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Review Article

A Review on Dry Emulsion: Formulation and Evaluation

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Abstract

The goal of the dry emulsion formulation is to decrease the adverse effects of drugs and increase their bioavailability. Because they are formulations that are both physically and microbiologically stable, dry emulsions are appealing. For lipophilic and poorly soluble medicinal compounds, they offer a possible oral drug administration method. Liquid o/w emulsions with a solid carrier in the aqueous phase are dried to create dry emulsion. Spray drying, lyophilization, and rotary evaporation are methods for creating dry emulsions. Lactose, mannitol, and maltodextrins are organic filters used in the preparation of dry emulsion. The oils employed in this study are olive oil, sesame oil, and peppermint oil. Pre-formulation experiments revealed that HPMC was the ideal gum for making dry emulsion, while mannitol was the organic filler. It was discovered through observations that the drug's stability and bioavailability were improved by manufacturing it as a dry emulsion.

Keywords: Dry emulsion, solid carriers, lyophilization

INTRODUCTION:

Dry Emulsion:

Dry emulsions offer a potential oral drug delivery system for lipophilic and low-soluble drug substances required for protection against light or oxidation. Because dry emulsion are powdery, lipid-based formulations that can be readily reconstituted into an o/w emulsion in vivo or when exposed to an aqueous solution. [1] Also many authors have studied this recent pharmaceutical form for its sustained release effects with hydrophilic drugs such as sodium salicylate and chlorpheniramine maleate. [2] In this study, the manufacture of dry emulsion containing a pharmacological ingredient through the spray drying of liquid emulsions is either only of lactose or in conjunction with maltodextrin as a water-soluble solid carrier. [3] This study confirmed that dry emulsions composed of HPMC were the most promising. Because HPMC can lower surface tension, it made it easier to emulsify liquid o/w emulsions. A smaller droplet size distribution was achieved by adding more HPMC to liquid o/w emulsions. [4] The aim of the study was to understand how the powder particles internal physical structure affects their surface characteristics and how these factors impact reconstitution properties like droplet size and degree of coalescence of the re-dispersed emulsions. [5]

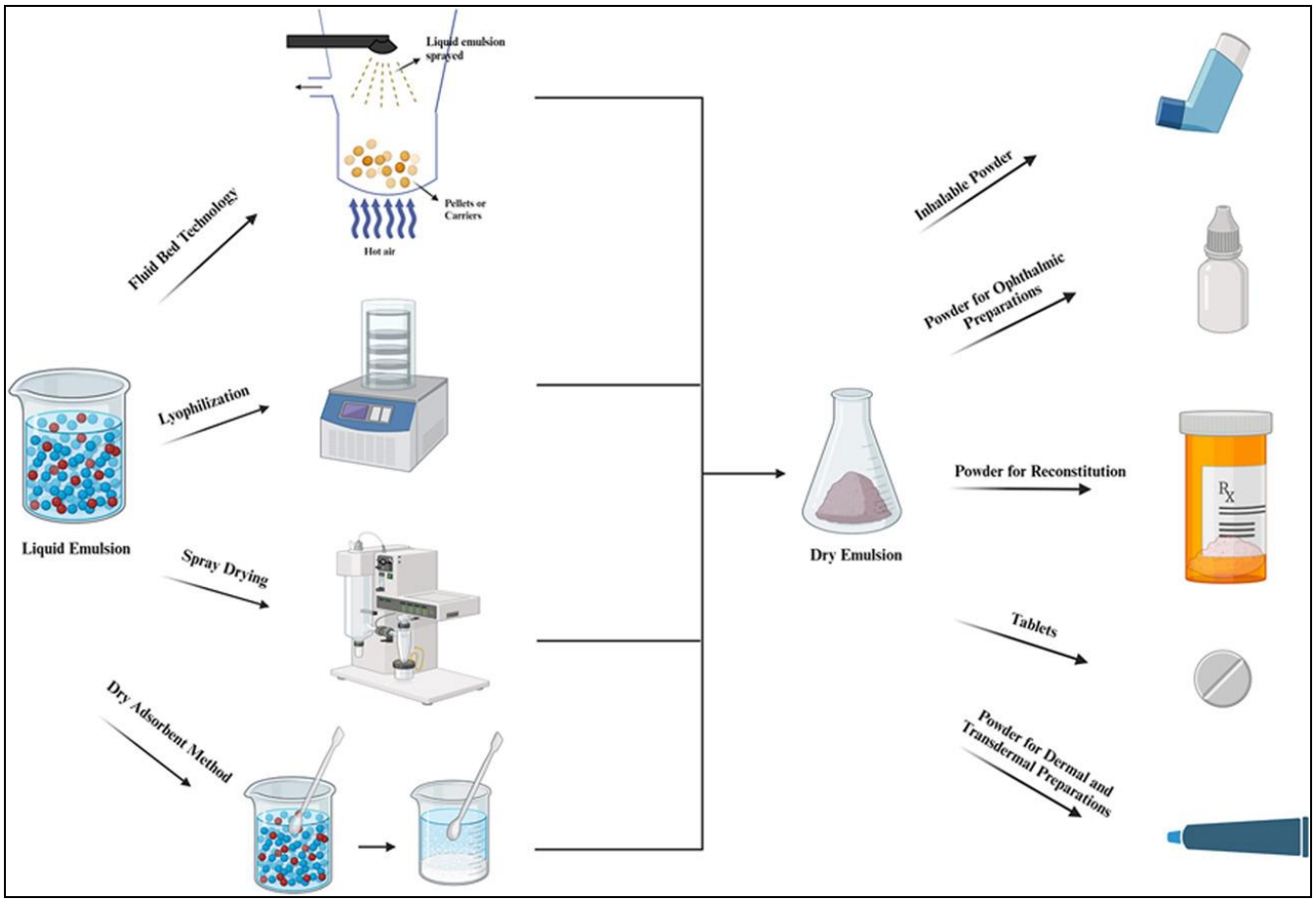

Figure 1: diagrammatic illustration of the process of converting liquid emulsion into dry emulsion and possible medicinal dose forms. [6]

Pharmaceutical emulsions, which are intended for both internal and exterior purposes, are often sold as liquid formulations or semisolid preparations. O/W liquid emulsions are injected or consumed; the active chemicals are contained in the oily phase. On the other hand, creams and other semisolid emulsions are mostly applied topically to the skin. [7]

Properties of the dry emulsion:

1. Dry emulsion reconstitution qualities varied depending on the rotary atomizer type and rotation rate. [8]
2. Dry emulsion with small particles exhibit limited flow and poor packing, resulting in reduced porosimeter density at higher rotation rate. [9]
3. Increasing lipid content led to a rise in droplet size distribution in liquid o/w emulsions during spray drying and reconstitution. Dry emulsion with lipid content less than 50% reformed the original emulsion. Increasing the lipid content from 30 to 80% increases the droplet size of dry emulsion reduced. [10]
4. The technical parameters of the dry emulsions containing 40% lipid were unaffected by the rotary atomizer type or rotation rate.
5. Dry emulsion with lipid content of up to 40% dry powder mass reformed the original o/w emulsion when reconstituted. As the liquid viscosity increases so does the size of the atomized droplets, resulting in larger powder particle sizes.
6. The cohesive powders that make up dry emulsions have poor flow characteristics because of their low density, particle size, and shape. One way to increase the technical qualities is to melt our moist granulation. The liquid O/W emulsions droplet size distribution before and after reconstitution and spray drying. [11]

Advantages of dry emulsion:

1. They improve the bioavailability of the drug's constituents.
2. The physical and microbiological characteristics of dry emulsions make them attractive. [12]
3. They exhibit potential as an oral drug delivery method for lipophilic and poorly soluble medications.
4. Decreased adverse effects. [13]
5. For medicinal substances that need to be protected from oxidation or light.
6. For extended periods of treatment, dry emulsions offer the most consistent and effective blood levels. [14]

Disadvantages of dry emulsion:

1. The preparation must be properly shaken before use.

2. To administer, measuring equipment is required. [15]
3. Measuring a dose demands a certain degree of technical precision.
4. Storage conditions have the potential to affect stability. [16]

Applications of dry emulsion:

1. The dried emulsion could be employed in plant protection compositions.
2. Used in antifoam formulations and cosmetics. [17]
3. Household, skin and infant care wipes.
4. For makeup removal wipes. [18]
5. In bath salt formulations.
6. In surface coating formulations, such as paints.
7. Oral, transdermal, and parenteral drug delivery. [19]

Characterization of dry emulsions:

1. **Drug content:** A dry emulsion containing 10 mg of medication is precisely weighed and dissolved in an appropriate solvent. Use Whitman filter paper number 41. The stock solutions have the proper dilution. A UV spectrophotometer is used to determine the drug content. [20]
2. **Scanning electron microscopy:** To examine surface morphology, SEM photomicrographs are captured using an analytical scanning electron microscope.
3. **Globule size determination:** The emulsion is examined under a microscope both before and after reconstitution. [21]
4. **Moisture content:** Using thermogravimetric analysis, the moisture content was found to be between 15.00 and 20.00 mg. Dry nitrogen was the effluent gas after the samples was put in the sample pan. In the 50-200^{0}C scan range, the scanning rate was 10^{0}C /min. The moisture content shows the decrease in weight between 50 and 120^{0}C. [22]
5. **Surface characterization:** The dry emulsions exterior macroscopic structure is examined using scanning electron microscopy (SEM). Samples were coated with gold or palladium using a Bio Rad E5200 Auto Sputter Coater for 300 seconds prior to microscopy. A voltage of 15KV was used to scan the samples. [23]

Method of preparation:

Dry emulsions are prepared by using:

1. Spray drying
2. Lyophilization
3. Rotary evaporation

1. Spray drying: Spray drying is a technique that uses a hot gas to quickly dry a liquid or slurry into a dry powder.[24] For many thermally sensitive goods, including foods and medications, this is the recommended drying technique.[25] Some industrial items, including catalysts, are spray-dried in order to achieve a uniform particle size distribution. The heated drying medium is air, although nitrogen is employed if the product is oxygen-sensitive or the liquid is a flammable solvent like ethanol. [26]

2. Lyophilization: The technique of lyophilization, also known as freeze-drying, turns a liquid medication into a solid powder or cake by removing the water. The lyophilized product can be stored at higher temperatures and is stable for a long period of time. [27] Stabilizers are added to protein formulations in order to replace the water and maintain the molecules' structure. [28]

A lyophilized medication is reconstituted as a liquid before delivery. [29] This is accomplished by mixing and injecting the freeze-dried powder with liquid diluents. To guarantee that the medication is properly blended and delivered, reconstitution typically necessitates a reconstitution and administration system**.** [30]

Principle: The occurrence of sublimation the direct, non-liquid transition of water from a substance is the fundamental idea behind freeze-drying. Water can be heated to temperatures below the triple point, which is 0.0099^{0}C and 4.579mm Hg. [31] When a product is first frozen and then heated under extreme vacuum using electricity, conduction, or both, the liquid is dried. Until the frozen liquid sublimates, this process keeps going. During the freeze-drying process, water is removed from the gradient of water vapor concentration between the condenser and the drying front. [32]

Processing:

The whole drying process has four steps:

1. Pre-treatment
2. Annealing and freezing
3. Primary drying
4. Secondary drying

1. Pre-treatment: Pre-treatment is the method applied to the product before freezing. This may require enlarging the area, decreasing the vapor pressure of the solvent, modifying the formula (e.g., adding additives to increase performance and/or improve stability), or concentrating on things. It is often necessary to select items based on concerns about cycle time or product quality, or based on an understanding of freezing and its parameters. Freezing concentration, solution phase concentration, product shape control formulation, reactant stabilization, surface area increase, and vapor pressure reduction are all part of the pretreatment procedure. [33]

2. Annealing and freezing: Heat a product below the triple point, which is the lowest temperature of the product; when freezing, the liquid and gas phases of the product can be mixed. This permits it to sublimate rather than dissolve in the next stage.[34] Larger ice is ideal for faster and more effective drying. Large ice crystals create a network inside the object during the sublimation process, making it possible to remove water

vapor. Larger rocks can be formed by progressively freezing particles or removing them through temperature cycling. [35] The stability of the product, its regeneration, the length of the drying cycle, and proper crystallization are all determined by the freezing step, which is the most important stage in the entire freeze-drying process. [36]

3. Initial drying: After the product is first frozen, it needs to be made dry and firm so that the ice can sublimate from it. In order to do this, both parameters must be appropriately controlled, with heat and pressure utilized in the dryer. The difference between the vapor pressure of the product and the vapor pressure of the frozen product affects the amount of ice sublimated from the frozen product. Molecules travel from the higher structure to the upper surface. Since vapor pressure and temperature are interrelated, the product temperature must be higher than the cold trap (ice collector) temperature. [37]

4. Secondary drying: Moisture remains in the product even after all the ice has reduced and the process has started to dry completely. [38] Even if the product looks dry, there can be 7-8% water left in it. It takes more drying at higher temperatures to get the right moisture balance. [39] The term "isothermal desorption" refers to the process of eliminating bound water from the finished product. This procedure is predicated on the idea that the ice has melted and there is no longer any cause for concern. Also, the remaining water after drying is stiffer and requires more work to remove. It has long been considered that water is more easily desorbed when the reservoir pressure decreases below the suction level. [40]

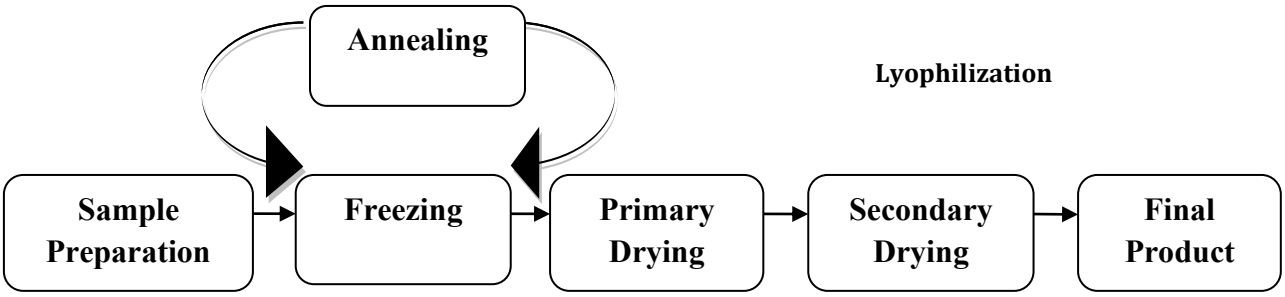

Figure 2: Steps involved in the lyophilization process, from preparing the sample to creating the finished product. [41]

Factors affecting freeze-drying:

Many product, container, equipment, and process-related factors can affect the freeze-drying process. The stability of the body against the stresses imposed by the freeze-drying process is determined by the design.

1. Nature of the surfactant: It is one of the most significant due to its interaction with drugs and cryoprotectants and the many modifications that occur during lyophilization and rehydration.

2. Solubility: During the freeze-drying process, the drug's solubility and dispersion characteristics will affect how quickly it enters the bilayer and separates from the emulsification system.

3. Rotary evaporation: Rotary evaporation is primarily used to extract solvents following chemical processes combined with the evaporator bath's mild heat. [42]

The drug was mixed with propylene glycol using a magnetic stirrer.

↓

In a separate beaker, the aqueous phase was prepared by adding gum, organic filter, surfactant, and sweetening agent and stirring until a homogeneous solution was obtained.

↓

The propylene glycol containing cephalexin monohydrate was added to the aqueous phase and mixed thoroughly.

↓

The oil phase was added drop by drop under continuous stirring to form a milky white emulsion.

↓

The emulsion was transferred to Petri plates and dried in an incubator at different temperatures (40^{0}C, 50^{0}C, 60^{0}C and 70^{0}C); 70^{0}C was selected as the optimum drying temperature.

↓

The dried emulsion powder was collected and stored in a well-closed container.

↓

The stability of the emulsion was evaluated for 48 hours. [43]

Figure 3: Method of Preparation of Dry Emulsion

Stability of the dry emulsions upon ageing:

Dry emulsions are physically stable during storage. After 6 months of storage, the dry emulsions retained their original structure and could be reconstituted in water to generate the o/w emulsion. Dry emulsions with a lipid concentration of 40% dry powder mass and have the potential for an oral medication delivery system.

Table 1: drugs formulated in the form of dry emulsion.[44]

SR.NO.	DRUG LOADED	CONCENTRATION	METHOD OF LOADING	RESULT
1.	Lovastatin	1%	Spray drying	Improved absorption
2.	Theophylline	7%	W/O emulsion , free flowing reconstitutable powder	Improved absorption
3.	Indomethacine/5-Fluorouracil	7.5%	Adsorption on carrier	Improved intestinal absorption
4.	Amlodipine	1.1%	Spray drying	Improved intestinal absorption
5.	Vitamin E	40%	Spray drying	Improved in-vitro release

Evaluation test for dry emulsion:

1. **Solubility:** The drug's solubility was assessed by adding an excess but measured amount to a 100 ml volumetric flask filled with 7.2 phosphate buffer, which was shaken for two hours at 37^0C^+-0.5 in a water bath. After passing the dispersions through Whatman filter paper, the amount of medication dissolved is measured.
2. **Drug content estimation:** To measure the percent drug concentration of dry emulsion formulations, 100 mg of the dry emulsion was dissolved in water. The samples were properly combined to dissolve the medication in water. Samples were ultrasonically sonicated for 15 minutes and then examined with a UV spectrophotometer to measure absorbance. The drug content for formulations F1, F2, and F3 was 95.24, 90.45 and 88.36% respectively. [45]
3. **Scanning Electron Microscopy:** Analytical scanning electron microscopes are used to take SEM photomicrographs in order to examine surface morphology.
4. **Density:** Helium pycnometry is used to calculate the dry emulsion's density. Every sample was measured seven times for a single determination. Mercury porosimetry was used to measure the density of the dry emulsions using a Pascal 140 fitted with a dilatometer type CD3P. [46]
5. **Moisture Content:** Moisture content is determined by thermogravimetric analysis. Samples weighing between 15 and 20 mg were put in the sample pan, and dry nitrogen was the effluent gas. In the 50-2000 C scan range, the scanning rate was 100 C per minute. The weight loss between 50 and 1200 C can be used to calculate the moisture content.
6. **In vitro drug release studies:** The dissolution profiles of pure drug, dry emulsion, dry suspension, and tablet are compared according to the time necessary to release the highest amount of medication. In vitro drug release studies revealed that dry emulsion formulations outperformed alternative dosage forms, such as dry suspension. The formulation with olive oil resulted in quick medication release. [47]

Future prospects of dry emulsion systems:

As dry emulsion technology is easier to handle and more stable than regular emulsions, it is becoming more and more popular in pharmaceutical drug delivery. Future studies are anticipated to concentrate on the creation of sophisticated formulation methods to improve drug loading, stability, and controlled release properties.

Dry emulsion systems combined with nanotechnology may open up new possibilities for increasing the solubility and bioavailability of medications that are poorly soluble in water, such as ibuprofen and curcumin. Furthermore, a deeper comprehension of the physicochemical characteristics of dry emulsions can be achieved by the use of contemporary characterization methods, including Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), and Scanning Electron Microscopy (SEM).

Additionally, there may be more uses for dry emulsions in nutraceutical formulations, controlled release systems, and targeted medication administration. Future research should address large-scale production, long-term stability, and regulatory issues to facilitate the wider availability of dry emulsion-based pharmaceutical products.

All things considered, dry emulsion systems offer a promising platform for enhancing medication administration and therapeutic effectiveness; further study in this area may result in the creation of dosage forms that are more effective and patient-friendly. [48]

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Conclusion

For the stability investigations, the dry emulsion formulation was examined for three months at 45^{0}C and 75±5% relative humidity. For three months, the emulsion was examined for drug entrapment and cumulative percentage drug release; no changes in the findings were noted. After three months, the dried emulsion was reconstituted, and the resulting emulsion showed no evidence of instability and was stable with the appropriate viscosity and consistency. According to the previous study, when compared to pure cefixime and other commercially available formulations, the dry emulsion formulation demonstrated an instantaneous release of medication.

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