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A REVIEW ON MICROEMULSION DRUG DELIVERY SYSTEM

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ABSTRACT

The term "microemulsion" refers to a thermodynamically stable isotropically clear dispersion of 2 immiscible liquids, such as oil & water, stabilized by an interfacial film of surfactant molecule. Nowadays microemulsion is an emerging trend and worldwide importance in a variety of technological applications.[1] This review article deals with feature and applications of microemulsion, a brief introduction and definition, structure, type, GMP and GLP requirements for microeulsion, optimisation techhniques, formulation characteristics, evaluation and stability studies.

KEYWORDS: Microemulsion, cosurfactant, Preformulation.

INTRODUCTION

The concept of microemulsion was first introduced by Hoar and Schulman in 1943; they prepared the first microemulsion by dispersing oil in an aqueous surfactant solution and adding an alcohol as cosurfactant, leading to a transparent, stable emulsion. Microemulsion are clear, thermodynamically stable, isotropic liquid mixtures of oil, water and surfactant, frequently in combination with a cosurfactant. The aqueous phase may contain salt or other ingredients, and the oil may actually be a complex mixture of different hydrocarbons and olefins. The microemulsion is formed readily and sometimes spontaneously, generally without high energy input.

In recent years, numerous studies have suggested that microemulsion have tremendous potential to enhance the bioavailability of drugs. Microemulsions have been successfully used to improve the solubility, chemical stability, and oral bioavailability of many poorly water-soluble drugs. Microemulsions can be easily distinguished from normal emulsions by their low viscosity, transparency and more accurately their thermodynamic stability. Alternative names for these systems are often used such as swollen micelle, transparent emulsion, solubilized oil and micellar solution.

Microemulsions are bi-continuous systems that are essentially composed of water and oil separated by a surfactant or cosurfactant rich interfacial region. Microemulsions are currently the subject of many investigations because of their wide range of potential and actual utilizations. The high capacity of microemulsions for drugs makes them attractive formulation for pharmaceuticals. These systems also offer several benefits for oral administration, including increased absorption, improved clinical potency and decreased toxicity. Microemulsions possess droplet sizes in the diameter range 10–100 nm. These small droplet sizes increase the surface area to volume ratio for drug absorption leading to improved bioavailability. Additionally, these small droplet sizes are able to resist gravitational separation and hence, enhance stability of the microemulsion system. The small droplet sizes of microemulsions also afford delivery via a wide variety of administration routes.

STRUCTURE OF MICROEMULSION

Microemulsions or Micellar emulsion are dynamic system in which the interface is continuously and spontaneously fluctuating. Structurally, they are divided in to oil in water (o/w), water in oil (w/o) and bi-continuous microemulsions. In w/o microemulsions, water droplets are dispersed in the continuous oil phase while o/w microemulsions are formed when oil droplets are dispersed in the continuous aqueous phase. In system where the amounts of water and oil are similar, the bi-continuous microemulsions may result. The mixture oil water and surfactants are able to form a wide variety of structure and phase depending upon the proportions of component.

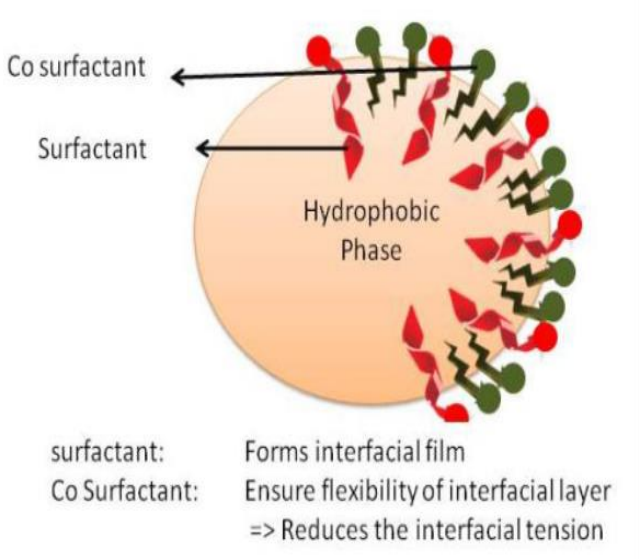

Fig. 1: Structure of Mircoemulsion.

TYPES OF MICROEMULSIONS

Microemulsions are thermodynamically stable, but are only found under carefully defined conditions. According to Winsor, there are four types of microemulsion phases exists in equilibria, these phases are also referred as Winsor phases. They are,

1. Oil- in- water microemulsion or winsor I
2. Water – in oil microemulsion or winsor II
3. Bicontinuous microemulsion or winsor III
4. Single phase homogeneous mixture or winsor IV

Oil in water microemulsion or winsor I

In Oil-in-water type of microemulsions droplets of oil is surrounded by a surfactant (and may be cosurfactant) film that forms the internal phase distributed in water, which is the continuous phase. This type of microemulsion generally has a larger interaction volume than the w/o microemulsions.

Water - in - oil microemulsion or winsor II

In Water-in-oil type of microemulsions droplets of water surrounded by a continuous oil phase. These are recognized as “reverse micelles”, where the polar headgroups of the surfactant are facing into the droplets of water, with the fatty acid tails facing into the oil phase. A w/o microemulsion used orally or parenterally may be destabilized by the aqueous biological system.

Bicontinuous microemulsion or winsor III

In bicontinuous microemulsion system the amount of water and oil present are similar, In this case, both water and oil exist as a continuous phase. An irregular channel of oil and water are combined, and looks like a "sponge-phase". Transitions from o/w to w/o microemulsions may pass through this bicontinuous state. These properties make them especially useful for topical delivery of drugs or for intravenous administration.

Single phase homogeneous mixture or winsor IV

In single phase homogeneous mixture or winsor IV the oil, water and surfactants are homogenously mixed

ADVANTAGES

1. Increase the rate of absorption.
2. Eliminates variability in absorption.
3. Helps in solubilization of lipophilic drug.
4. Provides an aqueous dosage form for water insoluble drugs.
5. Increases bioavailability.
6. Various routes like topical, oral and intravenous can be used to deliver the product.
7. Rapid and efficient penetration of the drug moiety.
8. Helpful in taste masking.
9. Microemulsions have low viscosity compared to primary and multiple emulsion.
10. Liquid dosage form increases patient compliance.
11. Less amount of energy requirement

DISADVANTAGES

1. Use of a large concentration of surfactant and co-surfactant necessary for stabilizing nano droplets.
2. Limited solubilizing capacity for high-melting substances. The surfactant must be nontoxic for using pharmaceutical applications.
3. Microemulsion stability is influenced by environmental parameters such as temperature and ph. These parameters change upon microemulsion delivery to patients. For unique dosage preparation in capsules, it may produce softening or hardening effect on capsule shell, so for long term storage it is undesirable.

GOOD MANUFACTURING PRACTICE(GMP)

GMP is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standard appropriate to their intended use and as required by the marketing authorization.

It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

PRINCIPLE OF GMP

- Design and construct the facilities and instructions
- Follow written procedures and instructions
- Document work
- Validate work
- Monitor facilities and equipment
- Writes steps by step operating procedures and work on instructions
- Design, develop and demonstrate job competence
- Protect against contamination

GUIDELINES FOR GMP

- Building and facilities
- Equipment
- Personnel
- Raw materials
- Production
- Sanitation
- Records
- Labelling
- Complaints

Building and facilities

Any building used in manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations. It shall have adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, closures, labelling, in- process materials, or drug products, and to prevent contamination. Operations

shall be performed within specifically defined areas of adequate size. Adequate lighting and ventilation should be provided in all areas. The designs of facilities are largely dependent upon the types of products manufactured and potential for cross contamination and microbiological contamination equipment. There must be appropriate facilities in the production area with proper supply of good quality of water.

Equipment

Equipment shall be located, designed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross- contamination, build – up of dust or dirt and in general any adverse effect on the quality of product. To avoid accidental contamination, wherever possible, nontoxic or edible grade lubricant shall be used and the equipment shall be maintained in a way that lubricants don't contaminate the products being produced. Equipment should be of sanitary design. This includes sanitary pumps, valves, flow meter which can be easily sanitized.

Personnel

The manufacture and testing shall be conducted under direct supervision of qualified technical staff. Number of personnel employed shall be adequate and in direct proportion to the workload. Staff with illness or open lesions should not handle starting materials, intermediates or finished products.

Raw materials

The physical characteristics particularly the particles size of drug substances are very important for microemulsion. All materials shall store under appropriate storage condition & follow 'first in/first expiry'- 'first out' rule. Raw material from each batch checked for quality and appropriately labels the storage area. There shall be adequate separate area for materials "under test", "approved ", and "rejected" with arrangement and equipment. It allow dry, clean and orderly placement of stored materials and products, wherever necessary, under controlled temperature and humidity.

Quality control

Quality control is important step in the manufacturing of the drug substance includes – The testing of bulk components, testing of finished products prior to sale, stability programmes.

Finished products offer packaging should be stored in the finished goods store within an area marked and subjected to quality control test.

Record

It is the essential part of quality assurance system. As such, shall be related to all aspect of GMP. The records shall be made or completed at the time of each operation in such a way that all significant activities concerning the manufacturing of pharmaceutical product are traceable. Records and associated SOP shall be retained for at least one year after the expiry date of the finished product.

Labelling

- Necessary for identification of the drugs and their use.
- Printed in bright colours and legible manner.
- All containers and equipment shall bear appropriate labels.
- Different colour coded labels can be used.
- Printed packaging materials & leaflets shall be stored separately to avoid mix-up.
- Record of receipt and use of all material shall be maintained.

Complaints

- All complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures. Each complaint shall be investigated or evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained.
- Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned Licensing Authority.
- There shall be written procedures describing the action to be taken, recall to be made of the defective product.

GOOD LABORATORY PRACTICES (GLP)

Good laboratory practices (GLP) is a quality system covering the organizational process and conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, reported, and archived.

OBJECTIVES

- To avoid duplication of research.
- To facilitate international acceptance of test data.
- To improve the protection of human health and environment.
- To prevent the creation of technical trade barrier.

GLP PRINCIPLES AND REQUIREMENTS

1. Test facility organization and personnel
2. Quality assurance programme
3. Facilities
4. Apparatus, materials, reagents
5. Test system
6. Test and reference items
7. Standard operating procedures
8. Performance of the study
9. Reporting of study results
10. Storage and retention of records and materials

Personnel

Before the study begins, the testing facility manager must appoint a study director who will be responsible for the overall conduct of the study and its GLP compliance. The testing facility must also have a quality assurance unit which is separate from or independent of the testing facility organization or management.

Facility and equipment

The testing facility should provide separation of activities to prevent interference and other disturbances which may compromise the study. There must be separate areas for:

- The receipt and storage of the test and control articles
- The mixing of the test and control articles with a carrier
- The testing facility should provide separation of activities to prevent interference and storage of the test and control article mixtures
- The housing of the test systems

All equipment used in the study should be periodically calibrated and maintain the records of calibration and maintenance should be kept and made available to operators of equipment.

Study plan or protocol

The study plan or protocol is the master guidance document for the conduct of the study. It outlines how the study should be performed and contains the general time schedule for the study and its various stages. It also includes the method and materials used in the study.

The protocol must go through approval, review, and discussion before the study begins. This process starts with the study director preparing the protocol and discussing its contents with personnel and other study staff. After discussion, the study director must then approve the protocol by affixing their dated signature.

Standard operating procedures

Each of the separate areas in the testing facility should have Standard Operating Procedures (SOPs), especially for routine procedures. SOPs must be approved by the testing facility manager and any deviations from SOPs need to be authorized by the study director.

Final report

The final report is ultimately the responsibility of the study director, who prepares and approves the report. Key features of the final report are:

- A complete and accurate account of the conduct of the study
- Any deviation from an intended course of action (such as SOP or protocol)
- Scientific interpretation of results and critical discussion
- GLP Compliance Statement by the study director.

Storage of records

Throughout the course of the study, the study director will be responsible for ensuring that all data pertaining to the study is captured and included in records that are safely stored. These records and documents such as the protocol, the final report, and standard operating procedures will then be archived at the end of the study.

Retention of records

Archived records must be retained at least 2 years after the date on which the study was completed, terminated or discontinued

PREFORMULATION

It is the study of physical and chemical properties of drug prior to compounding process. Preformulation is a group of studies that focus on the physicochemical properties of a new drug candidate that affect the drug performance and the development of a dosage form.

The main components of preformulation studies are:

- Development of a suitable spectroscopic assay method for determining concentration and purity.
- Determination of solubility and dissolution rates of parent compound and salts in water and other solvents.
- Chemical stability of parent compound and salts in solution and solid state.
- Determination of lipophilicity
- Determination of particle morphology, melting point and suitability for milling.
- Characterizations of importance for the dosage form of choice.

IDENTIFICATION AND CHARACTERIZATION

The droplet size of the dispersed phase in a microemulsion is less than 100nm. The droplet size, viscosity, density, turbidity, refractive index, phase separation and pH measurements shall be performed to characterize the microemulsion.

Organoleptic properties

Colour, odour, taste of the new drug must be recorded.

Solubility study

For preparation of microemulsion, different components were selected through solubility study using equilibration method. A known quantity of the drug was dissolved in each of the oils, surfactants and cosurfactants by vortexing in stoppered vials, followed by shaking at 100 rpm for 72 hr on an orbital shaker at 25 ± 10C. These mixtures were then centrifuged at 3000 rpm for 15 min and the supernatant was filtered through 0.45µm membrane filter. The dissolved drug was diluted within the linearity range and was measured spectrophotometrically using double beam uv-spectrophotometer (Shimadzu UV-1700) at 228 nm.

Droplet size

The droplet size of the dispersed phase in a microemulsion is less than 100nm. The droplet size distribution of microemulsion can be determined by either light scattering technique or electron microscopy. This technique has been suggested as the best method for predicting microemulsion stability.

- **Dynamic Light-Scattering Measurements:** The DLS measurements are taken at 90° in a dynamic light-scattering spectrophotometer using a neon laser of wavelength 632 nm. The data is processed by the built-in computer with the instrument.
- **Polydispersity:** Polydispersity is studied using Abbe refractometer.
- **Phase analysis:** The type of microemulsion forming the phase system (o/w or w/o) is determined by measuring the electrical conductivity using a conductometer.

Viscosity Measurement

The viscosity of microemulsions of several compositions is measured at different shear rates at different temperatures using Brookfield type rotary viscometer. The sample room of the instrument must be maintained at 37 ± 0.2°C by a thermo bath, and the samples for the measurement are to be immersed in it before testing.

Specific gravity

Specific gravity of microemulsion is determined by capillary gravity bottle method. It is a very important factor to study the stability of microemulsion.

FTIR

FTIR was used to study drug-excipient interaction by scanning the samples in the range of 400-4000 cm. The pure drug was mixed with surfactant, co-surfactant and oil and this mixture was analysed. Spectral comparison was done with FTIR of the pure drug to eliminate the possibility of important functional groups of the drugs interacting with the excipients.

Conductivity measurement

Electrical conductivity of the drug loaded microemulsions was studied using a conductivity meter. This measurement was done to study the effect of the amount of water in the microemulsion and to ascertain the type of the system; oil-continuous, bi-continuous, water continuous.

DSC (differential scanning calorimetry)

Thermal analysis is an important evaluation technique to find any possible interaction between the drug and excipients. Such interaction can be identified by any change in thermogram. About 1 mg of the sample was sealed in the aluminium pan and heated at the rate of 10°C/min, covering a temperature range of 30 °C to 300 °C under nitrogen atmosphere of flow rate 20 ml/min and DSC thermogram for pure drug and prepared microemulsion was obtained.

CRITERIA FOR EXCIPIENT SELECTION

Excipients are substances apart from the active pharmaceutical ingredient that are fittingly evaluated for safety and are by design enclosed in a very drug delivery system. Excipient can be considered as indispensable component of medicinal products and in most of the formulations they are present in greater proportion with regards to active pharmaceutical ingredients, as it forms the bulk of the formulation it is always necessary to select an excipient which satisfies the ideal properties for particular excipient.

The ideal characteristics of an excipient are given as under;

An excipient must be:

- No interaction with drug
- Pharmacologically and physiologically inert
- Should be effective at low concentration
- Chemically stable
- Non-reactive
- Low equipment and process sensitive
- Inert to human body
- Non toxic
- Economical

Table 1: Common excipients used to formulate microemulsions.

OILS	SURFACTANTS	COSURFACTANTS
Oleic acid	Polysorbate20	Ethanol
Castor oil	Polysorbate 80	Glycerine
Corn oil	Polyoxyl 35 castor oil	PEG 300
Peanut oil	Polyoxyl 60 castor oil	Poloxamer 407
Sesame oil	PEG 300 caprylic	Propylene glycol

FORMULATIONS OPTIMIZATION TECHNIQUE

Optimization is selecting the most suitable element from available influence decisions in any resources considering all the factors which in experiment. Designing quality formulation is obtained by the use of various technique of optimization. Quality by design enhances the assurance of safe and effective drugs to consumer and promise to improve manufacturing quality performance.in pharmaceutical industry optimization techniques used for the drug delivery systems are designed accordingly which include,

Defining the objective

Planning the experiments

Factors which influence is screened

Selecting the experimental designs

Formulation and evaluation of drug delivery system as instructed by experimental design

Search for the optimum by using computer aided modelling

Design of experiments methodology should be validated

Scale up plan and the obtained step by thus entire process is implemented in production the desired pharmaceutical drug delivery system.

FORMULATION

Various ingredients are used in the formulation and development of microemulsions. Mainly oil and surfactants are used in microemulsion they should be biocompatible, non-toxic and clinically acceptable. Main components of microemulsion are

1. Oil phase
2. Aqueous phase
3. Primary surfactant
4. Secondary surfactant(co-surfactant)

5. Co-solvent

1. Oil phase

Oil is one of the most important components of microemulsion because it can solubilise the required dose of the lipophilic drug and it increases the fraction of lipophilic drug transported via the intestinal lymphatic system. Oil is defined as any liquid having low polarity and low miscibility with water. The examples of such phase are cyclohexane, mineral oil, toluene, &vegetable oil etc.

Following are the different oils are mainly used for the formulation of microemulsion

- Saturated fatty acid-lauric acid, myristic acid, capric acid
- Unsaturated fatty acid-oleic acid, linoleic acid, linolenic acid
- Fatty acid ester-ethyl or methyl esters of lauric, myristic and oleic acid.

2. Aqueous phase

Generally, the aqueous phase contains hydrophilic active ingredients and preservatives. Sometimes buffer solutions are used as aqueous phase.

3. Primary surfactant

The term surfactant (surface-active-agent) denotes a substance which exhibits some affinity for polar & nonpolar solvents. The primary use of surfactant is to lower the interfacial tension to a very small value which will facilitates dispersion process during the preparation of the microemulsion and provide a flexible film that can readily deform around the droplets and be of the appropriate lipophilic character to provide the correct curvature at the interfacial region.

Surfactants used to stabilize microemulsion system may be

I. Non-ionic,

II. Zwitterionic,

III. Cationic, or

IV. Anionic surfactants.

In the formation of microemulsion the surfactant may be ionic or non-ionic, which determines the stabilizing interactions of the hydrophilic end of the surfactant with the aqueous phase. Thus, while a non-ionic surfactant is stabilized by dipole and hydrogen bond interactions with the hydration layer of water on its hydrophilic surface, an ionic surfactant is

additionally stabilized by the electrical double layer. Thus, the effect of salt concentration on the stability of an emulsion or a microemulsion is more profound in the case of ionic surfactant than non-ionic surfactants. However for pharmaceutical applications, ionic surfactants are not preferred due to toxicological concerns. Non-ionic surfactants are generally considered to be acceptable for oral ingestion.

4. Co-surfactant

- Cosurfactants are mainly used in microemulsion formulation for following reasons: They allow the interfacial film sufficient flexible to take up different curvatures required to form microemulsion over a wide range of composition.
- Short to medium chain length alcohols (C3-C8) reduce the interfacial tension and increase the fluidity of the interface.
- Surfactant having HLB greater than 20 often require the presence of cosurfactant to reduce their effective HLB to a value within the range required for microemulsion formulation.
- Increase the fluidity of the interface.
- Destroy liquid crystalline or gel structure which would prevent the formation of microemulsion.
- Adjust HLB value and spontaneous curvature of the interface by changing surfactant partitioning characteristic

Following are the different cosurfactant mainly used for microemulsion:
Sorbitan monoleate, sorbitan monostearate, propylene glycol, propylene glycol monocaprylate, 2-(2-ethoxyethoxy) ethanol and ethanol.

5. Co-solvent

The production of an optimum microemulsion requires relatively high concentrations (generally more than 30% w/w) of surfactants. Organic solvents such as, ethanol, propylene glycol (PG), and polyethylene glycol (PEG) are suitable for oral delivery, and they enable the dissolution of large quantities of either the hydrophilic surfactant or the drug in the lipid base. These solvents can even act as co-surfactants in microemulsion systems.

EVALUATION OF MICROEMULSION

Microemulsion can be evaluated by various methods. They are:

1. Physical appearance

2. Scattering techniques
3. Limpidity test
4. Drug stability
5. Globule size
6. Viscosity measurement
7. Electrical conductivity
8. Drug solubility
9. pH
10. In vitro drug release

1) Physical appearance

For Physical appearance microemulsion can be inspect visually for homogeneity, fluidity and optical clarity.

2) Scattering Techniques

Scattering techniques such as small angle neutron scattering, small angle X-ray scattering and light scattering have found applications in studies of microemulsion structure, particularly in case of dilute monodisperse spheres, when polydisperse or concentrated systems such as those frequently seen in microemulsions.

3) Limpidity Test (Percent Transmittance)

The limpidity of the microemulsion can be measured spectrophotometrically using spectrophotometer.

4) Drug stability

The optimized microemulsion was kept under cold condition (4-8°C), room temperature and at elevated temperature (50 ± 2°C). After every 2months the microemulsion can be analysed for phase separation, % transmittance, globule size and % assay.

5) Globule size and zeta potential measurements

The globule size and zeta potential of the microemulsion can be determined by dynamic light scattering, using a Zetasizer HSA 3000.

6) Rheological Properties (viscosity measurement)

The rheological properties play an important role in stability. It can be determined by Brookfield digital viscometer. Change in the rheological characteristics help in determining

the microemulsion region and its separation from other region. Bicontinuous microemulsion are dynamic structures with continuous fluctuations occurring between the bicontinuous structure, swollen reverse micelle, and swollen micelles.

7) Electrical conductivity

The water phase was added drop wise to a mixture of oil, surfactant and co-surfactant and the electrical conductivity of formulated samples can be measured using a conductometer at ambient temperature and at a constant frequency of 1 Hz.

8) Drug solubility

Drug was added in excess to the optimized microemulsion formulation as well as each individual ingredient of the formulation. After continuous stirring for 24 h at room temperature, samples were withdrawn and centrifuged at 6000 rpm for 10 min. The amount of soluble drug in the optimized formulation as well as each individual ingredient of the formulation was calculated by subtracting the drug present in the sediment from the total amount of drug added. The solubility of drug in microemulsion was compared with respect to its individual ingredients.

9) pH of the microemulsions

The microemulsion samples is taken into the sample tubes and a μpH meter is used to determine the pH of the different samples as the pH of the formulation is not the only factor and that the stability of the microemulsions also imparts a role to alter the bioavailability of the drug through microemulsion at the site of permeation.

10) In vitro drug release

The diffusion study can be carried out on a modified Franz diffusion cell, within volume of 20mL. The receptor compartment was filled with of buffer. The donor compartment was fixed with cellophane membrane, containing the microemulsion formulation and the plain drug solution, separately. At predetermined time intervals samples were withdrawn from the receptor compartment and analyzed for drug content, using a UV spectrophotometer at specific wavelength.

STABILITY OF MICROEMULSION

Physical stability of the microemulsion shall be determined under different storage conditions (4, 25 and 40°C) for 12 months. Fresh preparations as well as those that have been kept under

various stress conditions for extended period of time are subjected to droplet size distribution analysis. Effect of surfactant and their concentration on size of droplet are also studied.

Accelerated Stability Tests

Centrifugation stress testing

Stability studies is time consuming process, so accelerated stability test is preferred. Microemulsion are centrifuged at 5000 and 10,000 rpm for 30 min were applied in order to assess the physical instabilities like phase separation, phase inversion, aggregation, creaming and cracking of the formulations. Previously thermally tested formulation are taken in centrifuge sample tubes and placed in the centrifuge basket at a well-balanced equilibrium position at ambient temperature conditions.

Long Term Stability

Stability can be examined according to ICH guidelines. The Microemulsion are stored under ambient conditions for 6 months, and the system was examined periodically after 1, 3, and 6 months by visual inspection and measurement of percent transmittance, pH, specific gravity, and rheological evaluation.

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