Evaluation of Elixirs

Elixirs are clear, sweetened hydro-alcoholic solutions intended for oral use and are usually flavored to enhance their palatability.

Determination of alcohol content: Elixir usually contains 5 to 40% alcohol. The determination of alcohol unless otherwise specified in the individual monograph.

Viscosity measurement: Viscosity is a property of liquids that is directly related to the resistance to flow. Viscosity measurement is a very important quality control test in the case of syrups and elixirs.

Evaluation of Suspensions

A pharmaceutical suspension is a coarse dispersion in which insoluble particles, generally greater than 1 μm in diameter, are dispersed in a liquid medium, usually aqueous.

Sedimentation method: Two parameters are studied for the determination of sedimentation. They are (i) Sedimentation volume and (ii) Degree of flocculation.

Sedimentation Volume: The suspension formulation (50 ml) is poured separately into 100 ml measuring cylinders and sedimentation volume is read after 1, 2, 3, and 7 days, and thereafter at weekly intervals for 12 weeks. Triplicate results are obtained for each formulation. Sedimentation volume is calculated according to the equation:

$$F = \frac{V_u}{V_o}$$

where, F = sedimentation volume

V_u = ultimate height of sediment

V_o = initial height of total suspension

Degree of flocculation (β): It is the ratio of the sedimentation volume of the flocculated suspension (F), to the sedimentation volume of the deflocculated suspension, (F_∞).

$$\beta = \frac{F}{F_\infty} = \frac{\text{Floculated sedimentation volume}}{\text{Defloculated sedimentation volume}}$$

F has values ranging from less than one to greater than one.

Normally $F < 1$.

When $F < 1 \leftrightarrow V_u < V_o$

When $F = 1 \leftrightarrow V_u < V_o$

The system is in flocculated equilibrium and show no clear supernatant on standing.

When $F > 1 \leftrightarrow V_u > V_o$

Higher the value, higher will be the stability.

Rheological method: Viscosity of suspensions is of great importance for stability and pourability of suspensions. As we know suspensions have the least physical stability amongst all dosage forms due to sedimentation and cake formation. So as the viscosity of the dispersion medium increases, the terminal settling velocity decreases thus the dispersed phase settle at a slower rate and they remain dispersed for a longer time yielding higher stability to the suspension. On the other hand as the viscosity of the suspension increases, its pourability decreases, and inconvenience to the patients for dosing increases. Thus, the viscosity of suspension should be maintained within the optimum range to yield stable and easily pourable suspensions.

- A practical theological method involves the use of a Brookfield viscometer mounted on a helipad stand. The T-bar spindle is made to descend slowly into the suspension, and the dial reading on the viscometer is then a measure of the resistance the spindle meets at various levels in sediment.
- Data obtained on samples variously aged and stored indicate whether undesired changes are taking place. This measurement is made on undisturbed samples of different ages. The results indicate how the particles are settling with time.

Electrokinetic method: In this zeta potential is measured by using micro electrophoresis apparatus and zeta plus (Brookhaven instruments corporation, USA). It shows the stability of a dispersed system.

E.g. micro-electrophoresis apparatus MK-1.

Zeta potential: The zeta potential of the formulated suspensions is determined using a zeta plus (Brookhaven instruments corporation, USA). Approximately 1 ml of suspension is transferred into a plastic cuvette using a pipette and diluted with distilled water. The Brookhaven zeta potential software is used for the measurement. Parameters set to a temperature of 25°C and refractive index (1.33). The zeta potential of the formulations is determined on days 0, 7, 14, 21, and day 28 post formulation.

Micromeritic method: The stability of suspension depends on the particle size of the dispersed phase. Change in the particle size concerning time will provide useful information regarding the stability of a suspension. A change in particle size distribution and crystal habit can be studied by microscopy and the Coulter counter method.

Freeze-thaw test: Freeze-thaw test conducted by placing the sample in a freezer for 18 hours followed by thawing at room temperature for 4 to 6 hours. Repeat the freeze-thaw cycle 10 times. This test is conducted to determine the tendency to crystallize or color.

pH measurement: The measurement and maintenance of pH is also a very important step in quality control testing.

Visual inspection: With a visual inspection, the ingredients and the final products are carefully examined for purity and appearance. The physical appearance of products for patient adherence and compliance is critical so it should be:

- Good looking
- Elegance in appearance

Evaluation of Emulsions

An emulsion is a system consisting of two immiscible liquid phases, one of which is dispersed throughout the other in the form of fine droplets. A third component, the emulsifying agent, is necessary to stabilize the emulsion.

Determination of particle size and particle count: Determination of changes in the average particle size or the size distribution of droplets is an important parameter used for the evaluation of emulsions. It is performed by optical microscopy, sedimentation by using Andreason apparatus and colter apparatus.

Determination of viscosity: Determination of viscosity is done to assess the changes that might take place during aging. Emulsions exhibit the non-Newtonian type of flow characteristics. The viscometer which should be used maybe a cone and plate viscometer.

Determination of phase separation: This is another parameter used for assessing the stability of the formulation. Phase separation may be observed visually or by measuring the volume of the separated phases.

Determination of electrophoretic properties: Determination of electrophoretic properties like zeta potential is useful for assessing flocculation since electrical charges on particles influence the rate of flocculation. Oil in water emulsion having a fine particle size will exhibit low resistance but if the particle size increase, then it indicates a sign of oil droplet aggregation and instability.

Electrical conductivity: It is determined by using platinum electrodes (diameter 0.4 mm, distance 4mm) micro amperometrically to produce a current of 15 to 50 mA. Measurements are made on emulsions stored at room temperature or 37°C for short time. Stable o/w emulsion offers less resistance, but droplet aggregation increases resistance. A stable w/o emulsion does not conduct electrodes, but with the droplet, coagulation conductivity increases.