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Review on Formulation and Evaluation of Aceclofenac Tablet

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Abstract: *In 1843, the British painter and the inventor was William Brockedon is granted a patent for a machine capable of such "Shaping Pills, Lozenges and Black Lead by the Pressure in that Dies". The device was capable to be compressing powder into the tablet without use of an adhesive Aceclofenac it is an oral non-steroidal anti-inflammatory drug (NSAID) which having anti-inflammatory and analgesic properties. Although there are various differences in the authorized indications between countries, aceclofenac is mainly to recommended for the treatment of inflammatory and painful processes, such as the low back pain (LBP), scapulohumeral per arthritis, extraarticular rheumatism, odontalgia, and the osteo arthritis (O A), rheumatoid arthritis (RA), and the enclosing spondylitis (AS). The purpose that of study was to develop fast and rapid dissolving tablets of the Aceclofenac using different concentration superdisintigrents.Fast dissolving tablets of the Aceclofenac were prepared by wet granulation technique using the sodium starch glycol ate together with Polyplasdone xl-10 as super disintegrants. The porous granules where that compressed in to tablets. These tablets are were evaluated for drug content, weight variation, friability, hardness and wetting time and Dispersion time. All the formulations are showed at low weight variation with the dispersion time less than 90 seconds and the fast in vitro dissolution. These types of drug content of all the formulations was within the acceptable limits. The optimized formulation is showed good release of profile with maximum drug being released at prolong time intervals. That was concluded that fast dissolving tablets with improved the Aceclofenac dissolution could be prepared by wet granulation of tablet. The dispersion time and the dissolution parameter (t50% andt80%) decreased with increasing the concentration of Polvplasdone x1-10vertisement.*

Keywords: Aceclofenac

I. INTRODUCTION

1.1 Solid Oral Dosage Forms

Historically this is most convenient and commonly employed route of drug delivery has-been by oral ingestion. Oral drug delivery has been known for the decades as the most widely utilized route of the administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of the different dosage forms. It is considered as and the convenient a dose for route.

Tablets are solid dosage forms containing the medicinal substances with or may be without the suitable diluents. They are them widely preferred form of the medication both by the pharmaceutical manufacturer as well as physicians and the patients. They offer safe and convenient ways of active pharmaceutical ingredients (API) administration with the excellent physicochemical stability in comparison to some other dosage forms, and also provide means of the accurate dosing. They can be mass produced with robust quality controls and offer the different branding possibilities by mean so colored film coating, different shapes, sizes or logos

1.2 Introduction to Aceclofenac

Aceclofenac is a phenyl acetic acid derivative nonsteroidal anti-inflammatory drug (NSAID) with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of cyclooxygenase (COX), a key enzyme in the synthesis of prostaglandins and thromboxanes with selectivity for the COX-2 over COX-1 iso form. Aceclofenac was first approved in the Eropean country in 1990 and launched in the Spain in 1992. Since then, it has been approved for to use in 69 countries worldwide and they has an estimated exposure of about 171 million patients treated. The authorized indications of for the aceclofenac vary between countries, but in general, it is recommended for the treatment of

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inflammatory and the painful processes, such as lower to the back pain (LBP), odontalgia, scapulohumeral periarthritis, and extraarticular rheumatism, as well as for the treatment of osteoarthritis (OA), rheumatoid arthritis (RA), and the ankylosing spondylitis (AS).25 The pharmacological properties, efficacy and the tolerability of aceclofenac have been reviewed previously elsewhere. This article reviews the comparative efficacy and tolerability of aceclofenac 100 mg twice daily immunotherapy in musculoskeletal disorders, including OA, RA, AS, and LBP, focusing on relevant and more recent studies where available

II. HISTORICAL BACKGORUND

Pills are where thought to date back to around 1500 BC. Earlier in medical recipes, such as those which from 4000 BC, were for liquid preparations rather than the solids the first references to pills were found on papyruses in ancient Egypt, and the contained bread dough, honey or grease. The medicinal ingredients , such as the plant powders or spices, were mixed in and formed by the hand to make little balls, or pills. In the ancient Greece, such medicines were they called as katapotia ("something to be swallowed"), and the Roman scholar Pliny, who lived from 23 to 79 AD, first gave a name to what we now called as pills, calling them the pilula.

Pills have always been difficult to swallow and for efforts long have been made to make them go down easier. In the medieval times, people coated pills with slippery plant substances. Another approach is, used as recently as the 19th century, was to gild them in gold and silver, although this often meant that they would pass the through the digestive tract with no effect. In the 1800s the sugar-coating and gelatin-coating was invented, as were gelatin capsules

2.1 Advantages of Solid Oral Dosage Forms

1. They are themoststable dosage form with respect to their physical, chemical and microbiological attributes.
2. Provide an accurate, stable dose with greatest precision and least content variability, easy to use, handle and to be carried by the patient.
3. They are attractive and elegant in appearance.
4. The manufacturing cost of tablets is was compared to other dosage form and their manufacturing speed is also quite high.
5. The packaging and shipping of tablets is comparatively easy and cheap.

2.2 Disadvantages of Solid Dosage Forms

1. Drugs the amorphous in nature or have low density character are difficult to be compressed into tablet.
2. Hygroscopic drugs are not suitable candidate for compressed tablets.
3. Drugs having poor wetting properties, slow dissolution profile and high optimal gastrointestinal absorption are difficult or impossible to formulate a tablet.
4. Drugs having bitter taste and objection able odor require special treatment like coating or encapsulation which may increase their production cost.
5. Some drugs which preferably get or bed from the upper part of GIT may cause bioavailability problem min tablet dosage form.
6. Capsules cannot be used for extremely soluble materials such as potassium chloride, potassium bromide.

III. DIFFERENT TYPES OF THE FORMULATION

There are various types of the formulations which are prepared in the pharmaceutical industries and laboratories. Where that are used for the public health and population

- Tablet
- Capsule
- Emulsion and suspension
- Powder formulations
- Topical-Creams, ointments, gels, pastes
- Liquids
- Parental formulations

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- Sprays or inhalers
- Peccaries and suppository

Fig No 1

Fig No 2

IV. CONCEPT OF CGMP

CGMP refers to the Current Good Manufacturing Practice (CGMP) the regulations are enforced by US FDA. They are current Good Manufacturing Practices are the methods to be used in, the facilities or to controls to be used for, the manufacturing, processing, packaging or holding of a drug to assure that such drug meets to the requirements of the act, and has the identity and strength and meets the quality and purity characteristics that is represented to posses.

Definition of the cGMP as per the WHO GMP is the part of QA which assure that their product are consistently produced and to be controlled to the quality standards appropriate to with their intended use as required by marketing authorization.

4.1 Objective

Ensure that products are consistently manufactured and they controlled to the specified quality.

Concerned with all the aspects of the production and quality control.

In the manufacture of the cosmetic products, overall control and monitoring

Ensure that their consumer receives products of specified quality.

The quality of these product depends on the starting materials, production and quality control processes, building, equipment and personnel involved.

CGMP regulation assures these identity, strength, quality and purity of drug products

4.2 CGMP Covers

- Personnel
- Self inspection and audits
- Master formula records
- Premises
- Equipment's
- Sanitization
- Batch manufacturing records
- Warehousing area
- SOP's
- Labels and the other printed material
- Raw material

V. STEPS INVLOLVED IN THE FORMULATION OF THE TABLET FORMULATION

- Identification and characterization of tablet
- Excipients compatibility test
- Formulation development

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- Formulation optimization
- Evaluation of formulation
- Stability study

5.1 Types of the Tablet Formulation

There are various types of tablet which are depend upon such as

- Site of administration
- Release rate
- Size and shape
- Method of preparation
- Different on duration of action

5.2 Advantages of Extended Release Solid Oral Dosage Forms

• They are the most stable dosage form with respect to their physical, chemical and microbiological attributes.
• Provide an accurate, stable dose with greatest precision and least content variability, easy to use, handle and to be carried by the patient.
• These are attractive and elegant in appearance.
• The manufacturing cost of tablets is low as to be compared to other dosage form and their manufacturing speed is also quite high.
• The packaging and shipping of the tablets is comparatively easy and cheap
• The unpleasant taste and odour of the medicament(s)can be easily masked
• The in compatibilities of medicament(s) and their deterioration due to environmental factors are less.
• These are more suitable for the large scale production.
• Theiridentificationisprobablytheeasiestbecauseofvarietyofshapesandcolors.
• They areformulatedwithcertainspecialreleaseprofileproductssuchasentericordelayedreleaseproducts.
• They are the lighten stand most compact dosage.

5.3 Disadvantages of Extended Release Solid Dosage Forms

• Drugs that are amorphous in nature or have low density character are difficult to be compressed into tablet.
• The hygroscopic drugs are not suitable candidate for the compressed tablets.
• Drugs having poor wetting properties, slow dissolute on profile and high optimal gastrointestinal absorption are difficult or impossible to formulate tablet.
• Drug shaving bitter taste and objection able odor require special treatment like coating or encapsulation which may increase their production cost.
• Some drugs which having the preferably get absorbed from the upper part of the GIT may cause bioavailability problem in tablet dosage form.
• Capsules cannot be used for extremely soluble materials such as potassium chloride, potassium bromide.

5.4 Tablets

Different types of the tablet formulations are available, which they could be broadly classified based on route of administration such as tablets for oral, sublingual delivery, buccal delivery ,rectal delivery or vaginal delivery and the formulation characteristics such as immediate release tablets, effervescent tablets, melt-in-mouth or fast dissolving tablets, delayed release.

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Various Equipments and Instrument Handling

Tablet Compression machine

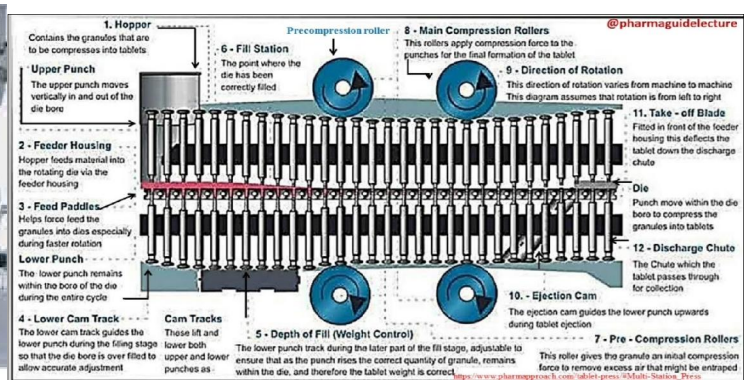
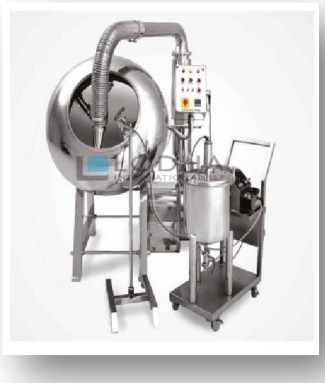


Fig no 3 Fig no 4

The basic principle behind the tablet compression machine is hydraulic Ensure that the electric power has not been discharged. Set all the related parts of the machine and check once before the process is carried out. Hopper should be applied as well according to the sops guideline. During the process the lubricated granules should be used serially numbers whether they are get numbered. Ensures that they are moving freely. And collect the formulation as per the guidelines

Tablet compression process understanding is resulted in the development of formulation.



Recent advances in there design of the tablet compression equipment has been conducted resulted in higher efficiency, minimized tablet variation, greater flexibility.

During these compression the bulk volume of material is reduces resulted in the displacement of air.

Increase in the force lead to particle of deformation and they rearrangement at this stage three principle mode of deformation are follows:-

1. Elastic deformation
2. Plastic deformation
3. Brittle fractures

Tablet Coater

Tablet coating is the process where the coating material is applied to the surface of the tablet to achieve the desired properties of these dosage form over the uncoated variety.

Reasons for coating:

1. To mask the unpleasant taste and the odor.
2. To improve the appearance of the various types of the tablets.
3. To prevent the medicament from the atmospheric effects.
4. To control the site of action of the drugs. Fig no
5. To produce to the sustained release product.

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Fluidized Bed Dryer

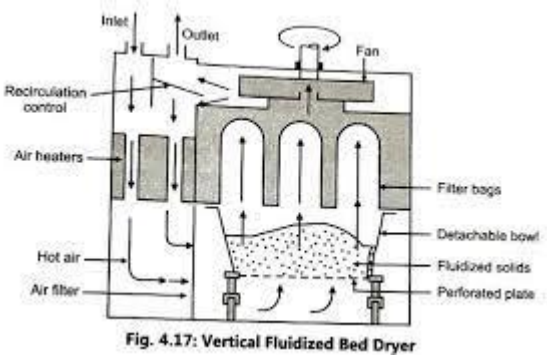

Fig No 6: Fluidized bed dryer

Fluid or Fluidized bed dryer is a kind of the equipment used extensively in the pharmaceutical industries to reduce the moisture content in raw ingredients like powder and granules. The working principle of this equipment which includes the fluidization of the fed materials

Before starting the operation production officer / executive shall affix these activity status label having the details such as product name. Stage etc. to equipment and area and inform to the IPQA officer / executive forthe line clearance.

VI. TYPES OF TABLET MANUFACTURING

The tablet manufacturing process can be variously classified as

- Direct compression
- Granulation

Direct Compression

It is used when a group of the ingredients can be blended, placed onto a tablet press and made into a perfect tablet without any of the ingredients having to be changed Powders that they can be blended and compressed are commonly referred to as directly compressible or as direct-blend formulations .There in here physical properties so the individual fill material highly critical, and variations can alter the flow and compression characteristics, make them unsuitable for the direct compression

Compression

The widely used direct compression fillers are cellulose derivatives (e.g. microcrystalline cellulose), saccharine (e.g. Lactose and mannitol), mineral salts (e.g. Declaim phosphate, calcium carbonate) and partially pre gelatinized starch

Granulation

Granulation is a process to improve the flow and density and compressibility of the particular material by size enlargement and densification. Granulation can be achieved by the use of the binder solution (wet granulation) or dry binder (dry granulation).

Wet granulation

When powders are very fine, tiny, fluffy, will not stay blended, or will not compress, then they must be granulated. The wet massing is the process of adding a solution to a blended powder and mixing for a predetermined period of time the given to mechanical speed. Once the process is complete, the wet mass is milled, spread on trays dried in the tray dryer. The formed granules are milled and compressed. Examples of the wet granulation methods include fluid bed, high shear, pelletization techniques, such as the extrusion and spray drying.

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Dry Granulation

The dry granulation (roll compaction or slugging) involves the compaction of the powders at high pressures into large, often poorly formed tablets or compacts. These compacts are then milled and screened to be form a granulation of the desired particle size. The advantage of the dry granulation is the elimination of heat and moisture in the processing. The dry granulations can be produced by extruding powders be twine hydraulically-operate droller stop thin cakes that are sub sequent screened or milled to give the desired granule size.

Table 1: Granulation Methods

Method	Advantage	Limitations
Direct compression	Simple, economical process, No heat or moisture, so good For unstable compounds.	Not suitable for all API, generally limited to lower dose compounds ,Segregation potential, expensive excipients
Wet Granulation	Robust process, reduce Elasticity problems, wettablity, reduced segregation potential.	Expensive, Time and energy consuming, Specialized equipment, Stability issues.
Wet Granulation (Non Aqueous)	Vacuum drying technique, Suitable for moisture sensitive API	Expensive equipment, solvent recovery Issues, needs organic facility ,health and environmental issues.
Dry Granulation	Eliminates exposure to Moisture and drying	Dusty procedure, slow process ,not Applicable for all API

Terminology

There are several term susedinter changeably for modified release dosage forms viz., controlled release, programmed release, prolonged release or sustained release, extended release, timed release, slow release, delayed release, repeat action, long acting, repository dosage forms etc.

Modified Release

They are designed to be modify the rate, the place or the timing of drug release and not absorption. The dosage forms are coated or may be uncoated.

Controlled Release

Controlled release systems provide are lease profile predominantly controlled by the design of the system.

Prolonged Release or Sustained Release

These dosage forms are only prolong the therapeutic blood or tissue level of the drug for anExtended period of the time that is not possible with conventional preparations.

Extended Release

The pharmaceutical dosage forms that release the drugs lower than normal manner.

Slow Release

Preparations formulated for the purpose of the avoiding toxicity associated with peaking effect.

Delayed Release

These preparations release the drug after a “time delay” or after these tablet has passedthrough one part of the GI tract into the another. All the enteric coated tablets are delayed release tablets but not all the delayed release tablets are enteric coated, due enteric- coated tablets release the drug rapidly.

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Repeat Action Tablet

In this one part of the tablet releases in the stomach, another part of releases in the intestine.The release depends upon the gastric emptying.time It is analternative to sustained release

Here multiple dose of the drug is retarded at a period interval.

Long Acting

They are used to encompass those drugs with an inherently long pharmacological effect because of their pharmacokinetic properties. Hence It can be seen that's us tainted release systems simply prolong the drug release, and hence plasma drug levels for an extended period of time, whereas controlled release systems control there and the duration of actions.

VI. IMMEDIATE RELEASE TABLETS

Immediate release tablets are designed to disintegrate and release the drug in absence of any controlling features such as coating or other formulation technique

Disintegrates are used to ensure that, when a tablet is ingested, it breaks down quickly in the stomach .Rapid disintegration is a necessary step-in ensuring that the active ingredients are bioavailable and readily absorbed. This is especially important for the immediate release products where rapid release of the drug substance is aimed at. The proper choice of disintegrates and its consistency of performance are critical to formulation development of immediate release tablets. Some super disintegrants are Cros caramellose sodium, Crospovidone, L-HPC (Low Sub situated hydroxyl propyl ether of cellulose),Sodium Starch Glycolate.

Tablet in Capsule Dosage Form

Tablet in capsule is a multi functional and the multiple unit system, which contains versatile mini-tablets in a hard gelatin capsule.

It can be developed by the preparing Rapid-release Mini-Tablets, Sustained-release Mini-Tablets, Pulsatile Mini-Tablets, and the Delayed-onset Sustained-release Mini-Tablets, each with various lag times of release and encapsulating in a capsule.

The system can be designed to contain rapid and delayed release mini-tablets of two different or similar

Fig no 7

drugs. Two tablets in a capsule is suitable for sequential release of two drugs in combination, separate two in compatible substances, and also For sustained release drug delivery in which one tablet in the capsule is immediate release as initial do send second is maintenance dose

Advantages of Extended Release Products

- Decreased local and systemic side effects.
- Reduced gastro intestinal irritation.
- Better drug utilization.
- Reduction in the total amount of the drug is used.
- Minimum drug accumulation and the chronic dosing/improved efficiency in the treatment.

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- Optimized the therapy.
- More uniform blood concentration.
- Reduction in fluctuation in drugs level and hence, more uniform pharmacological response.
- Improved patient compliance.

Disadvantage of Extended Release Products

- Dose dumping
- Reduced potential for accurate adjustment
- Need for additional patient education.
- Stability problems.
- Possible reduction in system ability.
- Increased variability among dosage units.
- Slow absorption may delay the onset of the activity
- Unpredictable and often poor in the in vitro and in vivo correlations
- Reduced potential for the dosage adjustment
- Increased potential for first pass clearance and poor system ability

Objective of the Work

To formulate a combination dosage form of the Aceclofenac Extended Release Tablet 200mg

Preformulation study shall be taken up to decide on the Drug – Excipient compatibility of the Aceclofenacand Misoprostol individually.15

A compact Aceclofenac Extended Release of Tablet 200 mg shall be prepared by using varying the grades of Hydrophilic polymer HPMC and Coleus KG 1000 (Microcrystalline cellulose).

The dissolution profile of Aceclofenac ER tablets for the period of 12 hr and mechanism of drug release from the ER tablet shall be determined.16.

In process Quality Control Checks like the Bulk Density, Tapped Density, Compressibility Index,Hausner's Ratio, Angle of Repose for the blend/granules and the Uniformity of the weight,Thickness , Hardness , Friability , Disintegration Times hall be measured for the tablets of every formulation trial.

Accelerated Stability Study of the combination product enclosed in the capsule packed in 60cc HDPE Bottle and 33mm PP Child Resistant Cap, Induction sealed with1

Gof6g/yard cotton as dunn age, shall be determine da tthe end of40±2°C/75±5%RH3rd Month and the following shall be used as raiders for evaluation while comparing with Initial.

Drug Profile

Aceclofenac has been showing to have the potent analgesic and anti-inflammatory activities similar to indomethacin and diclofenac, and due to its preferential Cox-2 blockade, it has a better safety than the conventional Non steroidal anti-inflammatory drug (NSAIDs) with respect to the adverse effect on gastrointestinal and cardiovascular systems. Aceclofenac is superior from and the other NSAIDs as it has selectivity for Cox-2, a beneficial Cox inhibitor is well tolerated, has better Gastrointestinal (GI) tolerability and improved cardiovascular safety when compared with other selective Cox-2 inhibitor. To provide the patient with the most convenient mode of the administration, there is need to develop a fast-disintegrating dosage form, particularly one that it disintegrates and dissolves/disperses in saliva and can be administered without the water, anywhere, any time.

- Drug name :Aceclofenac
- Chemical name : [[[2-[(2, 6-Dichlorophenyl) amino] phenyl] acetyl] oxy] acetic acid.
- Synonym : Aceclofenaco, Aceclofenacum, aceclofenakas
- CAS number : 89796-99-6
- Mol .formula :C16H13Cl2NO4
- Mol .weight :354.2
- Melting point : 149°to150°C

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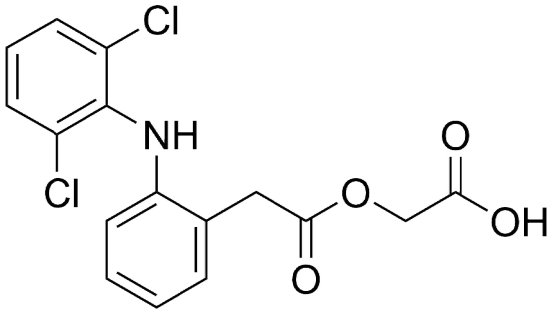
- Origin of substance: Synthetic
- Structure :



Category: Non Steroidal Anti-Inflammatory Drug
Solubility: It is practically in soluble in water, soluble in alcohol, Freely soluble in Acetone and dimethyl formamide.
Proprietary names: Arial, Barcan, Biofenac, Difucrem, Falcol, Gerbin, Preserve, Sane in. Aceclofenac relieve spa in and inflammation through a variety of mechanisms and in addition exerts stimulatory effects on cartilage matrix synthesis of the
Anti-Inflammatory activity: The anti-inflammatory effects of the Aceclofenac have been shown in both acute and chronic inflammation. It inhibit its various types of mediate or so f pain and inflammation including, the
PGE2 via cyclooxygenase inhibition (COX-1& COX-2) after intracellular metabolism to 4- hydroxyl-aceclofenac and the Diclofenac in human rheumatoid synovial cells and the other inflammatory cells.
IL-1β, IL-6and tumor necrosis factor in the Human Osteoarthritis Synovial celled and human particular chondrocytes
Reactive oxygen of the species (which plays a role in joint damage) has also been observed in the patients with osteoarthritis of the knee.
Expression of cell adhesion molecules (which is implicated in cell migration and Inflammation) has also been shown in human neutrophils

Composition of the Aceclofenac Tablet
Stimulatory effects on cartilage matrix synthesis
Aceclofenac stimulates glycosaminoglycan synthesis in human osteoarthritis cartilage byinhibitionofIL-1βand suppresses cartilage degeneration by inhibiting IL-1βmediated pro matrix metal oproteinase production and proteogly can release.

Materials and Nethods
Table 3: Composition of AceclofenacExtended Release Tablets

Sr. No	Ingredients	mg/tab							
		A1	A2	A3	A4	A5	A6	A7	A8
Intra granular Part(330mg)									
1	Aceclofenac	200	200	200	200	200	200	200	200
2	HPMCE50	130	-	-	-	-	65	50	40
3	HPMC K100LVCR	-	130	-	-	-	65	80	90
4	HPMCK4M CR	-	-	130	-	-	-	-	-
5	HPMC K15MCR	-	-	-	130	-	-	-	-
6	HPMCK100 MCR	-	-	-	-	130	-	-	-
7	IPA	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Extra granular Part(70mg)									
1	MCC(Ceolus KG1000)	62	62	62	62	62	62	62	**62**
2	Stearic acid	8	8	8	8	8	8	8	**8**

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Total weight (mg/tab)	400.00	400.00	400.00	400.00	400.00	400.00	400.00	**400.00**

Material Required for the Formulation

Table 4

Sr. No	Name of the material	Mfg/supplier	Uses
1	Aceclofenac	Schwitz biotech	Active ingredient
2	HPMC K4M	Dow Color on	Hydrophilic polymer
3	HPMC K100M CR	Dow Color on	Hydrophilic polymer
4	HPMC K LV CR	Dow Color on	Hydrophilic polymer
5	HPMC E50	Dow Color on	Hydrophilic polymer
6	HPMC K15 MCR	Dow Color on	Hydrophilic polymer
7	Microcrystalline cellulose Ceolus 100	Asahi , Japan	Diluents
8	Microcrystalline cellulose Vivapur type 102	JRS Pharma	Diluents
9	Stearic acid	Cogins, germany	Lubricant
10	Crospovidone	ISP technologies	Disintegrate
11	Colloidal silicon dioxide	Cabot sammar	glidant
12	Isopropyl alcohol	Rnaken	Solvent

Excipient Test

Drug-Excipient Compatibility Study-

The drug and the excipients chosen for the formulation were screened for compatibility by physical and assay methods.

Physical Compatibility Study

The physical compatibility studies were conducted to provide valuable information in selecting the appropriate excipients for the formulation. It was done by mixing the drug sand the excipients, taken in 2mlglass vial and kept at 40±2^{0}C/75±5%RH.Any change in color of the physical mixture was observed visually

Identification and evaluation of tablet

Dissolution of the tablet

Fig 8

Dissolution testing measures the extent and rate of the solution formation from the dosage form, such as the tablet, capsule, ointment, etc. The dissolution of the drug is important for its bioavailability and also for thetherapeutic effectiveness. Dissolution and the drug release are terms used interchangeably.

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Disintegration test for the tablet

Fig 9

Prior to the dissolution of thr solid dosage form, it should be established that the tablet or capsule must first disintegrate into smaller parts. Disintegration testing accurately measures, the standard conditions, the ability of a sample to break into smaller particles

The Disintegration test: we start with the 6 tablets and (each tablet in each tube), if one or two tablets failed to be disintegrate completely, test should be repeated for at additional 12 tablets, the requirement met if not fewer than 16 of the total 18 are as disintegrated.

The Enteric coated tablets are similarly tested. Except that the tablets are simulated gastric fluid for one hour, after which no sign of disintegration, cracking or softening must be seen. They are immersed in the simulated intestinal fluid for the time specified in the monograph, during which time the tablets disintegrate completely for a positive test.

Friability test

Fig 10

Formulation	% Friability
A1	0.45
A2	0.31
A3	0.61
A4	0.52
A5	0.49
A6	0.63

Friability testing is a laboratory technique which is used by the pharmaceutical industry to test the durability of thetablets during transit. This is testing that involves repeatedly dropping a sample of tablets over a fixed period of time, using this rotating wheel with a baffle.

Friable: "A friable substance is any substance that they can be reduced to the finer particles by the action of the small pressure and friction, such as the rubbing or inadvertently brushing up against the substance

Friability Test: Defined as percentage of the weight loss by the tablets due to the mechanical action during the test. Tablets are weighing before & the after testing & friability may be expressed as percentage loss on the pre test tablet

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weight. Friability test is done to the check the ability of there compressed tablet to avoid the fracture and the breaking during the transport

Hardness of the tablet

Table 6

Formulation	Hardness (kp)*
A1	6.1±0.0707
A2	6.1±0.0894
A3	6.12±0.8367
A4	6.1±0.1000
A5	6.1±0.1414
A6	6.1±0.0707
A7	6.1±0.0707
A8	**6.12±0.0447**

The three most the commonly used are the Brinell test, the Vicker's Diamond test, and the Rockwell test.
All three methods are involve the indentation of the material. The hardness is calculated by the measuring the force applied and comparing this to some geometrical aspect of the indentation such as the surface area or depth.

Weight variation test for the tablet

The weight variation test would be the satisfactory method for to determining drug content uniformity of drug distribution. Weight variation test is applicable when these tablets containing 50 mg or more of drug substance or when the drug substance represents 50% or more (by weight) of the dosage form

PHARMACOKINETICS

Absorption

Aceclofenac is absorbed the rapidally and completely after oral administration. Peak plasma concentrations are reached at approximately1-3hours after an oral dose. The presence off does not alter the extent of the absorption of the Aceclofenac but the absorption reduced
Aceclofenac is highly protein bound (~99.7%).The plasma concentration of Aceclofenac was Distribution
approximately twice that in synovial fluid and multiple doses of drug in patients with knee pain and synovial fluid effusion. The volume of the distribution is approximately 30L

Metabolism

Aceclofenac is metabolized into a major metabolite, 4- hydroxy Aceclofenac and to a number of other metabolites including 5-hydroxy Aceclofenac, 4- hydroxy Diclofenac, and 5-hydroxy Diclofenac. These other metabolites account forth fate of approximately 20% of each dose of Aceclofenac.

Excretion

Renal excretion is the main route of elimination of Aceclofenac with 70-80% of the administered dose found in the urine, mainly as the glucuronides of Aceclofenac and its metabolites. Of each of dose of Aceclofenac, 20% is excreted in the faeces.The plasma elimination half-life of the drug is approximately 4hour

Contraindications

Aceclofenac should not be administered to the patients hypersensitive to Aceclofenac or different NSAID's, or patients with history of Aspirin or NSAID's related allergic and to the patients with anaphylactic reactions with the peptic ulcers or GI bleeding, moderate of severe renal impairment.

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Drug interactions

Drug interactions associated with the Aceclofenac are similar to those observed with other NSAID's. Aceclofenac may increase in plasma concentrations of Lithium, Dioxin and Methotrexate, increase the activity of anti coagulants, inhibit activity of Diuretics, enhance Cyclosporine Nephrotoxicity and precipitate convulsions when co-administered with the Quinolone antibiotics. The co-administration of Aceclofenac with the other NSAID's or corticosteroids may result in increased frequency of adverse events

Adverse drug reactions

Aceclofenac is tolerated with the most adverse events being minor and reversible and affecting mainly the GI system. The most common events includes dyspepsia, and abdominal pain, dizziness, vertigo, purities,and dermatitis have been reported with the Aceclofenac, but the incidence of these events is less than 5%. Increased blood urea nitrogen and blood creatinine level have been reported with Aceclofenac treatment. As with other NSAID's, Aceclofenac can elevate circulating levels of hepatic enzymes.

Dose and Administration

The usual dose of the Aceclofenac is 100mg given orally twice daily. There is some evidence that the dose of Aceclofenac should be reduced in patients with hepatic impairment and it is suggested to that an initial daily dose of 100mg be used.

Over dosage

There are no human data available on the consequences of the Aceclofenac over dosage. The symptoms could tend to nausea, vomiting, stomach pain, dizziness, somnolence, and headache.

Therapeutic Uses of the Aceclofenac is used in

Osteoarthritis Rheumatoid arthritis Ankylosingspondylitis , Dental pain, Postoperative pain Dysmenorrheal Acute lumbago Musculoskeletal trauma Goalie(knee pain)

Sop Handlings

Preparation of the SOP's for different instruments and equipment.

The Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization

1. Focus on the process—not the tools. An SOP's should focus on these process, so try to be tool- or software-independent. ...
2. Be concise. ...
3. Write for your audience. ...
4. Clearly define steps and roles. ...
5. Seek input from the relevant team members and stakeholders. ...
6. Test your SOP. ...
7. Review regularly…

The organization should have the procedure in place for to determining what the procedures or processes need to be documented. Those SOPs should then written by the individuals knowledgeable and informable with the activity and the organization's internal structure. These individuals are essentially subject-matter experts who where actually perform the work or use the process. These team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical, which also promotes "buy-in" from potential users of the SOP.

SOPs should be written with the sufficient detail so that they someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised. The experience requirement for these performing an activity should be noted in the section on personnel qualifications. For example, if a basic chemistry or these biological course experience or additional training is required that requirement should be indicated

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Marketed Formulations

ACECLOFENAC

Table 8

TRADENAME	STRENGTH	DOSAGEFORM	MANUFACTURER
Indian brands			
Valus–A	100mg	Tablet	Glenmark
Aroff	100mg	Film coated tablet	Unichem
FastanacSR	200mg	Sustained release tablet	Lupine
Aceclo	200mg	Sustained release FC tablet	Aristo
ZerodolCR	200mg	Controlled release tablet	IPCA
Zynac	150mg/ml	Injection	Zydus
International brands			
Preservex	100mg	Film coated tablets	Almiralltd
Airtal	100mg	Tablet	Highnoon
Bristaflam	100mg	Oral powder	Bristol Mayer Squibb

Combination Products of Aceclofenac

Table 9

Tradename	Combination and Strength	Dosage Form	Manufacturer
Altraday	Aceclofenac200mg, Rabeprazole20mg	Spantules	Inventia
Altraflam-P	Aceclofenac100mg, Paracetamol500mg	Tablets	Ranbaxy
Peale	Aceclofenac1.5%w/w,MethylSalycilate105w/w,Oleumlini3%w/w,Menthol5%w/w,Capsaicin0.01%w/w,Benzylalcohol1%w/w	Gel	Cadila

VII. SUMMARY AND CONCLUSION

A Tablet in Capsule device containing Aceclofenac ER tablet tablet for Pain Management with Gastro protection was formulated. Rationale of the combining a NSAID and the prostaglandin analogue was well justified and the design of the drug delivery system was made simple by encapsulating two different tablets. Aceclofenac in singlecapsule and it offers advantage interms of GI protection, Patient Compliance and Chrono therapeutics.

Aceclofenac extended release tablet 200 mg was formulate dusing various grade so hydrophilic polymer such as HPMC E50, HPMC K100 LV CR, HPMC K4M CR and HPMCK1 5MC Rasrele as eretardanttoprolong the releasefor12hr

The study and the results revealed that the method of these preparation of formulation significantly affect the disintegration time, percentage friability, and release of drug. The present study underlines the importance of process variables. Then it is concluded that by adopting a systematic formulation approach, an optimum point can be reached in the shortest time with minimum efforts and direct compression technique would be an effective the alternative approach compared with wet granulation technique.

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Review of the Project

A tablet in capsule device containing Aceclofenac ER tablet Ir tablet for pain management with gastro protection was formjlated. Rationale of the combining a NSAID and a prostaglandin analogue was well justified and the design Aceclofenac it is an oral non-steroidal anti-inflammatory drug (NSAID) with the anti-inflammatory and the analgesic properties. Although these are some differences in the authorized and indications between countries, aceclofenac is mainly recommended for the treatment of inflammatory and painful processes, such as the low back pain (LBP), tehe scapulohumeral periarthritis, extraarticular rheumatism, odontalgia, and the osteoarthritis (OA), rheumatoid arthritis (RA), and ankylosing spondylitis (AS). The analgesic properties of and the tolerability profile of aceclofenac in musculoskeletal disorders are reviewed, focusing on the relevant and the recent studies. The efficacy and the safety is to comparison of the aceclofenac with the other analgesics and the anti-inflammatory agents in OA, AS, RA, and LBP is being described.the Relevant studies were identified following the literature search of the PubMed using the terms "aceclofenac" and the "clinical trials" published from 1 Jan 1992 to 1 Jan 2020. the Aceclofenac is at least as effective as the other NSAIDs in the reducing pain and/or to improving functional capacity in chronic pain conditions (OA, AS, RA, and LBP). It is generally well and being tolerated and they appears to have a more favorable GI profile than other NSAIDs. Thus, these current evidence to indicates that tehaceclofenac is a useful option for the management of pain and inflammation across a wide range of painful conditions.

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