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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment

To demonstrate the quality control test and evaluationof the emulsionas per the monographs.

Aim:

To demonstrate the quality control test and evaluationof the emulsionas per the monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 173 – 175

Apparatus and Materials Required :

Shide, beaker, dropper, test tubes, pipette and sucker, filter paper, emulsion sample, water soluble dye (Amaranth), oil soluble dye (Sudan-III), distilled water, centrifuge machine.

Procedure :

The evaluation tests carried out for emulsions are discussed below:

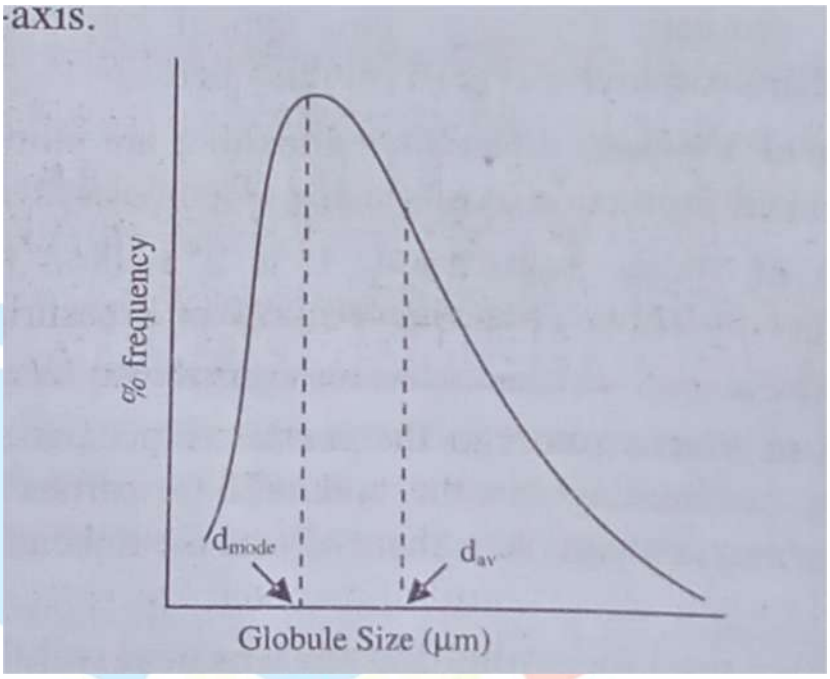
1) **Determination of Particle Size and Particle Count:** The emulsions are also evaluated for any changes in their average particle size or the size distribution of droplets Processes like optical microscopy and Coulter counter method are employed to perform this operation.
2) **Determination of Viscosity:** The emulsions that are stored for longer time periods are checked for their viscosity using viscometers.
3) **Determination of Phase Separation:** It is a method for examining the emulsion stability by either observing visually or measuring the volumes of separated phases.
4) **Determination of Electrophoretic Properties:** Flocculation of emulsion can be evaluated by determining its electrophoretic properties like

zeta potential, since electrical charge on particle surface affects the flocculation rate.

Following methods are used for evaluating the physical stability of emulsions

1) **Dilution Test:** If the emulsion remains stable after dilution with water, it is o/w type; and if it breaks after dilution, it is w/o type. This test is based on the fact that more of the continuous phase can be added into an emulsion without causing stability problem.
2) **Dye Test:** In this test, scarlet red dye is mixed with the emulsion, and a drop of this emulsion is viewed under a microscope. If the globules are red and ground is colourless, the emulsion is w/o type.
3) **Conductivity Test:** In this test, a pair of electrodes is connected to a lamp and an electric source is dipped in the emulsion. If the lamp glows, the emulsion is o/w type; and if the lamp does not glow, it is w/o type.
4) **Fluorescence Test:** In this test, the emulsion is exposed to fluorescence light and viewed under a microscope If the entire field fluoresces, the emulsion is w/o type; and if the emulsion is spotty, it is o/w type.
5) **Macroscopic Examination :** The physical stability of an emulsion is examined by its degree of creaming or coalescence occurring over a time period. This is carried out by calculating the ratio of volume of the creamed or separated part of the emulsion and the total volume and then comparing these values for different products.
6) **Extent of Phase Separation :** Study of phase separation provides a proper understanding of practical and commercial features of stability. This study involves a quick method and is used to evaluate poorly formed and rapidly breaking emulsions. Even if the indications of instability (creaming and coalescence) occur at an early stage, phase separation occurs after a certain time period.
7) **Globule Size Distribution :** The appearance of bigger size globules is an earlier sign of instability The small globules aggregate and coalesce on prolonged storage of emulsion, thus, leading to its instability The globule size distribution of emulsions can be analysed microscopically for evaluating their physical stability This method is almost similar to the optical microscopy method for particle size analysis in micromeritics.

Figure 16 represents a graph plotted between the globule diameters (globule size in um) on the x-axis and the frequency or number of globules of each size on the y-axis.



The surface area of globules is more associated with physical stability than the globale size distribution. After its manufacture, the emulsion immediately undergoes active coalescence for a time period, throughout which the emulsion becomes stable and independent of the strains induced in the preparation. After this time period, the emulsion remains stable on extended storage.

8) **Accelerated Stability Studies – Centrifugation :** Flocculation and creaming are slow processes which can be accelerated by using ultracentrifuge producing stress conditions within the system. At room temperature, the emulsions are exposed to diverse range of centrifugal speeds (2000-3000rpm) and the phase separation is examined at certain time intervals (figure 17).

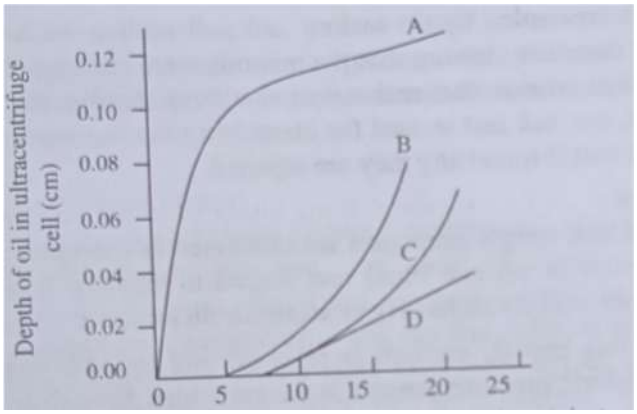


Figure 17: Oll coalescence-time profile of different emiddons fole types. Curve A is a had emaldian, and B, C and D are good emulsions

9) **Microwave Irradiation :** In this method, the emulsion is subjected to microwave radiations Subsequently, its surface temperature increases and the temperature gradient existing between the surface and the bottom should be small enough to maintain the stability.

Result :

The quality control test and evaluationof the emulsion as per the monographs was studied.

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