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A Review: A Simple Guide to Quality Control for Liquid Dosage Form

Shubham Hundekari, * Sarfaraz M. Kazi, Sanjay K. Bais
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India
*Corresponding Author: hundekarishubham52@gmail.com

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Abstract

Pharmaceutical liquid dosage forms are solutions intended for oral consumption, topical application, or intravenous administration. These formulations consist of a blend of active pharmaceutical ingredients and excipients, offering rapid onset of action and optimal therapeutic outcomes for specific patient groups. Thus, they are vital for the treatment and management of a range of medical conditions across the world. Even though the global population is aging and more patients are experiencing difficulties with swallowing, there remains a lack of commercially available oral liquid medications for both elderly and pediatric patients. The pharmaceutical industry has made extensive use of liquid dosage forms; these applications range from oral preparation and injection through the vaginal, optic, nasal, and rectal formulations. This chapter describes the various kinds of their distinct components and discussing their primary characteristic. A succinct summary of the most common ways to get ready has been incorporated, in addition to the vital physical characteristics that must be taken into account when creating them. In particular, emphasis has been provided to their implementation via several administration channels. This guide provides an overview of quality control (QC) processes essential for ensuring the safety, efficacy, and consistency of liquid dosage forms in pharmaceuticals. It outlines critical aspects such as raw material selection, formulation development, manufacturing practices, and testing methods.

Keywords - Solubility, Excipients, Suspension, Emulsion, Ointments, Liquid dosage, Bioavailability, Internal use, External use etc.

INTRODUCTION

Liquid dosage forms are a vital category of pharmaceuticals designed for the administration of medications in a liquid state. They are particularly beneficial for patients who have difficulty swallowing solid forms, such as tablets and capsules. This includes young children, the elderly, and individuals with certain medical conditions.[1] Liquid dosage forms come in various types, including solutions, suspensions, and emulsions, each offering unique characteristics and benefits.[2] these forms can facilitate easier dosing, faster absorption, and improved bioavailability of the active ingredients. Additionally, they can enhance patient compliance due to their ease of use and the ability to flavor them for better palatability.[3] Despite their advantages, the development of liquid dosage forms presents challenges, such as maintaining stability, ensuring accurate dosing, and managing solubility issues. The use of excipients, strategies for enhancing solubility, and appropriate mixing techniques play critical roles in the formulation of effective liquid medications. The demand for innovative and accessible liquid dosage forms remains crucial

in modern healthcare.[4]

Classification of liquid dosage forms

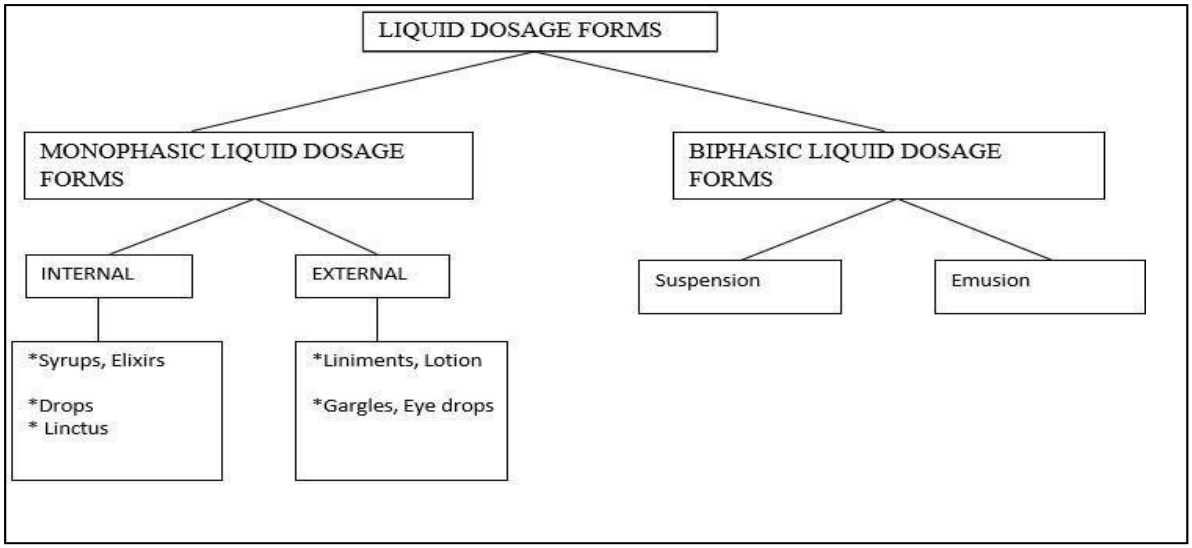

***Figure 1*:** *Liquid Dosage Form*

Solutions

Solutions are clear, homogeneous mixtures where a solute is fully dissolved in a solvent. In pharmaceutical contexts, they are often used to deliver medications in liquid form.

Types of Solutions

Aqueous Solutions

Use water as the solvent. Common for oral, injectable, and topical preparations.

Non-Aqueous Solutions

Use solvents other than water, such as alcohol or oils. Often used for drugs that are poorly soluble in water.

Syrup

Syrups are concentrated solutions of sugar (usually sucrose) in water, often containing medicinal ingredients. They are thick, sweet liquids used to mask the taste of unpleasant medications and facilitate easy administration, especially for children.[5]

Key Features

Composition

Sugar

Typically contains a high concentration of sugar, which acts as a preservative by inhibiting microbial growth.

Water

Serves as the solvent.

Active Ingredients

May include various medications, vitamins, or herbal extracts.

Flavouring Agents

Often added to improve palatability.

Types of Syrups

Simple Syrups

Made with sugar and water, without medicinal properties.

Medicinal Syrups

Formulated with active pharmaceutical ingredients (APIs) for therapeutic use.[6]

Elixirs

Elixirs are clear, sweetened hydro alcoholic solutions used for the oral administration of medications. They contain both water and alcohol as solvents, which helps to dissolve active ingredients that may be insoluble in water alone.

Key Features

Composition

Solvents

Typically composed of a mixture of alcohol (usually ethanol) and water, which enhances solubility for certain active ingredients.

Sweeteners

Often contain sugar or sugar substitutes to improve taste.

Active Ingredients

Can include various medicinal compounds, vitamins, or herbal extracts.

Flavouring Agents

Added to mask the taste of the medication and enhance palatability.[7]

Eye Drops

Eye drops are ocular formulations that administer medications in liquid form., typically at a concentration of 5%. They are designed for administration directly into the eye to treat various conditions, providing localized effects and facilitating absorption through the ocular tissues.[8]

Linctus

Linctus is a type of thick syrups liquid formulation used primarily for the treatment of coughs and throat irritations. It is designed to coat the mucous membranes of the throat, providing soothing relief.[9]

Gargles

A gargle is a liquid preparation intended for use in the oral cavity and throat. It is designed to be swished around in the mouth and throat before being expelled, providing therapeutic effects, particularly for soothing sore throats and maintaining oral hygiene.[10]

Lotions

Lotions are liquid or semi-liquid preparations designed for topical application to the skin. They are typically formulated to hydrate, soothe, and protect the skin. Dermatologists prescribe lotions containing antiseptic, antibacterial, antifungal, moisturizing and protective agents to treat or prevent various skin conditions. [11]

Liniment

These formulations contain ingredients with properties such as analgesic, relaxing, or stimulating effects. Liniments are intended for external use only and should not be applied to broken skin.[12]

Biphasic Liquid Dosage Form

Biphasic liquid dosage forms consist of two distinct phases, such as suspensions and emulsions. Typically, both phases are liquid; in the case of suspensions, small solid particles are dispersed within a liquid that serves as the continuous phase.

Suspensions

A suspension is a biphasic liquid dosage form where finely divided solid particles are distributed throughout a liquid medium, which acts as the continuous phase. These particles do not dissolve but remain suspended, necessitating agitation before use to ensure uniformity.[13]

Key Characteristics

Composition

Active Ingredients

The solid particles are usually the active pharmaceutical ingredients (APIs) intended for delivery.

Dispersion Medium

Typically, a liquid (often water or oil) that helps disperse the solid particles.

Excipients

These may include stabilizers, suspending agents, preservatives, and flavouring agents to improve stability, safety, and taste.[14]

Types of Suspensions

Oral Suspensions: Taken by mouth, these are commonly used for patients who have difficulty swallowing tablets or capsules.

Topical Suspensions

Applied to the skin for localized treatment.

Injectable Suspensions

Designed for intramuscular or subcutaneous injections where a prolonged drug release is desired.

Oral Suspensions

These formulations are intended for oral use and contain un dissolved particles along with active ingredients suspended in sweetened, flavoured, or viscous bases, often used to treat oral fungal infections. They offer flexibility in dosing and are cost-effective for patients needing dose adjustments. However, many pharmaceutical drugs are not available in suspension form. These suspensions require a dispersion medium and suspending agents to ensure even particle distribution and prevent clumping.

Advantages of oral suspensions

They should taste pleasant and be stable.

They must be free from gritty particles.

The suspended particles should not settle rapidly.[15]

Parenteral Suspensions

A parenteral suspension is an injectable formulation containing solid particles dispersed in a liquid medium, meant for administration via routes other than the digestive tract, such as intramuscular (IM) or subcutaneous (SC) injections.

Ideal characteristics of parenteral suspensions

The viscosity should allow for smooth injection.

The product must remain sterile during use and storage.

Dispersed particles should not settle quickly after shaking.

No cake formation should occur during the product's shelf life.

The appearance should remain visually appealing throughout its shelf life.

The suspensions should be non-irritating and isotonic.

Advantages of parenteral suspensions

They are used therapeutically and are insoluble in standard solvents.

These formulations are more resistant to hydrolysis.

Parenteral suspensions allow for controlled release of the medication.

Disadvantages of parenteral suspensions

Formulating these suspensions can be difficult, as selecting the appropriate suspending agents, viscosity modifiers, wetting agents, stabilizers, and preservatives is complex.

Maintaining physical stability in these formulations is particularly challenging.

The dose may not be uniform at the time of administration.

Factors influencing medication release from parenteral suspensions

Injectable suspension formulations rely on the solubility of the medication in biological fluids at the injection site.

Due to viscosity constraints, these suspensions are often diluted to enhance injectability and syringe ability.

The pKa of the medication and the rate at which the solid components dissolve from the dosage form also play a crucial role.[16]

Topical Suspensions

A topical suspension is a liquid formulation containing solid particles dispersed in a liquid medium, intended for application to the skin or mucous membranes. These suspensions are designed to provide localized therapeutic effects. [17]

Topical Drug Delivery

A topical drug delivery system is aimed at localized treatment, enabling the direct application of therapeutic agents to the skin to treat dermatological issues. These suspensions are often used for skin infections and are specifically designed to ensure that the medication acts effectively at the site of application. [18]

Emulsions

An emulsion is a biphasic liquid preparation that consists of two immiscible liquids, where one liquid is dispersed as small globules within the other. The liquid that forms these tiny globules is referred to as the disperse phase, while the liquid that suspends them is known as the continuous phase. Since two immiscible liquids typically do not remain mixed for long, an emulsifying agent is added. This agent creates a protective film around the globules, allowing them to stay evenly dispersed in the continuous phase and resulting in a stable emulsion.

Types of Emulsions

Emulsions are mixtures of two immiscible liquids, usually oil and water, stabilized by emulsifying agents. They can be classified based on which phase is continuous and which is dispersed.[19]

The main types of emulsions

Oil-in-Water (O/W) Emulsion

Description

In this type, oil droplets are dispersed within a continuous water phase.

Characteristics

O/W emulsions are typically lighter and less viscous, making them ideal for products like lotions, creams, and certain food items (e.g., mayonnaise).

Example

Milk and various cosmetic creams.

Water-in-Oil (W/O) Emulsion

Description

Here, water droplets are dispersed in a continuous oil phase.

Characteristics

W/O emulsions tend to be thicker and greasier, providing a more occlusive barrier on the skin, which is advantageous for treating dry skin.

Example

Butter and certain ointments.

Multiple Emulsions

Description

These emulsions contain droplets of one emulsion type dispersed within another. They can be

either O/W/O or W/O/W.

Characteristics

Multiple emulsions can provide sustained release of active ingredients and are used in specialized formulations.

Example

Some pharmaceutical formulations and advanced cosmetic products. [20]

Micro emulsions

Description

These are thermodynamically stable mixtures of oil, water, and surfactant that form spontaneously and have very small droplet sizes (usually 10 to 100 nm).

Characteristics

Micro emulsions are clear or translucent and can enhance the solubility of poorly soluble drugs, making them useful in pharmaceutical applications.

Example

Some topical drug delivery systems.

Nano emulsions

Description

Similar to Micro emulsions, but with droplet sizes ranging from 20 to 200 nm, Nano emulsions are formed using high-energy methods.

Characteristics

They are stable and can improve the bioavailability of drugs, often used in food and pharmaceutical applications.

Example

Nutraceuticals and certain cosmetic formulations.[21]

Advantages of liquid dosage forms

Ease of Administration

Liquid dosage forms are easier to swallow than solid forms, making them suitable for paediatric and geriatric patients, as well as individuals with difficulty swallowing.

Rapid Onset of Action

Liquids can be absorbed more quickly in the gastrointestinal tract compared to solid forms, leading to faster therapeutic effects.

Flexibility in Dosing

Liquid formulations allow for precise dosing adjustments, which is particularly beneficial for patients who require dose titration.

Improved Bioavailability

Liquids can enhance the solubility of poorly soluble drugs, leading to better bioavailability and effectiveness.

Taste Masking

The formulation of liquids can incorporate flavouring agents to mask the taste of unpleasant medications, improving patient compliance.[22]

Disadvantages of liquid dosage forms

Stability Issues

Liquid formulations can be less stable than solid forms, with susceptibility to degradation, microbial growth, and changes in potency over time.

Shorter Shelf Life

Many liquid medications have a shorter shelf life compared to solid dosage forms, requiring careful storage and handling.

Dosing Accuracy

Measuring doses can be less precise than with solid forms, leading to potential dosing errors if not administered properly.

Taste and Palatability

Some liquid medications may have unpleasant tastes or odour, which can deter patient compliance, especially in children.

Volume Limitations

Large volumes may be required for certain doses, which can be cumbersome or uncomfortable for patients to consume.

Potential for Adverse Reactions

The presence of solvents and preservatives in liquid formulations may cause irritation or allergic reactions in some patient.[23]

Excipient for liquid preparation

Excipients are inactive substances used in drug formulations to facilitate the manufacturing process, enhance stability, improve bioavailability, and ensure the overall effectiveness of the product.

Here are common excipients used in liquid formulations

Solvents

Water

The most common solvent for oral and injectable formulations.

Alcohol

Used in certain formulations (e.g., elixirs, tinctures) for its solvent properties and preservative effects.

Glycerine

A viscous solvent that also acts as a humectant.

Surfactants

Used to reduce surface tension and improve the solubility of active ingredients. Common surfactants include polysorbates (e.g., Tween) and sodium lauryl sulphate.

Emulsifiers

Help stabilize emulsions by preventing the separation of oil and water phases. Examples include acetyl alcohol, sorbitan esters, and lecithin.

Thickening Agents

Increase the viscosity of liquid formulations, improving stability and application characteristics. Examples include xanthan gum, hydroxypropyl methylcellulose (HPMC), and carbomers.

Preservatives

Protect against microbial growth and prolong shelf life. Common preservatives include benzalkonium chloride, parabens, and sorbic acid.

Stabilizers

Help maintain the physical and chemical stability of the formulation. Examples include citric acid and sodium citrate, which can also act as buffers.

Flavouring Agents

Used to improve the taste and palatability of liquid formulations, especially for paediatric or elderly patients. Natural or artificial flavours can be employed.

Sweeteners

Enhance taste, particularly in oral formulations. Common sweeteners include sucrose, sorbitol, and artificial sweeteners like aspartame.

pH Adjusters

Help maintain an appropriate pH level for stability and compatibility. Common agents include hydrochloric acid and sodium hydroxide.

Chelating Agents

Bind metal ions to prevent degradation of the active ingredients. Examples include EDTA (ethylenediaminetetraacetic acid).

Quality control for liquid dosage forms

Microbial Limits Testing

Assess total microbial count and specific pathogens to ensure. [24]

Quality Control (Qc):

It is essential in the development and production of liquid dosage forms to ensure their safety, efficacy, and consistency.

Here are key aspects of quality control for these formulations:

Physical Examination

Appearance

Check for clarity, colour, and any particulate matter.

Odour

Assess for any unusual or off-putting smells.

pH Testing

Measure the pH to ensure it is within the specified range for stability and compatibility with the intended use.

Viscosity Measurement

Evaluate the viscosity to ensure proper flow properties and consistency in the formulation, especially for suspensions and emulsions.

Density and Specific Gravity

Measure to ensure consistency in formulations, especially important for dosing accuracy in concentrated solutions. [25]

Microbial Contamination Testing

Conduct sterility tests (for parenteral products) and tests for microbial limits to ensure the formulation is free from harmful microorganisms.

Stability Testing

Perform stability studies to assess how the formulation holds up over time under various conditions (temperature, humidity, light). This includes accelerated stability testing.

Content Uniformity

Test samples from different containers to ensure uniform distribution of active ingredients. This can involve assays for drug content in each dosage unit.[26]

Dissolution Testing

For oral liquid formulations, evaluate the dissolution profile to ensure that the active ingredients are released appropriately.

Package Integrity Testing

Assess the integrity of packaging to ensure it protects the product from contamination and degradation. [27]

Labelling and Documentation:

Verify that all labels meet regulatory requirements and accurately reflect the content, dosage, and storage conditions.[28]

Test for quality control

Raw Material Testing

Identity Verification

Confirm the identity of all excipients and active ingredients.

Purity Testing

Assess the quality and purity of raw materials to prevent contamination. [29]

Formulation Testing

Homogeneity

Ensure that the active ingredient is uniformly distributed throughout the liquid.

Viscosity

Measure viscosity to confirm that it meets specified parameters for the intended use.

Microbial Testing

Sterility Tests

For parenteral and certain other liquid formulations, check for microbial contamination.[30]

Safety.

pH and Osmolality

pH Measurement

Confirm that the pH is within the desired range for stability and patient comfort.

Osmolality Testing

Particularly important for parenteral solutions to ensure compatibility with body fluids. [31]

Stability Studies

Accelerated Stability Testing

Conduct tests under elevated temperature and humidity to predict shelf life.

Long-term Stability Studies

Monitor changes over time under recommended storage conditions. [32]

Assay and Content Uniformity

Active Ingredient Assay

Use analytical methods (e.g., HPLC) to determine the concentration of the active ingredient.

Content Uniformity Tests

Check that each unit (e.g., bottle or vial) contains the correct amount of the active ingredient.[33]

Dissolution Testing

Evaluate the release profile of the active ingredient from the liquid formulation to ensure appropriate absorption characteristics. [34]

Packaging Integrity

Assess the physical integrity of the packaging to prevent contamination and degradation. [35]

Labelling Verification

Ensure that all labels comply with regulatory requirements, accurately reflecting the formulation and usage instructions. [36]

Documentation and Record Keeping

Maintain detailed records of all QC testing, results, and any deviations from specifications for regulatory compliance. [37]

CONCLUSION

Monophasic liquid dosage forms can be classified as true or colloidal solutions, with water commonly serving as the solvent for most formulations. The primary advantages of liquid dosage forms include high patient acceptability, ease of administration for both geriatrics and paediatrics, and their convenient formulation process. These products are created by combining active drug substances with various excipients, which perform multiple roles within the formulation. It's important to note that different excipients can behave uniquely depending on their concentration, and a single excipient can serve various functions based on the formulation's requirements. Additionally, the materials used for containers and packaging can differ significantly, as they are often in direct contact with the formulation.

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