Seminar on

Recent Advances in Formulation aspects And Manufacturing Of Monophasic Dosage Forms

By

Shilpa . Allabotharam

M pharm (I sem)

Department of pharmaceutics

Blue Birds College Of Pharmacy

Kakatiya University

Bheemaram , Warangal.

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INTRODUCTION

Monophasic dosage forms refers to liquid preparations in which there is only one phase, it is represented by true solution.

Classification

1) Liquids meant for internal administration

Eg: Syrups, Mixtures, Elixirs

2) Liquids meant for external administration

- Liquids applied to the skin eg: Lotions, Liniments
- Liquids used in mouth eg: Gargles, Mouthwashes , throat paints
- Liquids instilled in to body cavities eg: Douches, Eye drops, Nasal drops

LIQUIDS MEANT FOR INTERNAL ADMINISTRATION

Syrups

Concentrated or nearly saturated solutions of sucrose in purified water

1) **Flavoured Syrups**

Orange Syrup	**Sucrose based syrup** **For drugs stable in acidic medium**
Cherry Syrup	Sucrose based syrup For drugs stable in acidic medium

Medicated Syrups

SYRUP	COMMERCIAL PRODUCT	USE
Antiviral Amantadine Hcl Lamivudine	 Symmetrel Syrup Epiviral Oral Solution	 Respiratory tract infections HIV Treatment
Analgesic Meperidine Hcl	 Dimerol Solution	 Opiod analgesic

Formulation

1. Vehicles
2. Adjuncts

a) Chemical stabilizers- Glycerine, Sorbital

b) Colouring agents- Amaranth, Tartrazine

C)Flavouring agents

Tinctures- tincture of lemon, ginger

Fruit juices- Wild cherry

Essence- Vanilla, Orange

d) Preservatives- benzoic acid(0.1-0.2%)

e) Artificial sweeteners

Preparation of Syrups

Methods

1. Solution with the aid of heat
2. Solution by agitation without aid of heat
3. Addition of sucrose to a prepared medicated liquid
4. Percolation

The Recent Approach in formulation of Syrup

- Preparing palatable tasting cough syrup containing noscapine

Present invention involves formulation of noscaoine to obtain a liquid suspension

METHOD:

1. Preparing an aqueous liquid syrup type carrier solution &buffer to maintain the P^H of 7at all times.
2. Mixing alkaloid noscapine with the liquid carrier to form a fine suspension
3. Aqueous liquid carrier comprises sucrose, sorbitol, a preservative, CMC , glycerin and suspending agent

ELIXIRS

Clear sweetened hydroalcholic liquids intended for oral administation

Medicated Elixirs

Butabarbital	**Butisol sodium elixir**	**Sedative Hypnotic**
Dexamethasone	Dexamethasone elixir	Allergies RA

Nonmedicated Elixirs

Eg: Aromatic elixir, compound benzaldehyde elixir

FORMULATION

- Drug
- Water
- Solvent- Glycerine, Sorbital
- Sweetening agents- Sucrose
- Colour- Amaranth
- Flavouring agents- Orange Syrup, Lemon Syrup
- Preservatives- Methyl paraben, Propyl paraben
- Chemical stabilizers- Citric acid, EDTA

LIQUIDS FOR EXTERNAL APPLICATION

1) Liquids to be applied to skin

a. Liniments : liquid or semiliquid preparations meant for application to skin

- Alcholic liniments
- Oily liniments- Salicylate liniment
- Emulsion liniment- Turpentine liniment

b. Lotions : liquid preparation meant for external application with out friction

eg: Calamine lotion

Lead lotion

2) Liquids to be used in the mouth

a) Gargles- Aqueous solutions used to prevent or to treat throat infection

eg: potassium chlorate, Phenol gargle.

b) Mouthwashes- aqueous solutions with a pleasant taste and odour used to make clean , deodorize buccal cavity

Formulation:

Antiseptics-phenol derivatives, Quaternary Ammoniu compounds

Astringents-Zinc Chloride, Zinc Acetate

Deodorizing Agents- Chlorophyllin, Quaternary Ammonium compounds

Drug Extracts- Tincture of Myrrh

Tincture of Cinchona

Flavours - Peppermint oil , cinnamon oil

Surfactants - Tween 80

Sweetners - Saccharine

Colours - Saffron, Carmine

Vehicle - Alcohol, water

Prepartion of Aqueous flavoured mouth wash composition

This invention involves preparing visually clear, stable aqueous citrus flavoured mouth wash which reduces flammability hazards associated with mixing volatile alcohols

Formulation

Citrusflavor oil	-	0.01-0.5%
Emulsifier	-	0.1-2.0%
Alcohol	-	1-25%
Purified water	-	60-95%

c) Throat paints

These are viscous liquid preparations used for mouth and throat infections

Eg: Boro glycerine, Phenol glycerine, Compound Iodine paint

3) Liquids to be instilled in to body cavities

a) Douches- medicated solutions intended for rinsing body cavity

- Cleansingagent - isotoni sodiumchloride solution
- Antiseptics - mercuric chloride(0.001%)
  potassium permanganate(0.025%)
  Lactic acid(0.5-2%)
- Astringent - Alum(1%)

b) Eardrops

These are solutions of drops that are instilled into the ear with a dropper.

Contains- water, glycerine, propylene glycol

Used for cleaning the ear, softening the wax, treating mild infections.

Eg: soda glycerine

c) Nasal drops- aqueous solutions of drops that are instilled into nose with a dropper

Vehicle- oil or water

Should be isotonic with 0.9%NaCl

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Viscosity similar to nasal secretion

1) Isotonicity : Sodium chloride

2) Viscosity : Methylcellulose

CMC

3) P^H : Phosphate buffer

Acetate buffer

Beclomethasone dipropionate nasal drops

Formulation:

Beclomethasone dipropionate anhydrate	0.025-0.25%
Avicel RC	59 1-5%
Glycerol	0.1-6%
Propylene glycol	1.5-1.0%
Polyoxyethylene	0.007%
Purified water	QS

d)Eye drops

These are small volume sterile liquids designed to be instilled on to the eye ball or with in the conjunctival sac

Opthalmic formulation comprising a beta blocker and carbopol

The present invention relates the manufacturing of beta blocker which improves its I.O.P lowering effect

- Formulation:

Timolol - 0.5%

Timolol maleate - 0.72gm

Benzylconium chloride-0.72gm

Carbopol - 2.0gm

Sodium hydroxide- p^H 6.5-7.5

water for injection - 100ml

Formulation problems of liquid dosage forms

- Stability
- Sterility
- Organoleptic Qualities
- Viscosity
- Tonicity
- Specific gravity

Manufacturing Considerations and Equipment

Raw materials used in mfg liquid should have some specifications such as identity, purity, uniformity, and freedom from excessive microbial contamination

Equipment :

- Mixing tanks
- Measuring devices
- Filtration systems for sterilization

Conclusion

The possibility of simplifying complex process

Leading to new formulations or their optimisation

will depend on the avilability of basic needs related to ingredient combination, which will be gained by

Investigating ingredient properties

Understanding the effect of ingredients on product properties

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THANK YOU