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ACETAMINOPHEN: A PHARMACEUTICAL STUDY

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Analgesic and antipyretic drugs are widely used for the management of pain and fever, among which acetaminophen is one of the most commonly used drugs due to its safety and effectiveness. The present study focuses on the formulation and evaluation of acetaminophen syrup along with the preformulation studies required for successful dosage form development.

Preformulation studies were carried out to evaluate the physicochemical properties of acetaminophen such as solubility, melting point, pH, and compatibility with excipients to ensure suitability for syrup formulation. The formulation process involved the selection of suitable excipients including sweetening agents, preservatives, flavoring agents, and stabilizers to improve palatability, stability, and therapeutic effectiveness.

Evaluation tests such as physical appearance, pH, viscosity, drug content, organoleptic properties, and stability studies were performed to assess the quality, safety, and efficacy of the prepared syrup. The study concludes that proper preformulation, formulation, and evaluation processes are essential for developing a stable, safe, and effective acetaminophen syrup with good therapeutic performance and patient compliance.

PAINANDANALGESIA

Painisanunpleasantsensoryandemotionalexperienceassociatedwithactualorpotentialtissue damage. It acts as a protective warning signal and may be classified as acute or chronic, and as nociceptive or neuropathic based on its origin.

Analgesia is the relief of pain without loss of consciousness. It is achieved by analgesic drugs thatacteitherperipherallybyinhibitinginflammatorymediatorsorcentrallybymodifyingpain perceptioninthecentralnervoussystem.Effectiveanalgesiaisessentialforpatientcomfortand

improved therapeutic outcomes.

ANALGESICAGENTS

Analgesic drugs are agents used to relieve pain without causing loss of consciousness. They act by reducing pain perception at peripheral sites, the central nervous system, or both. Analgesicsarewidelyusedinconditionsassociatedwithinflammation,injury,and disease.

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.
Uses:Usedformildtomoderatepainsuchasheadachesandmuscleaches.

2. OpioidAnalgesics

Examples:Morphine,Codeine,Tramadol,Fentanyl,Buprenorphine. Mechanism of Action:
It binds with the opioid receptors in the brain and spinal cord and reduces the perception ofpain.
Uses:Usedformoderate toseverepainsuchaspost-surgicalorcancer-relatedpain.

3. AdjuvantAnalgesics

Thesearenotprimarilypainkillersbutcanrelievecertaintypesofpainorcanenhanceanalgesic action.
Examples:Amitriptyline(Antidepressants),Gabapentin&Pregabalin(Anticonvulsants),Dexame thasone (Steroids).
MechanismofAction:
Workthroughmechanismsthattargetnervepainorchronic conditions.
Uses:Commonlyusedfornerve-relatedpain(e.g., diabeticneuropathyorfibromyalgia).

4. LocalAnalgesics

Examples:Lidocaine,Bupivacaine. Mechanism of Action:
They block voltage-gated sodium (Na^+) channels in nerve membranes, preventing initiationand conduction of nerve impulses.
Uses:Oftenemployedaslocalanestheticinsurgeriesortomanagechronicpainthroughtopical applications.

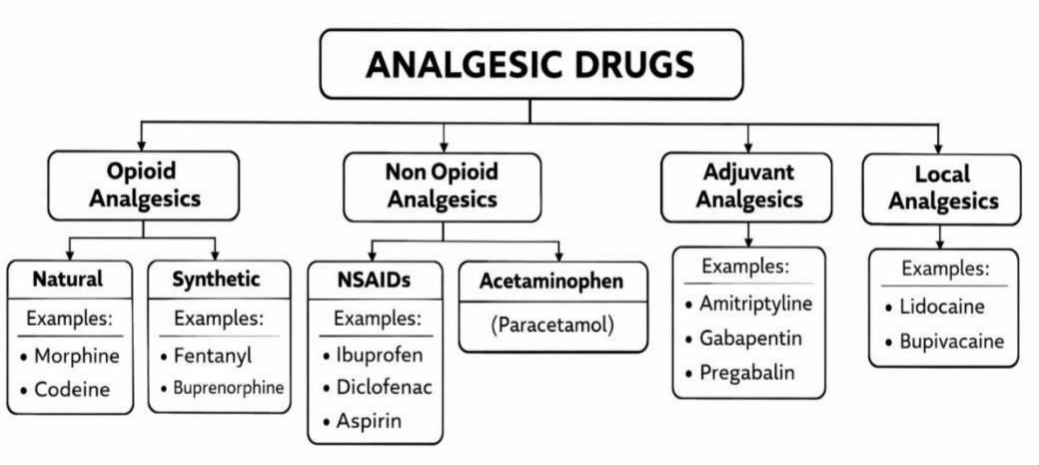
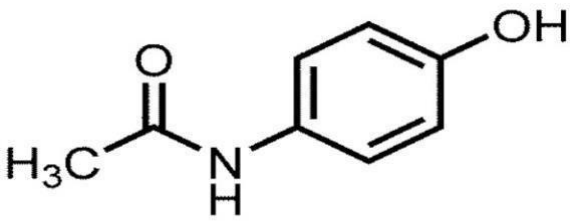


Fig1.1 Classification of Analgesics.

ACETAMINOPHEN

Acetaminophen, also known as paracetamol, is a widely used non-opioid analgesic and antipyreticagentusedforthetreatmentofmildtomoderatepainandfever.Itisoneofthemost prescribedandover-the-countermedicationsworldwideduetoitsefficacy,safetyattherapeutic doses, and wide patient acceptance. It acts mainly by inhibiting prostaglandin synthesis in the centralnervoussystemandmodulatingthehypothalamicheat-regulatingcentertoreducefever.



Acetaminophen

Fig.1.2 Structure of Acetaminophen.

MolecularFormula: $C_8H_9NO_2$

MolecularWeight: 151.16g/mol

BCSClassification: ClassI(HighSolubilityandHighPermeability)

MECHANISMOFACTION

Acetaminophen is a widely used analgesic (pain reliever) and antipyretic (fever reducer). Unlike NSAIDs (like ibuprofen), it does not have significant anti-inflammatory effects. Its exact mechanism was unclear for a long time, but research has identified multiple pathways.

1. Inhibitionofcyclo-oxygenasepathway

- Acetaminophen inhibits cyclo-oxygenase (COX) enzymes (mainly COX-1 and COX2) in the central nervous system.
- COX enzymes are responsible for converting arachidonic acid into prostaglandins, which are chemical mediators of pain and fever.
- ThisinhibitionleadstoreducedsynthesisofprostaglandinsespeciallyPGE2inthebrain.
- Prostaglandins normally sensitize pain receptors, so their reduction results in analgesic (pain-relieving) effect.
- UnlikeNSAIDs,Acetaminophendoesnotsignificantlyinhibit COXinperipheraltissues, which explains:

➢ Minimalanti-inflammatoryaction
➢ Nogastricirritation
➢ Noplateletinhibition

2. AntipyreticAction(EffectonHypothalamus)

- Acetaminophenactsonthehypothalamicthermoregulatorycenter.
- Itreducesprostaglandin-mediatedelevationofthe hypothalamicset-pointduring fever.
- Thispromotesvasodilationandsweating,leading toareductioninbodytemperature.

3. MinimalAnti-InflammatoryActivity

- Inperipheralinflamedtissues,highperoxideconcentrationsinhibittheactionof acetaminophen on COX enzymes.
- Therefore,acetaminophenhasnegligibleanti-inflammatoryeffectscomparedto NSAIDs.

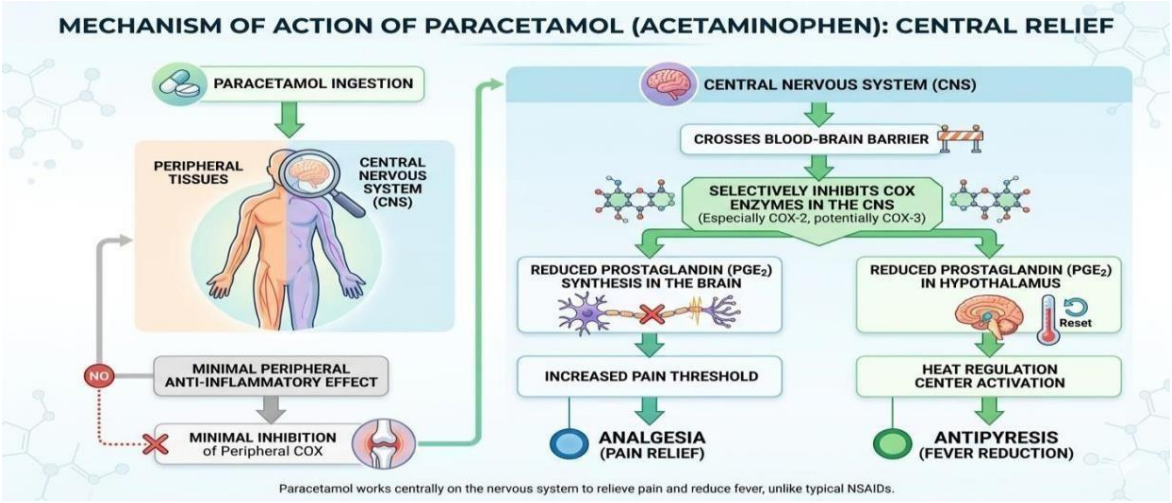


Fig.1.3 Mechanism of action.

PHARMACOKINETICS

1. Absorption

- Rapidandalmostcompleteabsorptionfromthegastrointestinal tract
- Peakplasmaconcentration:30–60 minutes

2. Distribution

- Widelydistributedinbodyfluids.
- Crossesplacentaandblood-brain barrier.

3. Metabolism

- Occursmainlyinliverby Glucuronidation(Majorpathway:60-70%).

4. Excretion

- Excretedmainlyinurineasconjugatedmetabolites.
- Eliminationhalf-lifeisabout 2–3 hours.

ADVERSEEFFECTS

- Nausea,vomiting
- Elevatedliver enzymes.
- Allergicreactions(Rashes,Urticaria).
- Hepatotoxicity
- Acuteliver failure

TOXICITY AND OVERDOSE

- **Mechanism:**Overdose→toxicmetaboliteNAPQIaccumulates→glutathionedepletion →hepaticnecrosis
- **Symptoms:**Earlynausea/vomiting;severecases →acuteliverfailure
- **Diagnosis:**Serumacetaminophenlevel+Rumack–Matthewnomogram
- **Antidote:**N-acetylcysteine(NAC)→Restoresglutathionelevelsandpreventsliverdamage.
- **RiskFactors:** Over dose, chronical coholuse, malnutrition, liver disease, enzyme inducing drugs.

THERAPEUTICUSES

1. Analgesic(Mildtomoderatepain)

- HeadacheandToothache
- Muscleand joint pain
- Post-operativepain

- Menstrualpain

2. Antipyretic(FeverReduction)

- Feverdueto infections
- Feverafter vaccination

3. AlternativetoNSAIDs

- WhenNSAIDsarecontraindicated(gastriculcer,bleedingrisk).

4. Adjuncttherapy

- Usedwithopioidstoenhancepainrelief andreduceopioiddose.

CONTRAINDICATIONS

- Allergytoacetaminophen
- Severeliverdiseaseor activehepatitis
- Chronicalcohol use(caution)
- Malnutritionorfasting(caution)
- Concurrenthepatotoxicdrugs(caution)
- Severekidney disease(usecarefully)

MARKETEDFORMULATIONSOFACETAMINOPHEN

1. Tablets

- Strengths:325mg,500mg, 650mg.
- Examples:Crocin,Dolo650,Tylenoltablets.

Fig1.4 AcetaminophenTablets.

2. Capsule

- Strength: 500mg.
- Examples:Panadol,Tylenol,Calpol.

Fig1.5 Acetaminophen Capsules.

3. Syrup

- Strength:120mg/mLand250mg/mL.
- Examples:Calpolsyrup,Crocinsyrup.

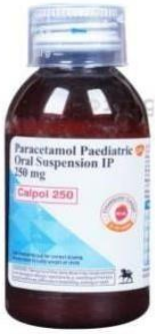


Fig1.6 Acetaminophen Syrup.

PRE FORMULATION STUDIES

Preformulationstudiesarethefirststepinthedevelopmentofapharmaceuticaldosageform.These studies provide information about the physicochemical properties of the drug substance and help in designing a stable, safe, and effective formulation.

OBJECTIVES OFPREFORMULATIONSTUDIES

- Todeterminesolubilityprofileinaqueousvehicles
- TostudypH-dependentstability
- Toevaluatecompatibilitywithsyrupexcipients
- Toassesschemicaldegradationinliquidmedium
- Todeterminepreservativecompatibility

PARAMETERSEVALUATED

1. OrganolepticProperties

The organoleptic properties are used for identification and checking of drug molecules

through moleculesthrougheyeexaminationmethod,tocompareitwithstandardsmentionedintheIP.For identification of sample drug color, odor and taste are observed. Color : Pure White Odor: OdorlessTaste:Slightlybitter

2. Bulk Characterization

- **Bulk density:** The bulk density of a powder is equal to the ratio of the mass of an untapped powdersampleanditsvolumeandexpressedingm/ml.Itismeasuredbypouringtheweighed sample powder/granules into the graduated cylinder using bulk density apparatus (no tapping is required), record the reading. and perform same procedure three times.

Db =M/Vo

Where,

Db = Bulk Density, M=Massofpowder,

Vo=Bulkvolumeofsamplepowder

- **Tapped density:**Todeterminethetappeddensity,agraduatedcylindercontainingtheweighed granulesorpowderistapped100timesusingabulkdensityapparatus.The minimumvolume (Vt) occupied in the cylinder and the weight (m) of the granules/powder are measured and recorded.

Where,

M=Massof powder,

V=Tappedvolumeofpowder

D=M/Vt

- **Angle of repose:** Itisthemaximumangleformedbetweentheheightofthepileofthepowder andthehorizontalplane.Tomeasuretheangleofrepose,thetestsampleisfilledintoafunnel tothebrim(topofthefunnel)andallowedtoflowdownwardontoapieceofgraph paper.The cone formed on the graph is taken to measure the surface area of pile by using height of pile and radius of pile.

Where,

θ=Angle of repose

$\theta = \tan^{-1}h/r$

h=heightofthepowderincm r = radius of heap of powder

Table2.1AcceptancecriteriaforAngleof Repose.

SL.NO	AngleofRepose(θ)	TypeofFlow
1.	<25	Excellent
2.	25-30	Good
3.	30-40	Fair/Passable
4.	>40	Verypoor

• **Carr's Index:**Also known as the Compressibility Index is a measure used in pharmaceutics to evaluate how easily a powder can be compressed.

$$Carr's\ Index = \frac{Tapped\ density - Bulk\ Density}{Tapped\ Density} \times 100$$

• **Hausner's Ratio:** The ratio of the tapped bulk density to the bulk density is known as the Hausner ratio. This ratio serves as a useful cohesiveness indicator since it represents particle friction.

$$Hausner's\ Ratio = \frac{Tapped\ density}{Bulk\ Density}$$

Table2.2AcceptancerequirementsforHausner'sratio&Carr'sindex.

Carr'sIndex	FlowCharacter	Hausner'sRatio
≤10	Excellent	1.00-1.11
≤11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	VeryPoor	1.46-1.59
>38	Extremelypoor	>1.60

f. Hygroscopicity

Hygroscopicity is the ability of a substance to absorb moisture from the atmosphere. Weigh acetaminophen, keep it in a desiccator for 24–48 hours, then reweigh and compare to check moisture absorption.Acetaminophen is non-hygroscopic in nature, it does not readily absorb moisture from the environment.

g.Polymorphism

Polymorphismistheabilityofadrugtoexistindifferentcrystallineforms.Acetaminophenhas Form I (stable) and Form II (metastable) Form II shows better compressibility than Form I.

3. Solubility

Itisthemaximumamountofasolute(solid,liquid,orgas)thatcandissolveinaspecific amount of solvent to form a stable, homogeneous solution at a given temperature and pressure.Add excess drug to 10 mLsolvent in conical flask. Shake for 24 hours at room temperature in a mechanical shaker.Filter through Whatman filter paper. Dilute filtrate suitably. Measure absorbance at 243 nm using UV spectrophotometer.

Result:FreelysolubleinHotwaterandethanoland~14mg/mLinWaterat25°C.

4. MeltingPoint

Themeltingpointisthetemperatureatwhichasolidsubstancechangesintoaliquidat atmospheric pressure.

Procedure:

- Takeasmallamountoffinelypowdereddrug.
- Fillitintoacapillarytubesealed atone end.
- Placethe capillarytube in amelting point apparatus.
- Heatslowly andobserve the sample.
- Recordthetemperatureatwhichitstartsandcompletelymelts. Result: The observed melting point should be around 169–170 °C.

5. pH Determination

pH is defined as the measure of acidity or alkalinity of a solution on a scale of 0 to 14, where 7 is neutral, values below 7 are acidic, and above 7 are basic.

Procedure:

- Preparea1%w/v solution ofthe acetaminophen in distilled water.
- CalibratethepHmeterwithstandardbuffersolutions.
- Diptheelectrodeintothe solution.
- RecordthepH afterthereadingstabilizes.

Result:ThepHisfound to beintherangeof 5.5– 6.5, indicatingaslightly acidicnature.

6. pKa pKaisthenegativelogarithmoftheaciddissociationconstant(Ka),indicatingthe strength of an acid and the pH at which a substance is 50% ionized and 50% unionized.

Procedure:UseapHmetertomeasurethepHofdrugsolutionsatdifferentconcentrationsand determine the pKa from the pH at half ionization.pKa of acetaminophen ≈ 9.5.

7. PartitionCoefficient(LogP)

Partition coefficient is defined as the ratio of unionized drug concentrations between the organic and aqueous phases, at equilibrium, where aqueous phase is water and organic phase is octanol.

Procedure:

- Prepareequalvolumesofn-octanolandwater.
- Addacetaminophen syrupto themixtureandshakewellfor24 hours.
- Allowlayerstoseparate(usuallyusingaseparatingfunnel).
- Measuredrug concentrationin eachlayer (UVat243nm or HPLC).
- CalculatelogPusingconcentrationvalues.

Result:LogP≈0.46(slightlylipophilic);drugremainsmostlyintheaqueous phase.

8. CompatibilityStudiesWithGellingAgents

Compatibility studies evaluate whether the drug interacts with gelling agents used in formulation.Gelling Agents: Carbopol, HPMC (Hydroxypropyl Methylcellulose), Sodium CMC.

Procedure:

- MixAcetaminophenwithselectedgellingagents.
- Storethe mixtureunder normal conditions.
- AnalyzeusingFTIRorobservephysical changes.

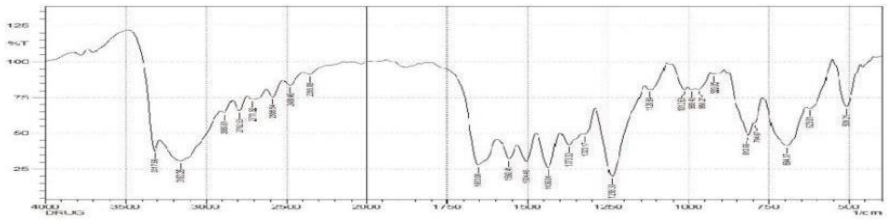


Fig2.1 FTIRSpectraofAcetaminophen.

MODULE-III

FORMULATIONOFACETAMINOPHENSYRUP

TYPICALFORMULA

Table3.1 Formulation of Acetaminophen Syrup.

INGREDIENTS	QUANTITY	PURPOSE
Paracetamol	2.4g	Activeingredient
Sucrose	40-60g	Sweeteningagent
Methylparaben	0.1g	Preservative
Propylparaben	0.02g	Preservative
Glycerin	5-10mL	Sweetener,viscosityenhancer
Sorbitolsolution (70%)	20mL	Sweetener,viscosityenhancer
Xanthangum	0.1-0.2g	Suspendingagent
Citricacid	0.05-0.1g	pH adjuster
Flavoring agent	q.s.	Improvestaste
Colorant	q.s.	Improvesappearance
PurifiedWater	Up to 100mL	Solvent

METHODOFPREPARATION

Step1:Dissolutionof Paracetamol

Heatabout60-70%oftherequiredpurifiedwaterto60-70°C.Dissolveparacetamolintheheated water while stirring continuously.This may take time since paracetamol has limited solubility in water. Heating helps enhance solubility.

Step2:PreparationofSweeteningSolution

Inaseparatecontainer,dissolvesucroseinsomepurifiedwater.Addglycerinandsorbitolsolution to the sugar solution while stirring to ensure complete dissolution.

Step3:AdditionofPreservatives

Dissolvemethylparabenandpropylparabeninasmallamountofwarmwater.Addthissolutionto the paracetamol solution with continuous stirring.

Step4:SuspendingAgent

Preparea slurry of xanthan gum with a small amount of water.Add this slurry to the paracetamol solution to improve the suspension properties and viscosity of the syrup.

Step5:AdjustmentofpH

Addcitricacid to thesolution to adjustthepH.Thedesired pHshould bearound4–5 forstability and palatability.

Step6:Flavoringand Coloring

Addflavoringagentand coloranttoenhancetaste andappearance.

Step7:MakeUptheVolume

Addtheremaining amountof purified water tomakeup thevolume to 100mL.

Step8:Filtrationand Packaging

Filterthesolutiontoremoveanyparticulatematter.Fillthesyrupintoclean,amber-coloredbottles to protect the solution from light. Seal the bottles tightly and label them with the appropriate dosage instructions.

EQUIPMENTSREQUIRED

Table3.2 Equipments Required.

Sl. No.	EQUIPMENT	FUNCTION
1.	WeighingBalance	Measuresrawmaterial
2.	SSMixing Tank	Dissolvesandmixes ingredient
3.	Homogenizer	Ensuresuniform mixing
4.	FilterPress	Removesimpurities
5.	SSStorageTank	Storesfinishedsyrupbetween units
6.	TransferPump	Transferssyrupbetween units
7.	BottleWashingMachine	Cleansbottlesbeforefilling
8.	LiquidFillingMachine	Fillssyrupintobottlessyrup
9.	CappingMachine	Sealsbottles
10.	LabelingMachine	Applieslabelsto bottles

Fig3.1 Syrup Manufacturing Equipments.

EVALUATIONOFACETAMINOPHENSYRUP

1. OrganolepticEvaluation

Syrup is examined visually and by sensory evaluation for color, taste, appearance, clarity and odour. Should be clear, uniformly colored, pleasant in taste and oduor, and free from visible particles.

2. pH Examination

The pH ofAcetaminophen syrup was measured using a calibrated pH meter.About 20 mLof the syrup sample was taken in a clean beaker, and the pH electrode was immersed after calibrationwithstandardbuffersolutions.Thereadingwasrecordedafterstabilizationatroom temperature (25°C). The pH was found to be within the acceptable range of 4.0–6.5.

3. Density Examination

Weighanempty,completelydryspecificgravitybottleusingananalyticalbalance.Recordthis massasW1.Fillthebottlewithdistilledwater,placethestopper,wipeoffanyexcessliquidon theoutsidewithtissuepaper,andweighit.RecordthisasW2.Emptyanddrythebottle.Fillit entirely with your syrup, cap it, wipe off the excess, and weigh it. Record this as W3.

The acceptable density range of Acetaminophen syrup is typically 1.15–1.30 g/mL at room temperature, depending on the formulation.

4. ViscosityExamination

Usedacetoneorothersuitableorganicsolventtothoroughlycleantheostwaldviscometer.Set the viscometer on a suitable stand in a vertical position. Filled the dry viscometer with water to the G mark. The time it took for water to flow from pointA to mark B was measured in seconds.To get an accurate reading, this step was repeated at least three times.After cleaning the viscometer with a sample liquid and filling it to markA, notice how long it takes for the liquid to reach mark B. The acceptable viscosity range is typically 50–150 cP, depending on the formulation.

$$\text{Viscosity} = \frac{\textit{Density of the test liquid} \times \textit{Time required to flow test liquid}}{\textit{Density of water} \times \textit{Time required to flow water}} \times 100$$

5. DeterminationOfSucroseConcentration

Concentration ofsucrose isvery important in syrup becausehigh amount of sucrosein syrup maycausecrystallizationofsyrupwhilelowamountmaycauselossofpreservativeproperty ofsyrup.Theconcentrationofsucroseinsyrupis determinedusinganalyticaltoolsHPLCor U-V

spectrophotometer. Sucrose concentration in acetaminophen syrup: ~66.7% w/v (≈ 67 g/100 mL).

6. ClarityTest

Itisperformedtocheckwhetherthesyrupisclearandfreefromsuspendedparticles,crystals, orturbidity.Asampleofsyrupisplacedinaclearglasscontainerandobservedagainstablack and white background under proper light. A good-quality syrup should appear clear, transparent, and free from any visible impurities.

7. MicrobialTest

Itisperformedtodeterminethepresence ofmicroorganismsinthesyrup.Ameasured sample ofsyrupisdilutedwithsterilewaterandinoculatedontosuitableculturemedia.Theplatesare incubatedatappropriatetemperatures,andthenumberofmicrobialcoloniesformediscounted. Limits:Totalaerobicmicrobialcountshouldgenerallynotexceed10^2CFU/ml,totalyeastand mold count should not exceed 10^1 CFU/ml.

8. StabilityTesting

Thesynthesizedsyrup underwent stability testing whilesampleswerekept under.accelerated temperature conditions. Culture tubes were used to receive the finished syrup.

Table4.1 Stability Testing Conditions for Syrup.

Study Condition	Temperature	Humidity	Duration	Purpose
Long term stability	25°C ± 2°C	60%RH±5%	12monthsor more	Normal storage condition
Accelerated stability	40°C ± 2°C	75%RH± 5%	3-6months	Predictshelflife quickly

PACKAGING

- Primarypackaging (Bottle)
  - Amber-colouredglassorplasticbottle(protectsfrom light).
  - Child-resistantcap.
  - Labelwithdrugname,strength (e.g.,100mg/5mL),dosage, warnings.
- Secondarypackaging (Carton/Box):
  - Printedcartoncontaining:
  - Brand/drug name.
  - Composition.
  - Directionsfor use.
  - Storageconditions.
  - Manufacturerdetails.

- Additionalfeatures
  - Measuringcuporspoon(foraccuratedosing).

Fig4.1 Packaging of Acetaminophen Syrup.

LABELLINGREQUIREMENTS

The label should include the name of the medication, strength, dosage instructions, storage instructions,nameandaddress ofmanufacturerandexpiry,precaution,caution,directionforuse, etc.

Fig4.2 Labeling of Acetaminophen Syrup.

STORAGE

Storethesyrupatroomtemperaturebetween20–25°Cinacoolanddryplace,protectedfromlight. Do not freeze the product, and always keep the bottle tightly closed to maintain its stability and effectiveness.

CONCLUSION

The formulation and evaluation ofAcetaminophen syrup proved to be a successful approach

in developing an effective oral liquid dosage form for pain and fever management. Compared to solid dosage forms, syrup offers better patient compliance, especially for pediatric and geriatric patients, due to ease of administration and improved palatability.

Preformulation studies confirmed the physicochemical suitability ofAcetaminophen for syrup formulation,highlightingitssolubility,stability,andcompatibilitywithselectedexcipients.The syrup was formulated using suitable sweetening agents, preservatives, flavoring agents, and stabilizers to ensure quality, safety, and effectiveness.

Evaluation parameters such as appearance, pH, viscosity, drug content, and stability confirmedthequalityandperformanceofthepreparedsyrup.Theformulationshowedsatisfactoryre sults, good stability, and acceptable organoleptic properties, indicating its suitability for therapeutic use.

In summary, Acetaminophen syrup is a safe, stable, and effective formulation that provides convenientadministrationandreliabletherapeuticaction,makingitasuitablechoiceforroutine clinical use.

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