



C) Emulsifying agent assists in the formation of emulsion by forming following interfacial films

- a) Formation of rigid interfacial film (mechanical barrier of coalescence)
- b) Formation of electrical double layer – (electrical barrier to approach of particles)

a) The dispersed globules are known to acquire an electric charge during the process of emulsification. The globules gather two charged layers around themselves called Helmholtz double layer. The electrical double layer consists of stern layer i.e. the layer of charged ions on the surface and the diffuse layer consisting of charged ions distributed upto varying distances around stern layer. The potential produced by the double layer creates a repulsive effect between the oil droplets and thus hinder coalescence.

b) The surface active agents tend to concentrate at interfaces and the emulsifiers are adsorbed at oil – water interfaces as monomolecular films. If the concentration of the emulsifier is high enough, it forms a rigid film between the immiscible phases which acts as a mechanical barrier to both adhesion & coalescence of emulsion droplets.

D) Particulate matter is defined as extraneous, mobile, undissolved substances other than gas bubbles, unintentionally present in injections – (1 mark)

Sources of particulate matter – (1 ½ mark)

- a) Intrinsic Contamination:- the materials which are originally present in parenteral solution are known as intrinsic contamination eg. Barium ion leach in parenteral product which may react with sulphur ion in the product to form barium sulphate crystals.
- b) Extrinsic Contamination:- It is the material which comes from environment and contaminate product eg. Shedding of material from the body & clothes of the person, ceiling, wall, furniture of the room, eg. cotton, glass, rubber, plastics, tissue, insect, fragments, dust, paper etc.

Methods for detection of particulate contamination

- a) Visual Method
- b) Coulter Counter Method
- c) Filtration Method
- d) Light Blockage Method

(1 Mark)

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Lingsheng Yao



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