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DICLOFENAC: A PHARMACEUTICAL STUDY

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ABSTRACT

Analgesic and anti-inflammatory drugs are widely used for the management of pain, inflammation, and fever. Among these, diclofenac sodium is one of the most commonly used non-steroidal anti-inflammatory drugs (NSAIDs) due to its analgesic, antipyretic, and antiinflammatory properties. Diclofenac exerts its pharmacological action by inhibiting cyclooxygenase enzymes (COX-1 and COX-2), thereby reducing prostaglandin synthesis.

The present study focuses on the formulation and evaluation of diclofenac tablets along with the necessary preformulation studies required for successful dosage form development.

Preformulation studies were carried out to evaluate the physicochemical properties of diclofenac sodium, including solubility, melting point, pka, partition coefficient, polymorphism, hygroscopicity, and flow properties such as angle of repose, bulk density, tapped density, Hausner's ratio, and Carr's index. Compatibility and stability studies were also performed to ensure the suitability of the drug for tablet formulation.

The formulation process involved the selection of suitable excipients such as diluents, binders, lubricants, glidants, disintegrants, and coating materials to achieve efficient tablet compression and optimum drug release. Various manufacturing methods including direct compression, wet granulation, and dry granulation techniques were studied.

Evaluation tests such as weight variation, hardness test, friability test, thickness, content uniformity, dissolution test, disintegration test, moisture content determination, and stability studies were carried out to assess the quality, safety, and efficacy of the formulated tablets.

The study concludes that proper preformulation, formulation, manufacturing, and evaluation processes are essential for the development of stable and effective diclofenac tablets with good therapeutic performance and improved patient compliance.

PAINAND ANALGESIA

Pain isanunpleasant sensoryandemotionalexperienceassociatedwithactualorpotentialtissue damage. It acts as a protective warning signaland may be classified as acute or chronic, and as nociceptive or neuropathic based on its origin.

Analgesiaisthereliefofpainwithoutlossofconsciousness.

ANALGESICAGENTS

Analgesic drugs are agents used to relieve pain without causing loss of consciousness.Theyact byreducingpainperceptionat peripheralsites, thecentralnervoussystem, orboth.

CLASSIFICATION

1. Non-OpioidAnalgesics

Examples:Paracetamol,Aspirin,Ibuprofen,Diclofenac,Celecoxib. Mechanism of Action: Acetaminophen mainly acts on the central nervous system to reduce pain and fever but has minimalanti-inflammatoryeffects. NSAIDsreducetheproductionofprostaglandins, which are chemicals involved in pain, inflammation, and fever, by inhibiting cyclooxygenase (COX) enzymes

2. OpioidAnalgesics:

Examples:Morphine,Codeine,Tramadol,Fentanyl,Buprenorphine.

MechanismofAction:It bindswiththeopioidreceptorsinthebrainandspinalcord and reduces the perception of pain as post-surgical or cancer-related pain.

Uses:Usedformoderatetoseverepainsuch

3. AdjuvantAnalgesics:

Thesearenotprimarilypainkillersbutcanrelievecertaintypesofpainorcan enhance analgesic action.

Examples: Amitriptyline (Antidepressants), Gabapentin & Pregabalin (Anticonvulsants), Dexamethasone (Steroids).

4. LocalAnalgesics:

Examples:Lidocaine,Bupivacaine.

Mechanism of Action: They block voltage-gated sodium (Na^+) channels in nerve membranes, preventing initiation and conduction of nerve impulse.

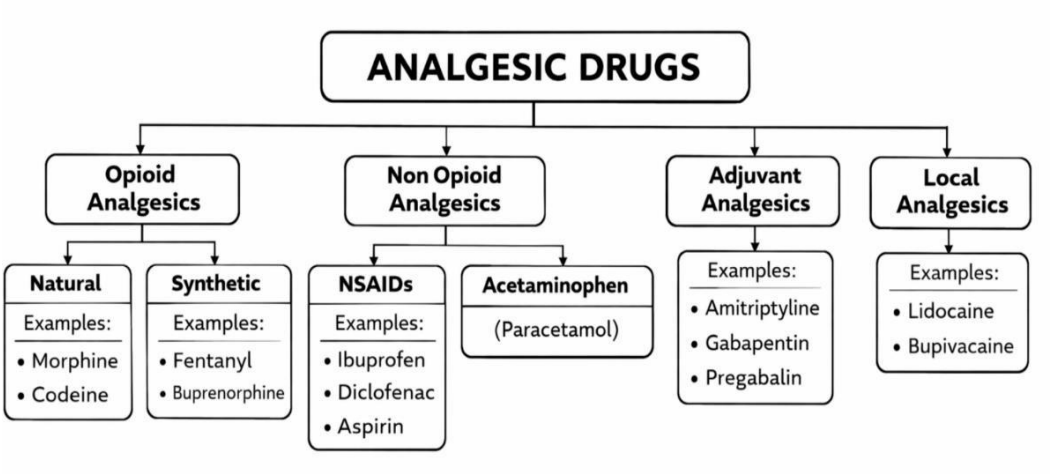

Fig.1Classificationofanalgesicdrugs.

DICLOFENAC

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) used to relieve pain, inflammation,andswelling.Itworksbyinhibitingcyclo-oxygenase(COX) enzymestherebyreducingprostaglandinsynthesis.Diclofenaciscommonlyprescribed for arthritis,musculoskeletal pain, dental pain, and post-operative pain.

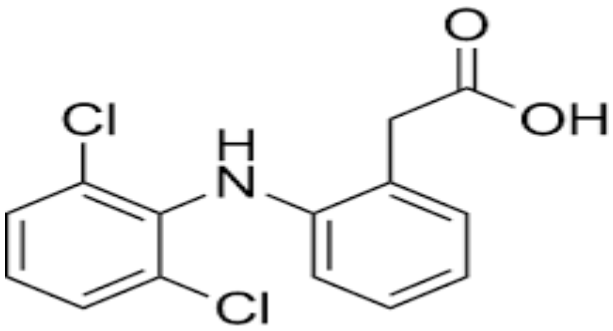

Fig2.ChemicalstructureofDiclofenac.

- MolecularFormula:**$C_{14}H_{11}Cl_2NO_2$**
- MolecularWeight:**296.15g/mol**
- IUPACName:2-[(2,6-dichlorophenyl)amino]benzeneaceticacid

MECHANISMOFACTION

Diclofenac isanon-steroidalanti-inflammatorydrug(NSAID)that worksmainlybyinhibiting cyclo-oxygenase (COX) enzymes.

➢ Whenthereisinflammation,thebodymakeschemicalscalledprostaglandins**.**

➢ Prostaglandinscausepain,swelling,redness,andfever**.**

- ➢ Diclofenac blockstheenzymecyclo-oxygenase(COX-1andCOX-2).
- ➢ Thisenzyme isneededtomakeprostaglandins.
- ➢ Whendiclofenac blocksCOX→lessprostaglandinsareformed.
- ➢ Reducedprostaglandinsynthesisleads to:
  - ↓Inflammation
  - ↓Pain(analgesic effect)
  - ↓Fever(antipyreticeffect)

PHARMACOKINETICS

Absorption

- Wellabsorbedafteroraladministration.
- Undergoessignificantfirst-passmetabolism
- Bioavailability:50–60%
- Peakplasmaconcentrationreachedin1–2hours(oral)

Distribution

- Highlyplasmaproteinbound(99%),mainlytoalbumin
- Widelydistributedintissues

Metabolism

- Extensivelymetabolizedintheliver
- Formshydroxylatedandmethoxylatedmetabolites
- Somemetabolitesarepharmacologicallyactivebutweakerthantheparentdrug

Excretion

- Eliminatedmainlyasmetabolites
- 65%excretedinurine
- 35% excretedinbile/feces
- Verylittleunchangeddrug excreted

Half-life

- Plasmaeliminationhalf-life:1–2hours.
- Clinicaleffectlastslongerduetopersistenceintissues

PHARMACOLOGICALACTIONS

- **Anti-inflammatory**:(reducesinflammation)
- **Analgesic**:relievespain

- **Antipyretic**:(reducesfever)
- **Mild**:reversibleinhibitionofplateletaggregation

DOSAGEFORMS

- **Tablets**:50 mg
- **Sustained-releasetablets/capsules**:75mg,100mg
- **Injection(IM/IV)**:75mg/3mL
- **Suppositories**:50mg,100mg
- **Topicalgel/cream**:1%(10mg/g)
- **Ophthalmicdrops**:0.1%

ADVERSEDRUGREACTIONS

- Gastrointestinal:
- gastric irritation
- dyspepsia,
- nausea,
- pepticulcer,
- GIbleeding

THERAPEUTICUSES

1. **ArthritisManagement:**

- Reducesjointstiffness
- inflammationinosteoarthritis,rheumatoidarthritis
- PainRelief:Treatsmildtomoderatepain.

2. **Topical/OphthalmicUses:**

- Diclofenacgel/eyedropsareusedforlocalizedpainorreducingeye inflammation.

PREFORMULATIONSTUDIES

Preformulationstudiesofdiclofenactabletsaretheinitialinvestigationscarriedouttoevaluatethe physicaland chemical properties of diclofenac before developing it into atablet dosage form. These studieshelp inunderstanding the drug'sstability, solubility, compatibilitywithexcipients, and other characteristics necessary for designing a safe, effective, and stable tablet formulation.

OBJECTIVESOFPREFORMULATIONSTUDIES

1. Tostudyphysiochemicalproperties
2. Toevaluatesolubilityand dissolution
3. Toassessstability
4. Tocheckdrug–excipient compatibility
5. Tostudymicromeriticproperties
6. Toselectsuitableformulationandmanufacturingmethod
7. Toensurequality,safety,andefficacy

PHYSICALPREFORMULATIONSTUDIESOFDICLOFENACTABLET

Physicalpreformulationstudiesevaluatethephysicalcharacteristicsofdiclofenac beforetablet formulation.

1. OrganolepticPropertiesProcedure:

- Observethedrugsamplevisuallyunderdaylight.
- Smellcarefullytodetectodor.
- Tastetestisusuallyavoidedinthelab(refer toliterature)

2. PhysicalState&CrystalNatureProcedure:

- Examineunderamicroscope.
- PerformpowderX-raydiffraction(ifavailable).

Purpose: Determinescrystallineoramorphousnature.

3. Particle Size AnalysisProcedure(SieveMethod):

- Weighabout10–20gofdrug.
- Placeinasetofstandard sieves.
- Shakemechanicallyfor10–15minutes.
- Weighpowderretained oneachsieve.

Purpose: Affectsdissolutionrateandflowproperty.

4. BulkDensity&TappedDensity Bulk Density

Procedure

- Weighaccuratelyabout10gofpowder (M).
- Transferintoa50mlmeasuring cylinder.
- Notetheinitialvolume(V_0).

Bulk Density=M/V_0

TappedDensity Procedure:

- Tapthecylinder100timesusing a tapped densityapparatus.
- Notethefinalvolume(Vt).

Tapped Density=M/Vt

Purpose: Determinespackingability.

5. FlowProperties

a. AngleofRepose Procedure:

- Allowpowderto flowthroughafunnelfixed ataheight.
- Measureheight(h)andradius(r)oftheformedheap.

tanθ=h/r

b. Carr'sIndex

Carr'sIndex=[(Tapped–Bulk)/ Tapped]×100

c. Hausner'sRatio

Hausner'sRatio=TappedDensity/BulkDensity

Purpose: Indicatesflowabilityfortabletcompression.

6. MeltingPoint

Procedure:

- Filla smallamountofdiclofenacina capillarytube.
- Placeinmeltingpointapparatus.
- Recordtemperatureatwhichdrugmelts(≈165–166°Cfordiclofenac sodium).

Purpose: Checkspurityandstability.

7. SolubilityStudy

Procedure:

- Adddrugtodifferentsolvents(water,methanol, ethanol).
- Shakefor 24hours.
- Filterandanalyzeconcentrationspectrophotometrically.

Purpose: Helps inselectionofdissolution medium.

8. Moisture Content (Losson Drying)

Procedure:

- Weighsampleaccurately.
- Dryinhot airovenat105°Cfor2–3 hours.
- Weighandcalculateweightloss.

%Lossofdrug= (Initialweight–Finalweight/Initialweight)× 100

Purpose: Determineshygroscopicnature.

9. Polymorphism

Procedure:

- StudyusingX-raydiffractionordifferentialscanning calorimetry(DSC).

Purpose: Differentformsmayaffectsolubilityandbioavailability.

10. COMPATABILITYSTUDIESOFDICLOFENACTABLET

a. FTIR (FOURIERTRANSFORMEDINFRARED**)**

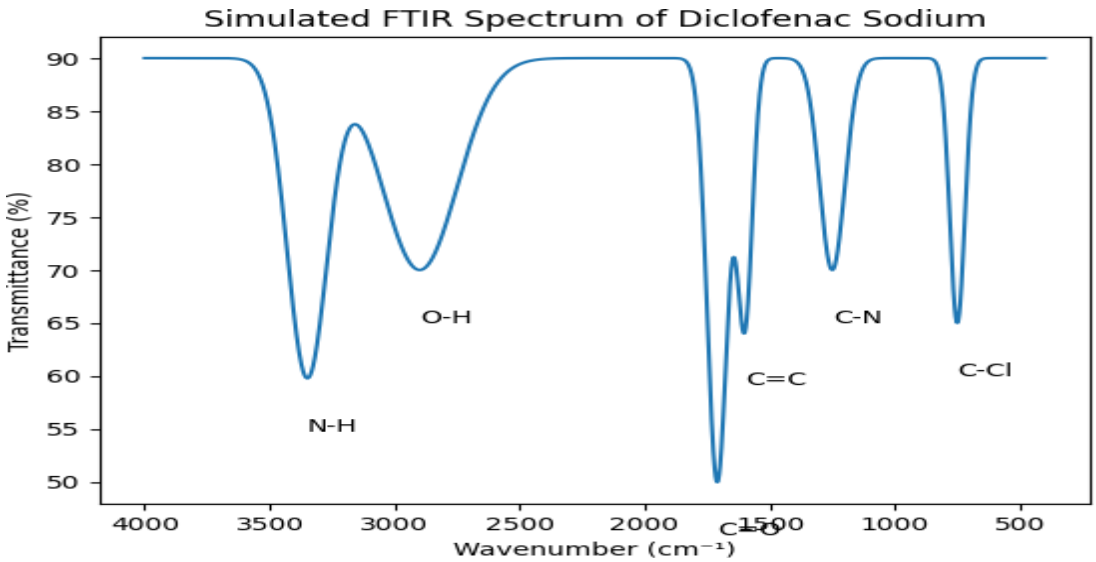

Fig3.FTIR SpectrumofDiclofenac.

Thepresenceofallpeaksconfirmsthe identityandpurityofdiclofenac.Nosignificant shift indicates compatibility with excipients in tablet formulation

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FORMULATIONOFTABLETS

Tablets maybedefinedassolidpharmaceuticaldosage formscontainingdrugsubstanceswithor withoutsuitablediluentsandpreparedeitherbycompressionormoulding methods.Accordingto the Indian Pharmacopoeia, 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.

ADVANTAGES

- Theyareeasytoswallow.
- Theyareattractiveinappearance.
- Unpleasanttastecanbemaskedbysugar coating.
- Anaccurateamount ofmedicament,even ifverysmall,can beincorporated.

DISADVANTAGES

- Difficulttoswallowincaseofchildrenandunconscious patients.
- Somedrugsresistcompressionintodensecompacts,owingtotheiramorphousnature.
- Bittertastingdrugs,objectionableodour.

TYPESOFFORMULATIONOFTABLETS

1. Direct Compression Method.
2. Wet GranulationMethod.
3. DryGranulationMethod.

DIRECTCOMPRESSIONMETHOD

Direct compressionisthepreferred methodifpowderblend hasadequateflow,compactibility, andcohesionwithlowsegregationpotential. Thisisthesimplest processthat involvesthe least extent of material handling.

- Milling
- Weighing
- Sieving
- Blending
- Compression

WETGRANULATIONMETHOD:

Wet granulation is most used process ofgranulation inpharmaceutical industryduring tablet manufacturing.Theformulationofgranulesalso helpstoreducesegregationand improvethe

content uniformity of the final product.

MixingofAPI(active pharmaceuticalingredient)andexcipient

↓

Preparingadampmassusingbinder solution

↓

Screening–granulationand drying

↓

Sizing thisgranulationbydryscreening

↓

Lubricantandcompression.

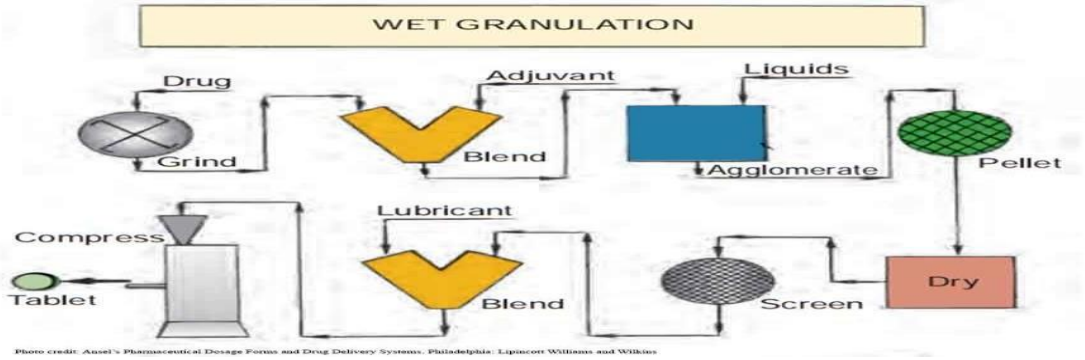

Fig3.Wetgranulation.

DRYGRANULATIONMETHOD

Drygranulation,isa pharmaceuticalmanufacturingprocessusedtocreategranulesfrompowderswithout the use of a liquid binder or solvent. It's especially beneficial when dealing with moisture-sensitive or heat-sensitive materials.

- **MaterialPreparation**
- **Compaction**
- **Milling:**
- **FinalBlend**

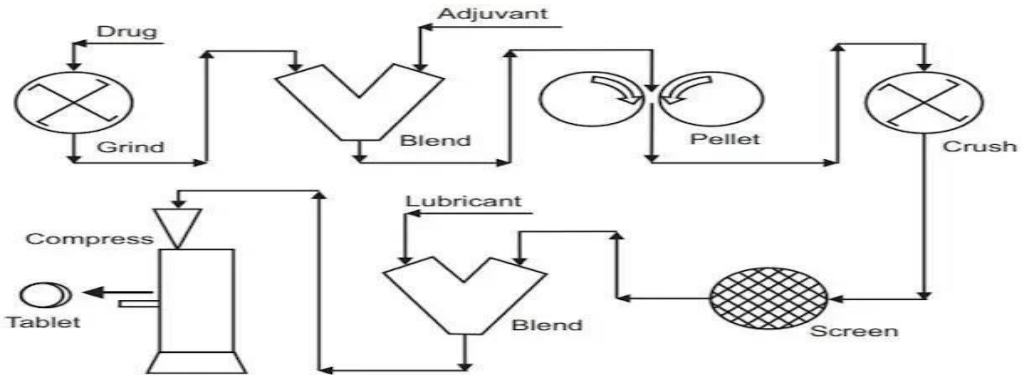

Fig3. DryGranulation.

FORMULATION OF DICLOFENAC TABLET

1. MATERIALSREQUIRED

INGREDIENT	CATEGORY	FUNCTION
Diclofenacsodium	Active ingredient	Anti-inflammatorydrug
Lactose	Diluent	Adds bulk
Starch/PVP	Binder	Helpsgranuleformation
Sodiumstarchglycolate	Disintegrant	Helpstabletbreakquickly
Magnesiumstearate	Lubricant	Prevents sticking
Talc	Glidant	Improvesflow
HPMC/Eudragit	Coatingpolymer	Forentericcoating

2. METHOD OF PREPARATION

Step-by-stepprocess:

1. Weighing

Accuratelyweighallingredients:

- Diclofenacsodium
- Diluent(lactose/MCC)
- Binder,disintegrant,lubricant

2. Sieving

- Passallpowdersthroughsieve (#40or#60)
- Removes lumpsandensuresuniformparticlesize

3. DryMixing

- Mixdiclofenacwithdiluentthoroughly
- Ensuresuniformdistributionofdrug

4. PreparationofBinderSolution

- Preparebinder(e.g.,PVP)inwateroralcohol
- Helpsgranulesticktogether

5. WetGranulation

- Addbinder solutionslowlytopowdermix
- Mixuntila cohesivewetmassisformed

6. Screening (Wet)

- Passwetmassthroughsieve(10–16)
- Formsuniformwetgranules

7. Drying

- Drygranulesintraydryeror oven
- Temperature:**40–60°C**
- Removesmoisturetopreventinstability

8. DryScreening

- Passdriedgranulesthroughsieve (#20)
- Ensuresuniformgranulesize

9. Lubrication

- Add:
  - Magnesiumstearate(lubricant)
  - Talc(glidant)
- Mixgentlytoavoidover-lubrication

10. Compression

- Compressgranules intotabletsusingtabletpress
- Adjust:
  - Hardness
  - Weight
  - Thickness

11. EntericCoating

- Appliedaftercompression
- Usespolymerslike:
  - Eudragit
  - Celuloseacetate phthalate

Purpose:

- Protectsstomachfromirritation
- Releasesdruginintestine

12. Packing

- Protectfrommoisture,light,andair

- Preventmechanicaldamage
- Maintainstabilityandshelf life.

13. Labelling

- Everydiclofenactabletpackmustinclude:
- Genericname:Diclofenacsodium
- Brandname(ifany)
- Strength: e.g.,50mg, 75mg
- Dosageform:Tablet(enteric-coated/sustained release)
- Batch number
- Manufacturingdate (Mfg.)
- Expirydate(Exp.)
- Manufacturerdetails
- Druglicensenumber

EQUIPMENTS USED FOR MANUFACTURING OF DICLOFENAC TABLETS

- Electronicweighingbalance
- Vibrosifter
- Doubleconeblender
- V-blender
- Rapid mixergranulator(RMG)
- Planetarymixer
- Fluidizedbeddryer(FBD)
- Traydryer

Fig.4doubleconeblender

Fig.5weighingscale.

Fig.6mixergranulator

Fig.7.Traydryermachine

Fig.8Singlepunchtablet.

Fig.9Sieveshaker

EVALUATIONOFTABLET

The compendia, such as the United States Pharmacopeia (USP), and the regulatory bodies, such as the United States Food and Drug Administration (FDA), in addition to historic product-development experience, inform the desired quality attributes of the tablets. Tablets are usually tested for the following characteristics.

TYPESOFEVALUATION

PHYSICALEVALUATION

- **APPEARANCE**

Appearance is the first most required quality for the acceptance oftablet. General elegance and its identity play a major role for the consumer acceptance.

- **SIZEANDSHAPE**

Size and shape ofa tablet has beendetermined by itsthickness. Size and shape oftable plays an important role in itspatient compliance asthe size ofthetablet increases it isnot mucheasier for its administration.[27]

- **HARDNESS TEST**

Hardness Test is the most important feature for assessing tablet in the study it was found that Tablet passed the test of tablet crushing strength or hardness both these brand have acceptable crushing strength of Between 5Kg/Cm^2 to 10kg/ Cm^2This test done from Pfizer Test machine

- **WEIGHTVARIATIONTEST**

20Tabletsofallthe batcheswerecollectedrandomlyduringcompressionandweight ofindividual tablet wascarriedout. Limit: Weightofallindividualtabletsshouldbe inthe limit ofAveragewt ± 7.5%. Average weight was carried out by calculating the total wt. of 20 tablets (individually weighed) and dividing this value by 20.

► **FRIABILITYTEST**

Rochefriabilatoristheequipment whichisusedforthedeterminationoffriability.Itisexpressed inpercentage. Notedowntheinitialweightofthetablets individually(Winitial).Tabletsareplaced ina plastic chamber which revolves at 25 rpm and they are subjected to fall
froma height of6inches inthe friabilatorfor about 100revolutions.Then measure the weight of the tablet (W final) and observe any weight difference before tablet and after the friabilatorprocessing .Limits: loss in weight less than0.5 to 1% ofthe initialweight ofthe tablet should be considered as acceptable limits. Percentage of friability is calculated as:

F={(Winitial)-(Wfinal)/(Winitial)}×100.

► **THICKNESSTEST**

Themostcommonlyusedinstrumenttomeasuretabletthicknessistheverniercalliper.Thevernier callipergivesreading inmillimetresand it isavailablebothindigitaldisplayand manualreading.

Tomeasurethetabletthicknesssimplyplacethetablet inbetweenthejawsandslidethescalejaw to press the tablet against the stationary .

CHEMICALEVALUATION

► **ASSAY OF TABLET**

Thistest measuresthe exact amount ofactive drug inthe tablet. It ensuresthe tablet containsthe same amount of medicine as stated on the label.

Principle:Measurestheactualamount ofactivepharmaceuticalingredient (API). Procedure:

- Preparesampleandstandardsolutions.
- Analyzeusingtitration,spectrophotometry,orHPLC.
- CalculateAPI content.

► **CONTENTUNIFORMITY TEST**

Initiallyweighthetabletandthenpowderit.Nowthepowderedtabletistransferredintoa100ml volumetric flask and adds 0.1 N HClup to mark. Now filter the solutionand discard first few ml offiltrate.Take10mloffiltrateshould betakeninto a50mlvolumetric flaskandadd0.1NHCl up to the mark and analysed spectrophotometrically at 274 nmand 234.5 nm. The concentration of the content of the drug (µg/ml) was calculated by using the standard calibration curve of the respective drug.

Drugcontentiscalculatedbyusingthebelowformula:Concentrationofthedrugin(µg/ml)×100 ×50/10×1000

PHARMACEUTICALEVALUATION

► **DISINTEGRATIONTEST**

Tabletdisintegrationisevaluatedtoensurethatatabletbreaksintosmallerparticlesinthepresence of water, allowing the drug to dissolve and be absorbed from the GI tract. The test is performed using a standard apparatus with six tablets in a suitable medium at 37°C. The time taken for completedisintegrationiscalledthedisintegrationtime.Forimmediate-releasetablets,itisusually not more than 15 minutes. This test is used for orally administered tablets except chewable and sustained-release tablets.

► **DISSOLUTIONTEST**

Dissolution, or drug release, is an important propertyoftablets because drug absorption depends on the drug being dissolved at the site of absorption. Dissolution tests are performed in vitro to determine the rate and extent of drug release. The setestsareusedasqualitycontroltoolstoensure uniformitybetweenbatchesandtablets,andtheymayalsohelpestablishinvitro–invivocorrelation (IVIVC) between drug release and absorption.

STABILITYSTUDIESOFTABLET

Stability studies of pharmaceutical products may be expressed as the time during which the pharmaceuticalproductsretainitsphysical,chemical,microbiological,pharmacokineticproperties andcharacteristicsthroughouttheshelflifefromthetimeofmanufacture.Shelflifeoftheproduct canbedefinedasthesubstancereducesto90%ofitsoriginalconcentration.Shelflifeisatechnical termusedtodenotethestabilityoftheproductandit isexpressedasexpirydate.Expirationvaries for each pharmaceutical preparations.

IMPORTANCEOFSTABILITYSTUDIES

Productinstabilityofactivedrug mayleadtounder medicationduetothe loweringofthedrugin dosage form.

- Duringthedecompositionofthedrugor productitmayleadtotoxicproducts.
- Duringthe marketing fromoneplaceto anotherduringthetransportationthedrug hasthe compatibility to change its physical properties

TYPESOFSTABILITYSTUDIESONDRUGSUBSTANCES

- **Physicalstability**

The original physical properties such as appearance, colour, dissolution, palatability, suspendability are retained. The physical stability may affect the uniformity and release rate, hence it is important for the efficacy and safety of the product.

- **Chemicalstability**

It is the tendencyto resist its change or decompositiondue tothe reactions that occurdue to air, atmosphere, temperature, etc.

- **Microbiologicalstability**

The microbiological stability ofthe drugs is the tendency to resistance to the sterility and microbialgrowth.Theantimicrobialagentsusedinthepreparationretaintheeffectiveness within specified limits. This microbiological instability could be hazardous to the sterile drug product.

- **Therapeuticstability**

Thetherapeuticeffect (DrugAction)remainsunchanged.

- **Toxicologicalstability**

Toxicologicalstabilityhasnosignificantincrease inthetoxicityoccurs.

STABILITY TESTING METHOD

Stabilitytesting is a procedure performed for allthe pharmaceuticalproducts at various stagesof the product development. Inthe earlystages, the stabilitytesting is performed bythe accelerated stability studies which mainly are performed at high temperature\ humidity.

TYPES OF STABILITY TESTING

- Long-Timestabilitytesting-25^{O}C/60%RHor30^{O}C/65%RHfor12months
- IntermediatestabilityTesting–30±2^{O}Cand65±5% RHfor 6months
- AcceleratedStabilityTesting-40^{O}C/75%RHfor6 months

PACKAGING, STORAGE, LABELING

PACKAGING

Packaging in the pharmaceutical industry varies from drug to drug and normally there are three levels of packaging commonly referred to as the primary, secondary, and tertiarypackaging.

TYPESOFPACKAGING

► STRIPPACKAGING

Strip packaging is a method in which drugs, whether in tablet or capsule form, are enclosed in a continuousstripofflexiblematerial.Thestripisusuallymadeofplasticoraluminumandprotects the drugs from elements, ensuring their high efficacy.

► BLISTER PACKAGING

Blister packaging consists of a pre-formed plastic cavity or blister bonded to a lidding material that contains single-unit doses. The product is easy to see, and you can also ensure proper protection from heat and moisture.

► BOTTLE PACKAGING

Bottles are often made of glass and plastic (polyethylene or polypropylene)andareusedtosecurelyholdtabletsandcapsules.Theycanalsofeaturechildproof safetymechanismsandareamber-coloredtoprotectlight-sensitive medicationsfromdegradation or other chemical reactions.

Fig.10 Packaging of DiclofenacTablets.

LABELLING

Labellingis the process of providing written,printed, or graphicinformation on the container, package, or product to identify and describe the drug and its usage

► MANUFACTURER LABEL

Alabelwhichcontainsdruginformationfortheuseofmedicalpractitioners,pharmacists,or nurses supplied by the manufacturer, packer, or distributor of the drug (FDA).

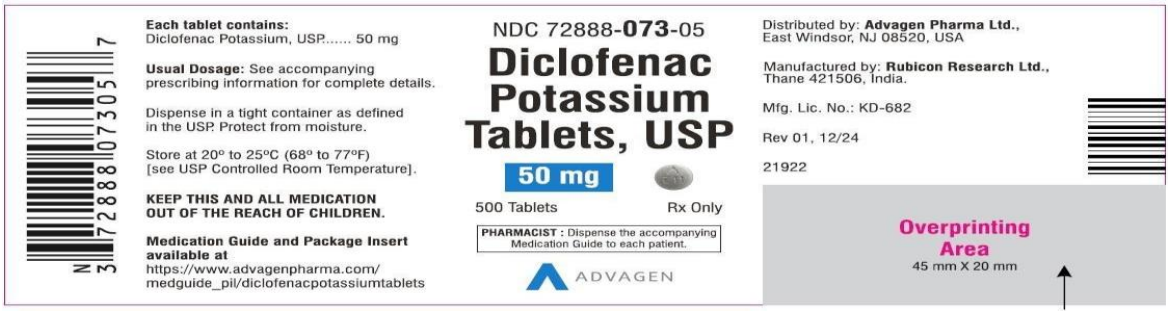

Fig11.LabelingofDiclofenacTablets.

LEGALREQUIREMENTSOFAMANUFACTURERLABEL

- The name ofpreparation
- Strengthand dosageform
- Quantity
- Instructionsfortheuse
- Precautions&warnings
- Registrationnumber
- Batch number
- Manufacturing&Expirydate
- Price
- Thenameand addressofpharmaceuticalindustry

CONCLUSION

The formulation and evaluation of Diclofenac tablets were successfully carried out. The tabletsshowedsatisfactoryphysicalproperties,properdrugrelease,andgoodstability,indicatingtha tthe formulation is suitable for effective management of pain and inflammation

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