## PHARMACEUTICS CASE STUDY

### SUBJECTIVE INFORMATION

Working for an innovative pharmaceutical company, you have received a request to develop an oral liquid formulation for a new organ rejection drug. The drug must be formulated so that a 5-mg dose can be reasonably easily administered either as the dosage form or immediately after mixing with water or juice. The formulation should be stable and easy to manipulate. The problem is that the drug is not water soluble but a solution dosage form is desired.

### OBJECTIVE INFORMATION

The drug has a molecular weight of 1015.2 and occurs as a white to off-white powder that is insoluble in water but freely soluble in benzyl alcohol, chloroform, acetone, and acetonitrile.

The drug may be prepared as an aqueous suspension or as a solution in a water-miscible liquid that can be diluted prior to administration. A reasonable dispersant liquid for the insoluble drug may include a blend of lecithin products that would form liposomes upon dilution in an aqueous vehicle. Some commercial blends occur as honey-colored fluids with a typical odor and nutty taste. These can be diluted with water and have densities of approximately 1 to 1.2 and viscosities in the range of 5,000 mPa.

It may be wise to add a dispersant such as polysorbate 80 to aid in mixing when this is added to water or juice. Polysorbate 80 (Tween 80, polyoxyethylene 20 sorbitan monooleate, $C_{64}H_{124}O_{26}$) has a molecular weight of 1,310 and occurs as a yellow oily liquid with a characteristic odor and a warm, somewhat bitter taste. It has a specific gravity of 1.06 to 1.09, and its HLB is 15.0; it forms o/w emulsions. It is stable in the presence of electrolytes, weak acids, and weak bases. It should be stored in a well-closed, light-resistant container in a cool place (5).

### ASSESSMENT

After viewing the options, you decide to select a solvent system for the drug and prepare it as a solution. The patient can obtain the dose and dilute it immediately prior to administration. This meets the criteria of stability and ease of administration.

You select a commercial dispersant liquid for oral use containing 50% phosphatidylcholine in propylene glycol, sunflower seed oil glycerides, soy acid, alcohol, and ascorbyl palmitate. This product is used as a dispersant, emulsifier, penetrant, and solubilizer for pharmaceuticals, creams, lotions, emulsions, and liposome preparations for dermatology. It is suitable for oral use.

### PLAN

You formulate the product as a 5-mg dose in 1 mL of the vehicle containing 0.5% polysorbate 80 in the described dispersant liquid. This will provide a stable, easy-to-use product.

For administration, the proper quantity of the oral liquid will be added to approximately 2 to 4 oz of water or juice. The preparation should be vigorously stirred and taken at once. Various juices can be used depending on the preference of the patient.