formulation development project is to deliver drug to the patient in the required amount, at the required rate, consistently within a batch, from batch to batch, and over the product's shelf life.
2. To study the comparative quality evaluation of paracetamol tablet with marketed paracetamol tablets to select the best formulation.
3. To analyze formulation ingredients in the tablet dosage form.
4. To formulate paracetamol tablets by using direct compression method.
5. Binder plays important role in formulation of tablet dosage form.
6. It may be added either dry or in solution form to the tablets prepared by wet granulation.
7. It help the powder to turn into granules which possesses good flow properties and compact ability and enhances cohesiveness.

Sr. No.	Ingredients	For 1 tablet (mg)
1.	Paracetamol	125
2.	Lactose (diluent)	375
3.	Sodium alginate (binder and disintegrent)	48
4.	Starch (glidant)	40
5.	Magnesium Stearate (lubricant)	12

Plan of work

- Literature survey.
- Selection of material used for development.
- Carrying out pharmaceutical development studies of drug comprising of determination of API characteristics.
- Selection of Excipients.
- Selection of material and equipment.
- Formulation of tablet by using various concentration.
- Evaluation of all physical parameters of prepared paracetamol tablets.
- Prepare Granules.
- Compression tablet.
- Packing.

IV. MATERIAL & INSTRUMENTS

Ingredients

Fig 1: Material used in the manufacturing of tablet

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1. Material use:

In own laboratory, paracetamol, lactose, starch, magnesium Stearate, sodium alginate.

2. Methodology:

The usual methods of formulation include wet granulation, dry granulation and direct compression. The most widely used and most general method of tablet preparation is the wet granulation method. The active ingredients, diluent and disintegrent are mixed or blended well. Solution of the binding agent are added to the mixed powder with stirring. The powder mass is wetted with the binding solution until the mass has the consistency of damp snow. If the granulation is over wetted the granules will be hard, if not wetted sufficiently, the resulting granules will be too soft, breaking down during lubrication. The wet mass is forced through a 6 or 8 mesh screen or several mills can be used. Moist material from wet milling steps is placed on large trays and placed in drying chamber with circulating air current and thermostable heat controller. Commonly used dryers are tray dryer, fluidized bed dryer. After drying, the granulation is reduced in particle size by passing smaller mesh screen.

After drying granulation, the lubricant or glidant is added as fine powder to promote flow of granules These granules then compressed to get tablet. Tablets are evaluated for their general appearance, hardness, friability, drug content, weight variation, dissolution and disintegration properties.

Formulation of paracetamol tablet:

Wet granulation method

Paracetamol, lactose and half the quantity of starch were weighed and mixed thoroughly. It was granulated using 5% starch mucilage as binding agent and passed through no.10 mesh screen. The obtained the granules were dried at 55°C for 1 hr. After drying, dry screening was done using no.22 mesh screen. The rest of the starch powder along with starch and magnesium Stearate were added and mixed. These granules were compressed into tablet.

Tablet punching :

Wet granule and place punching mould and required quantity of tablet where punch using hand operating tablet punching machine.

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Process of tablet formation can be divided into three stages :

• Die filling :

This is normally accomplished by gravitational flow of the powder from a hopper via the die table into the die. The die is closed at its lower end by the lower punch.

• Tablet formation :

The upper punch descends and enters the die and the powder is compressed until a tablet is formed. During the compression phase, the lower punch can be stationary or can move upwards in the die. After maximum applied force is reached, the upper punch leaves the powder, i.e. the decompression phase.

• Tablet ejection :

During this phase the lower punch rises until its tip reaches the level of the top of the die. The tablet is subsequently removed from the die table by a pushing device.

• Single punch tablet machine :

A single-punch press possesses one die and one pair of punches. The powder is Held in a hopper which is connected to a hopper shoe located at the die table. The hopper Shoe moves to and fro over the die, by either a rotational or a translational movement. When the hopper shoe is located over the die, the powder is fed into the die by Gravitational powder flow. The amount of powder filled into the die is controlled by the Position of the lower punchy. When the hopper shoe is located beside the die, the upper Punch descends and the powder is compressed. The lower punch is stationary during Compression and the pressure is thus applied by the upper punch and controlled by the Upper punch displacement. After ejection, the tablet is pushed away by the hopper shoe as It moves back to the die for next tablet

• Prerequisites:

1. **Compression**
2. **Compaction**
3. **Consolidation**
4. **Deformation**

V. EXPERIMENTAL WORK

Evaluation parameter:

Weight variation:

20 tablets are weighed individually. Calculated the average weight and individual weight are compared with the average weight.

Hardness Test:

Tablet hardness was measured using Monsanto hardness test apparatus. Hardness is a force required to break a tablet across the diameter. The hardness of the tablet is an indication of its strength. This is a valuable test which might influence tablet disintegration and dissolution rate. The test measures crushing strength property defined as the compressional force Applied diametrically to a tablet which just fractures it .Hardness is a property which is Dependent on density and porosity of the material on one hand and pressure of the

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Compression on the other. The resistance of tablet to chipping, abrasion or breakage Under condition of storage, transportation and handling factor before use depends on Hardness of tablet

Friability Test :

Friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport or handling . Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablet are dusted and reweighed ; the loss in the weight of tablet is the measure of friability and is expressed in percentage as: % Friability= 1-(loss in weight/ Initial weight) × 100.

Disintegration Study:

Experimental conditions were:

Medium: water

Speed: 30 cycles/ minute

Temperature: 37°C

One tablet was added into each of the 6 tubes of the apparatus and the assembly was suspended in a beaker containing water and time required to disintegrate each tablet was noted. From this average disintegration time was determined.

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Thickness study:

Tablet thickness should be controlled within 5% or less of a standard value. The crown thickness of individual tablets is measured with a micrometer. The crown thickness of individual tablets is also determined for the purpose of determining the density of tablet compacts. Mostly tablet have uniform diameter unless they have prepared by using different dies. Small variation in tablet thickness and diameter significantly affects hardness and dissolution profile of tablet. The tablet diameter and thickness is measured by using vernier calliper. Least count of measuring instrument is the ratio of smallest division on main scale and total number of divisions on vernier scale or thimble scale.

VI. RESULT AND DISCUSSION

As per the data obtained by the experiment, binder derived from natural or synthetic source showed a good binding property. The prepared tablet for a post compression parameters such as weight variation, hardness, friability and thickness. The readings were obtained and values were presented. Weight variation among all the tablets range between 10.00 gm to 11.00 gm, hardness values which were obtained within a limited range from 5.00 kg/cm2 to 8.00 kg/cm2. The thickness of all the tablets range between 0.50 mm.The friability was determined by measuring the weight loss of the tablets in a friabilator.

Observation Table :

Parameters	Sodium Alginate	Methyl Cellulose	Gelatin
1. Wt. variation (gm)	10.31	10.51	10.91
2. Hardness (kg/cm2)	6	8	8
3. Friability (%)	0.76	0.80	0.75
4. Thickness (mm)	0.5	0.5	0.5
5. Disintegration Time (sec)	176	178	174

Comparison between different binder (Sodium alginate, Methyl cellulose, Gelatin).

VII. CONCLUSION

As a result of this study, we have concluded that all the six brands of paracetamol tablets meet the criteria laid in the Official monographs and though they differ slightly in terms of various parameters like weight variation, hardness, Friability, shows its complete release at in the range of 4 to 7 mins. All marketed paracetamol tablets of 500 mg were all under specified IP limits. Various stories are heard about this very helpful at the Same time deadly drug. While some appreciate it for its Relief of muscle and joint pain, cold and flu symptoms, common headache, antipyretic, anti-inflammatory functions, others curse it for its ability to lead to renal and hepatic complications in the human body. Paracetamol is one drug Known and recognized by many but its chemistry is known by a select few. This article has brought to light the chemical properties of Paracetamol which can be used as a pre-cursor in the production of other chemical substances. One of its Chemistry that should be taught to all is the drug interaction of this very powerful drug. In the presence of other drugs like Warfarin, it causes excessive bleeding; patients should also stay away from Alcohol when taking this drug. Its adverse Effects that results from over dosage should not be taken lightly as it can lead to range of sicknesses from skin rashes, Vomiting to even a damaged liver or kidney, therefore the right dosage should be given to the patient and the

patients should adhere to it. There are large numbers of natural polymers have been used in pharmaceutical preparations. Natural substances like starches, mucilages , gums and also dried fruits can be used as binding agent. They have been shown good potential as binding agent as well as they posses some other properties like disintegrating agent, fillers, sustain releasing agent. Natural polymers shown good binding property in wet granulation, granules are stable and less friable in comparison with other binders. They can also be used to modify the release of drug, thereby, influencing the absorption and subsequent bioavailability of the incorporated drug. Furthermore, they act as vehicles which transport the incorporated drug to the site of absorption and are expected to guarantee the stability of the incorporated drug, the precision and accuracy of the dosage, and also improve on the organoleptic properties of the drugs where necessary in order to enhance patient adherence. They should optimize the performances of dosage forms during manufacturing as well as when patients ingest them.

VIII. FUTURE SCOPE

Paracetamol (acetaminophen) is well established as a leading non-prescription antipyretic analgesic drug. Future developments are likely to include new formulations to achieve rapid absorption for a fast onset of action, and prolonged absorption to extend the duration of action for regular long-term administration. Better dosage forms are also required for rectal administration. The availability of intravenous paracetamol has greatly extended the use of this drug as an adjunct to postoperative analgesia and for control of fever in the intensive care setting. Intravenous paracetamol is available in only a few countries at present, but it seems inevitable that it will be marketed much more widely in the future. The misuse of paracetamol as a fashionable agent for self-poisoning seems likely to continue, and liver failure may still occur in the small proportion of overdose patients who present too late for effective antidotal treatment with N-acetylcysteine. Much effort is being devoted to the study of the molecular mechanisms of paracetamol hepatotoxicity, and it is hoped that further advances may make it possible to prevent liver failure in all patients, irrespective of delays in presentation. At the same time, there is great interest in the mechanisms of the therapeutic actions of paracetamol and its effects on the different isoforms of cyclo-oxygenase. There will probably be important new findings in this area and these may lead to wider clinical use. Meantime, possible novel therapeutic applications for paracetamol include its use as an antioxidant to prevent atherosclerosis and cardiovascular disease by inhibiting the oxidation of low-density lipoproteins, and to prevent the formation of cataracts. Natural biopolymer will provide a good scope over synthetic polymers which has various downfall actions which include lack of intrinsic biocompatibility and bioactivity, they are toxic to human health in economical, water solubility problems. Naturally available polymers from various sources like plants, animals, and microbes. Natural polymers meaningfully affect quick-dissolving tablets more than manufactured polymers. Regular polymers expanded the drug release rate from the tablet and decremented the crumbling and breaking personal time, and they are utilized as folio super disintegrant and diluent. They are loved over fabricated engineered polymers as they are nontoxic, basically open at a negligible cost, utilized in fewer sums, and are typically removed to give a Healthful enhancement.

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