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STABILITY STUDY OF NEWLY FORMULATED EMULSION WITH MARKETED FORMULATION

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ABSTRACT: The aim of the article is to formulate and evaluate emulsion also perform comparative study with marketed formulation. Emulsion is a heterogeneous system consisting of at least one immiscible liquid dispersed in another in the form of droplets. Emulsion is prepared with castor oil and liquid paraffin. One marketed formulation was taken for comparison. Identification tests, evaluation tests and stability studies were performed. The emulsion was evaluated by the parameters like pH, viscosity and organoleptic properties. The stability study was performed by testing pH and viscosity. The results of the study showed the good organoleptic properties, pH, viscosity.

INTRODUCTION:

Emulsions: A heterogeneous system known as an emulsion is made up of at least one immiscible liquid dispersed in another in the form of droplets that typically have a diameter greater than 0.1 um. Because the droplets quickly coalesce and the two liquids separate, the system has a minimum stability. By using an additional component known as an emulsifying agent or emulsifiers, the stability of the emulsion is improved. While the liquid in which they are dispersed is known as the continuous phase or the dispersion medium or the external phase or the continuous phase, the liquid droplets are typically referred to as the emulsion phase or emulsion globules, dispersed phase, internal phase, or interrupted phase.

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The inclusion of a third material known as the emulsifying agent stabilises the system, making it possible to describe an emulsion as a dispersion system made up of two immiscible liquids, one of which is spread throughout the mixture in the form of tiny globules. For instance, milk is the best and most natural emulsion [8-13].

Purpose of Emulsion: Numerous medications that are unstable in aqueous solution become more stable.

1. It makes unpleasant substances taste better and more palatable.

2. Enhances the appearance of materials that are typically meant for acceptable topical form.

3. Emulsions can be used to make several medical substances that are otherwise difficult to swallow, such as cod liver oil, shark liver oil, castor oil, *etc*., more palatable for oral administration.

4. To create an immiscible liquid mixture (oil and water) that is homogenous.

5. By emulsifying the medication in an appropriate vehicle, certain drugs' activity can be boosted and their effect can be prolonged.

6. Patients who are unable to consume these essential substances orally can be given sterile, stable intravenous emulsions with lipids, carbs, and vitamins all in one preparation.

7. When used externally, dermatological preparations such as liniments, lotions, and creams aid in the fast absorption of medications from the skin surface [2, 3].

Advantages:

1. Medicines with a disagreeable taste or aroma may be more tolerable when taken orally as an emulsion, such as castor oil, cod liver oil, *etc*.

2. Emulsion offers defence against medications that are susceptible to hydrolysis or oxidation.

3. Emulsion is used in the formulation of several external medicines, including creams, lotions, and aerosols.

4. For patients who are unable to consume them orally, sterile stable intravenous emulsions including fats, carbs, and vitamins can be given.

5. When ingested, emulsions enhance the absorption of oil [1-5, 11].

Disadvantages: Emulsions are difficult to produce because they are thermodynamically unstable.

(1) Emulsion stability may be impacted by storage conditions

(2) Emulsions are heavy, challenging to move, and vulnerable to container damage.

(3) Susceptible to microbiological contamination, which may cause emulsion cracking

(4) For consistent and precise dosing, emulsions must be thoroughly shaken before use [1-5, 11].

Types of Emulsions:

1. Oil in water type (o/w) emulsions.

2. Water in oil type (w/o) emulsions.

3. Multiple emulsion

(a) Water-in-oil-in-water (w/o/w)

(b) Oil-in water-in oil (o/w/o)

4. Miscellaneous: Globule size or the disperse phase size of emulsion can vary enormously but are commonly in the range of 0.25-25um diameter.

On the basis of size emulsions are mainly of three types

(a) Coarse emulsion: globule size more than 25.0 μm.

(b) Fine emulsion: globule size less than 5.0 um

(c) Microemulsion of miceller emulsion: globule size range of 10-75 nm such emulsions appears transparent to the human eye in daylight.

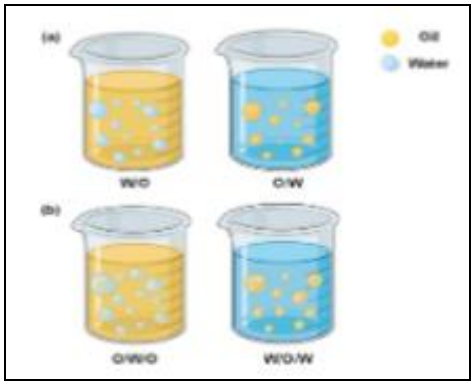

FIG. 1: TYPES OF EMULSIONS

Emulsifying Agents: Emulsifying agents, also known as emulgents, are compounds that lower the interfacial tension between the two phases, namely the aqueous phase and the oily phase, causing them to mix and create a stable emulsion.

Because no one emulsifying agent possesses all the traits needed to prepare a stable emulsion, it is occasionally necessary to combine two or more emulsifying agents in place of one to produce a product with the desired qualities. Emulsifying substances frequently employed include:

Natural Emulsifying agents from Vegetable Sources: Acacia, tragacanth, agar, chondrus and starch.

Natural Emulsifying agents from Animal Sources: Gelatin, egg yolk and wool fat.

Semi-synthetic Polysaccharides: Methyl cellulose and sodium carboxymethyl cellulose.

Synthetic Emulsifying agents: Anionic, cationic and non-ionic.

Inorganic Emulsifying agents: Milk of magnesia, magnesium oxide, magnesium trisilicate magnesium aluminium trisilicate, bentonite *etc* [1-4, 10].

Instabilities in Emulsions: When the globules in an emulsion maintain their initial characteristics, such as mean size and size distribution, and are evenly dispersed throughout the continuous phase, the emulsion is said to be stable. Emulsion instability during storage is supported by creaming, cracking, reversible or irreversible aggregation, *etc*.

Creaming: Two-region separation of an emulsion. One area is richer than the other in the disperse phase, but this instability is not severe. Shaking causes uniform dispersion, however creaming might cause cracking. Causes of Creaming Increasing of the differences in densities between the disperse phase and the dispersion medium. Changes in the storage temperature. Prevention of Creaming by using phases with equal densities, the density variations between the two phases are reduced. Storing in a cool location

Cracking: Redispersion cannot be done by shaking because the globules of the disperse phase reduce and segregate into a distinct layer. The preparation doesn't seem to an emulsion anymore. Causes of Cracking Addition of emulsifying agents of the opposite type: Soaps of monovalent metals -O/W emulsions and soaps of divalent metals - W/O emulsions. Oil is Stale. Prevention of Cracking Select the appropriate emulsifying agent. Make use of fresh oil when preparing.

Phase Inversion: Oil-in-water emulsion changes to a water-in-oil emulsion Or Water-in-oil emulsion changes to oil-in-water emulsion. Causes of Phase Inversion is using incorrect emulsifying agent addition. Which is prevented by using proper emulsifying agent [1, 2, 4, 10].

MATERIALS AND METHODS:

Materials: Eva Q Plus (Manufactured by Medley Pharmaceutical Ltd.) Was purchased as marketed formulation.

Methods: All required materials was collected and weighed according to formula given below: For 30 ml

Formulation 1:

TABLE 1: FORMULA OF CASTOR OIL EMULSION (F1)

Ingredients	Quantity
Castor Oil	8 ml
Purified water	Q.S
Gum Acacia	2 gm

Formulation 2:

TABLE 2: FORMULA OF LIQUID PARAFFIN EMULSION (F2)

Ingredients	Quantity
Liquid paraffin	8 ml
Purified water	Q.S
Gum acacia	2 gm

Type: Both the emulsions were O/w type emulsion for oral use.

Theory: Castor oil is a fixed oil and is not miscible with water. To make it miscible a third substance known as emulsifying agent in the ratio of 4:2:1 i.e. oil: water: gum will be used for the preparation of primary emulsion. Gum acacia will be used as emulsifying agent because emulsions prepared with gum acacia remain stable for sufficient long time.

Formula for primary emulsion: Oil: Water: Gum, 4: 2: 1, 8 ml: 4 ml: 2 ml

Procedure: Both the emulsion were prepared by wet gum method.

Wet Gum Method: Clean and dry a pestle and mortar thoroughly. 2 gm of gum acacia should be weighed out and added to the mortar. To create mucilage, triturate 4 ml of water with gum. Add 8ml castor oil to this, stirring thoroughly after each addition in little amounts. Triturate quickly and continuously until you hear a clicking sound and the product turns white or nearly white. The emulsion is referred to as primary emulsion at this point. In order to obtain a homogeneous product, add an additional 10 ml of vehicle in little amounts at a time while continuously triturating. Obtain the final volume of 30 ml by transferring the emulsion to a measure, adding extra vehicle, and carefully stirring.

Characterization of Emulsion:

Identification Tests for Emulsion:

Dilution Test: This test is based on the fact that an emulsion is miscible with its external phase. As a result, if water is added to o/w emulsion, it will readily disperse in an emulsion, but, if oil is added, it will not be dispersed. The reverse is true with w/o emulsion

Staining Test (Dye Solubility Test): In this experiment, an emulsion is mixed with a little amount of a water-soluble dye, such as methylene blue. Methylene blue will dissolve evenly in the system if the continuous phase is water (o/w emulsion), but if the continuous phase is oil (w/o emulsion), then the dye will remain as a culture on the surface [1, 2, 4, 5, 10].

Evaluation of Emulsions:

pH Determination: The pH of the emulsion is determined by using digital pH meter. Some amount of sample of emulsion is taken in beaker and rod of pH meter is dipped in sample and pH of sample is measured [5-7, 11, 15].

Viscosity Determination: Viscosity of the emulsion is measured by using Brookefield's Viscometer. For measuring the viscosity the appropriate spindle should be attached to the Brookefield's Viscometer for correct measurement. Set the appropriate speed [1, 2, 5, 6, 8, 9, 11, 15].

Organoleptic Properties: For evaluation of the organoleptic properties of the emulsions the colour of emulsion and odour of the emulsion us checked [2, 5].

Accelerated Stability Test: This test was carried out to determine any changes made to the emulsion system's physical characteristics. The emulsion was kept in a 40°C oven for 24 hours at an excessive temperature. After the sample has been removed from the oven, characteristics including pH and viscosity are assessed [6-8, 10, 14, 15].

RESULT AND DISCUSSION:

Identification Tests:

Dilution Test and Staining Test (Dye solubility Test): Prepared formulations and marketed formulation of emulsion was diluted with the water and shaked result was observed and in Staining Test (Dye solubility test) methylene blue was added to the F1, F2 and F3 and the result was observed.

TABLE 3: RESULT OF DILUTION TEST AND DYE SOLUBILITY TEST

Formulation	Dilution test	Dye solubility test	Conclusion
F1	Oil and water phases were separated. Oil floats on water	Uniformly dissolution in system	O/W Emulsion present
F2	Oil and water phases were separated. Oil floats on water	Uniformly dissolution in system	O/W Emulsion present
F3	Oil and water phases were separated. Oil floats on water	Uniformly dissolution in system	O/W Emulsion present

The formulations were diluted with water and oil phase separated and methylene blue were added in Formulations uniform dissolution of methylene blue in system was observed. Therefore water is continuous phase and oil is dispersed phase. So emulsions are o/w emulsions.

Evaluation of Emulsions:

TABLE 4: ORGANOLEPTIC PROPERTIES, VISCOSITY, PH DETERMINATION OF SAMPLES

Spindle no 61 was used for measurement of the viscosity of emulsions at 100 rpm speed.

Formulations	pH	Viscosity in cP	Colour	Odour
F1	9.89	6.24	Creamy White	Insignificant
F2	15.98	12.50	Creamy White	Insignificant
F3	11.20	26.82	Creamy Pink	Insignificant

Accelerated Stability Test: The sample was kept in oven for 24 hours at 24ºC and result were observed of the pH and viscosity change. The samples withdrawal was done after 12 hours and the pH and viscosity were measured. The sample withdrawal was done after 24 hours and the pH and viscosity were measured.

TABLE 5: PH DETERMINATION AFTER ACCELERATED STABILITY TEST

Formulations	Initial pH At 0 hour	After 12 hours	After 24 hours
F1	9.89	7.03	5.93
F2	15.98	9.97	7.50
F3	11.20	9.10	8.97

TABLE 6: VISCOSITY DETERMINATION AFTER ACCELERATED STABILITY TEST

Formulations	Initial viscosity At 0 hour	After 12 hours	After 24 hours
F1	6.24	4.26 cP	3.36 cP
F2	12.50	10.56 cP	10.26 cP
F3	26.82	23.81 cP	Sample solidified

After 24 hours, F1 samples colour get brownish. The pH of the sample get decreased and the viscosity of sample get decreased. F2 samples oil phase and water phase is separated. The pH of the sample get decreased and the viscosity of sample get decreased. F3 sample get solidified so the viscosity cant be determined. The pH of the sample get decreased.

CONCLUSION: All the required quantity was collected and preparation of the castor oil emulsion and liquid paraffin emulsion was successfully done. The identification tests like Dilution test, dye test were performed for identification. The Evaluation parameters like organoleptic properties, pH, viscosity of the emulsion were measured and the result was acceptable. The formulated emulsions showed good organoleptic properties, pH, viscosity. The accelerated stability study was performed and result showed that the pH and viscosity of sample decreases. So it is concluded that when emulsions were kept for 24 hours its pH and viscosity were affected.

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