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DESIGNANDEVALUATIONOF HYDROXYZINE SYRUP

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ABSTRACT

Hydroxyzine is a first-generation antihistamine widely used for the treatment of anxiety, allergic conditions, pruritus, and nausea. The syrup was prepare dusing suitable excipients such as sweetening agents, preservatives, flavoring agents, and viscosity enhancers. Preformulation studies including organoleptic properties, solubility, partition coefficient, melting point, compatibility study, pH determination, and stability testing were carried out to ensure drug suitability for syrup formulation. The formulated syrup was further evaluated for organoleptic characteristics, physicochemical parameters, microbial quality, stability, and pourability. The study concludes that Hydroxyzine syrup can be successfully formulated as a stable and effective oral liquid preparation.

INTRODUCTION

Anxiety disorders are a group of mental health conditions characterized by excessive fear, worry,andnervousnessthatinterferewithdailyactivities.Theyareamongthemostcommon psychiatric disorders worldwide, affecting quality of life, work productivity, and social functioning.Anxiety disorders happen when excessive anxiety interferes with your everyday activities such as going to work or school or spending time with friends or family. Anxiety disorders are serious mental illnesses. They are the most common mental disorders. Anxiety disorders are more than twice as common in women as in men.

Syrups are oral liquid dosage forms containing medicinal substances dissolved in a concentratedsugarsolutionorsugarsubstitute.Syrupformulationsareespeciallybeneficial for pediatric and geriatric patients who have difficulty swallowing tablets or capsules. The present work aims to formulate and evaluate Hydroxyzine syrup with acceptable stability,

palatability, and effectiveness.

Types of Anxiety Disorders

1.GeneralizedAnxietyDisorder(GAD)

Excessive anxiety and worry about a number of events or activities occurring for more days thannotoveraperiodofatleast6monthswithassociatedsymptoms(suchasfatigueandpoor concentration.

2.SpecificPhobia Markedandpersistentfearofclearlydiscernibleobjectsorsituations (such as flying, heights a

3.PostTraumaticStressDisorder

Flashbacks,persistentfrighteningthoughtsandmemories,angerorirritabilityinresponsetoa terrifying experience in which physical harm occurred or was threatened (such as rape, child abuse, war or natural disaster).

4.SocialPhobia,alsoknownasSocialAnxiety Disorder

Exposure to social or performance situations almost invariably provokes an immediate anxietyresponsethatmayincludepalpitations,tremors,sweating,gastrointestinaldiscomfort lead to panical attack.

5Obsessive-CompulsiveDisorder

Obsessions:

Persistentthoughts,ideas,impulsesorimagesthatareintrusiveandin appropriate and that cause marked anxiety or distress.

6. Panic disorder

Presenceofrecurrent,unexpectedpanicattacks,followedbyatleast1monthofpersistent concern about having additional attacks, worry about the implication of the attack or its consequences, or a significant change in behaviour related to the attacks.

SymptomsofAnxiety

- Excessiveworrying
- Restlessness
- Rapidheartbeat
- Sweating
- Trembling
- Difficulty concentrating
- Insomnia

- Irritability

Anxiolytics

Anxiolyticsaredrugsusedtoreduceanxietyandpromotecalmness.Thesedrugsactonthe central nervous system and help in controlling anxiety-related symptoms.

ClassificationofAnxiolytic

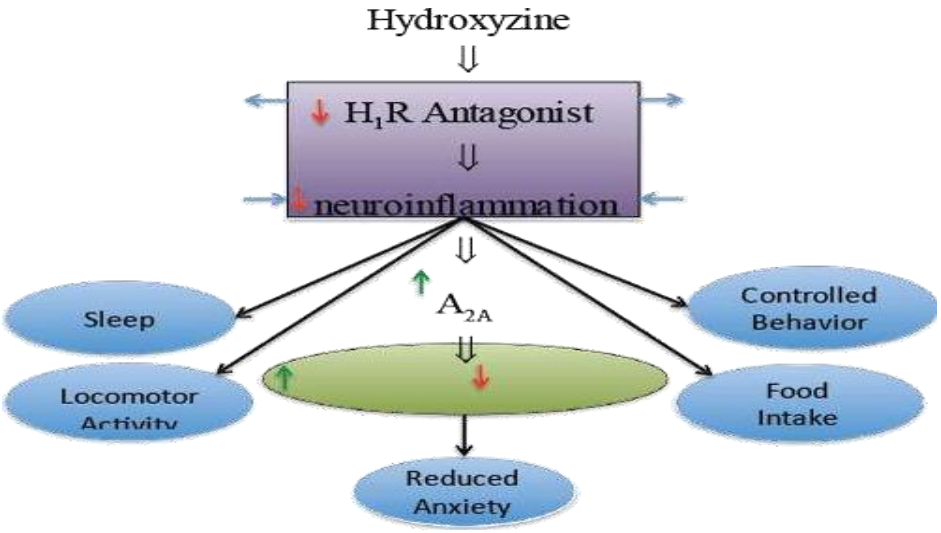
1. Benzodiazepines
2. Barbiturates
3. Antidepressants
4. Antihistamines
5. Beta-blockers

HydroxyzineasanAntihistamine

Hydroxyzineisafirst-generationantihistaminewithanxiolytic,sedative,antiemetic,and antipruritic properties. It is available in tablet, capsule, and syrup dosage forms.

Mechanismof Action

HydroxyzineactsbyblockinghistamineH1receptorsandsuppressingsubcorticalactivityin the central nervous system. This action produces sedative and anxiolytic effects.



AdverseReactions

- Drowsiness
- Dry mouth
- Dizziness

- Headache
- Fatigue
- Blurredvision
- **USES**

1. Short-termtreatmentofanxiety
2. Acuteanxietyandagitation
3. Pre-operativeanxiety(Premedication)
4. associatedwithinsomnia
5. Alternativetobenzodiazepines
6. Anxietywithallergicconditions.

MARKETEDFORMULATIONOFHYDROXYZINE

Hydroxyzineismarketed indifferentformulationstosuit variousroutesof administrationand patient needs. The two main salt forms available are hydroxyzine hydrochloride and hydroxyzine pamoate, which differ in pharmacokinetic properties and clinical use.

PREFORMULATIONSTUDIESOFHYDROXYZINESYRUP:

Preformulation studies are the first step in dosage-form development. They evaluate the physicochemicalandbiopharmaceuticalpropertiesofadrugtodesignastable,safe,and effective formulation.

1. SolubilityStudies

Solubilitystudiesareperformedtodeterminetheextenttowhichadrugdissolvesin various solvents and to select a suitable solvent system for formulation.

2. Partition2.Coefficient(LogP)

Partition coefficient is defined as the ratio of concentrations of an un-ionized drug distributedbetweentwoimmisciblesolvents,usuallyn-octanol(oilphase)andwater (aqueous phase), at equilibrium and constant temperature.

3. StabilityStudies

Stabilitystudiesarethestudiescarriedouttodeterminethephysical,chemical,andmicrobial stability of a drug or formulation under different storage conditions.

4. CompatibilityStudies

Compatibility studies are preformulation investigations carried out to evaluate possible interactionsbetweenthedrugandexcipients,additives,orcontainermaterialstoensure stability,

safety, and efficacy of the final dosage form

5. PHDETERMINATION:

MaintainedbetweenpH 3.5–5.5

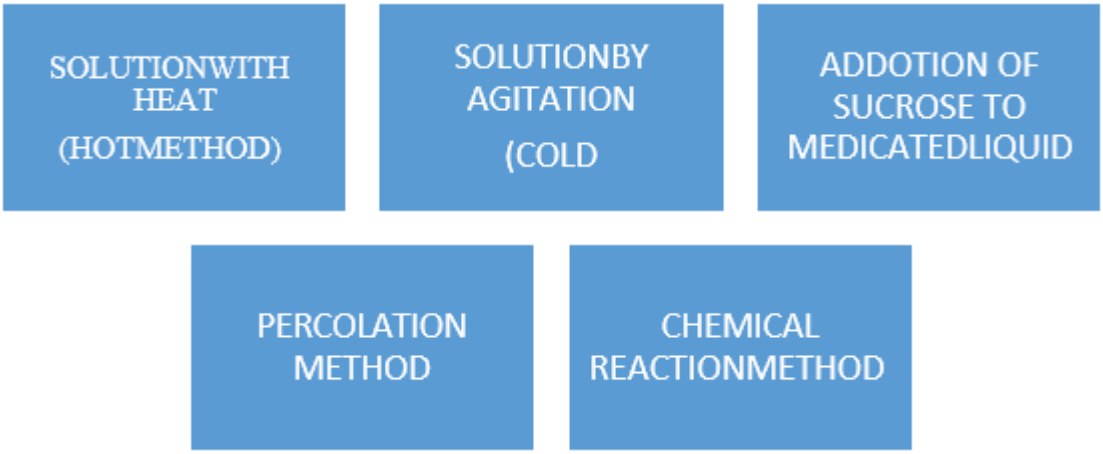
6. IDENTIFICATIONTESTS:

- UV spectroscopy
- FTIRspectrum
- Meltingpoint

FORMULATIONOFHYDROXYZINESYRUP

Formulationistheprocessofcombiningdifferentingredientsinspecificproportionsto produce a final product with desired properties such as effectiveness, stability, and acceptability.

GENERALFORMULATIONMETHODOFSYRUP.



TYPICALCOMPOSITION

HYDROXYZINEHCL	**AS PRESCRIBED**
SUCROSE	60-65%
PURIFIEDWATER	qs
FLAVOURING AGENT	qs
COLORINGAGENT	qs
PRESERVATIVE	SMALLQAUNTITY

SPECEFICMETHODFORHYDROXYZINESYRUPFORMULATION:

HydroxyzineHCLwasaccuratelyweighedanddissolvedinsmallquantityofpurifiedwater. Preservative ,sweetening agent,coloring agent was added separately.The final volume was adjusted with syrup base and mixed thoroughly to get a homogenous syrup **EVALUATION**

Hydroxyzinesyrupisan oralliquiddosageformcontainghydroxyzinehydrochloride,a first-generationantihistamineusedforallergy,pruritus,anxiety,andsedation.Itisevaluated to

ensure quality, safety, efficacy, and compliance with pharmacopoeial standards (USP/IP/BP).

EvaluationTestsforHydroxyzineSyrup

1.OrganolepticTests

Color,odour,tasteandappearancewereevaluated.

PhysicochemicalTests

ParameterssuchaspH,viscosity,anddensityweredetermined.

ChemicalTests

Drugcontentandassay wereperformedtoensureuniformity.

PhysicalStabilityTest

Theformulationwascheckedforprecipitation,crystalformation,andcolor change.

MicrobialTest

Microbialcontaminationstudieswereconducted toensure safety.

StabilityStudies

Thesyrupwasstored underdifferentenvironmental conditionstoevaluatestability.

PourabilityTest

Theflowpropertyand easeof pouringwere evaluated.

LABELLING

Labeldetails:

- Drug name
- Strength
- Storageconditions
- Expirydate

PACKAGING

Syrupsarepackedinwell-closedcontainerstoprotectthemfromcontamination,moisture,light,and microbial growth. Proper packaging also helps maintain the stability, taste, and effectiveness of the preparation

IdealRequirementsofSyrupPackaging

- Shouldbechemicallyinertandnon-reactive
- Mustprovideairtightsealing
- Shouldprotectfromlightand moisture
- Easytohandle,transport,anddispense

STORAGE

Syrupsshouldbestoredundersuitableconditionstomaintaintheirstability,quality,and effectiveness.

Storage Conditions

- Storein a **cool anddryplace**
- Protectfrom **directsunlightandexcessiveheat**
- Keepthecontainer **tightlyclosed**
- Storeat **roomtemperature(usuallybelow 25°C)**

CONCLUSION

The design and evaluation of Hydroxyzine syrup was carried out successfully by considering suitable pharmaceuticalformulationprinciples andevaluation parameters. Hydroxyzine,anantihistamine with anxiolytic activity, is widely used in the management of anxiety and allergic conditions. The formulationwaspreparedusingappropriateexcipientstoachieveacceptablestability,palatability,and therapeutic effectiveness.

Various preformulation studies such as organoleptic properties, solubility, partition coefficient, melting point, pH determination, compatibility studies, and stability studies confirmed the suitability ofthedrugforsyrupformulation.Thepreparedsyrupwasfurtherevaluatedthroughphysicochemical, chemical, microbial, and stability tests, and the results were found to be within acceptable limits.

Overall, the formulated Hydroxyzine syrup showed good appearance, stability, pourability, and safety,indicatingthatitisaneffectiveandpatient-friendlyliquiddosageform.Properpackaging, labeling, and storage conditions also contribute to maintaining the quality and efficacy of the formulation.