nature of the active substance(s) and to provide organoleptic characteristics appropriate to the intended use of the preparation.

Several categories of preparations may be distinguished:

- powders and granules for oral solutions and suspensions
- powders and granules for syrups
- powders for oral drops
- powders for injection.

Powders and granules for solution or suspension

Powders and granules for the preparation of oral solutions or suspensions generally conform to the definitions in the normal pharmacopoeial standards for oral powders or granules as appropriate. They may contain excipients, in particular to facilitate dispersion or dissolution and to prevent caking. After dissolution or suspension, the resulting product should comply with the requirements for oral solutions or oral suspensions, as appropriate.

The label should explain the method of preparation of the solution or suspension from the powder or granules, and the conditions and the duration of storage after reconstitution.

Powders and granules for syrups

Syrups are aqueous preparations characterized by a sweet taste and a viscous consistency. They may contain sucrose at a concentration of at least 45%. The sweet taste can also be obtained by using other polyols or sweetening agents. Syrups usually contain aromatic or other flavouring agents.

All of the necessary ingredients for the syrup may be manufactured and stored in the dry powdered or granular state and then reconstituted (usually by the addition of water alone) at the time of dispensing or administration. After dissolution, the resulting syrup must comply with the normal pharmacopoeial requirements for syrups.

Antibiotic syrups. For patients who have difficulty taking capsules and tablets, e.g. young children, a liquid preparation of a drug offers a suitable alternative. Unfortunately, many antibiotics are physically or chemically unstable when formulated as a solution or suspension. The method used to overcome this instability problem is to manufacture the dry ingredients of the intended liquid preparation in a suitable container in the form of a powder or granules. When the product is dispensed, a given quantity of water is added to reconstitute the solution or suspension. This enables sufficient time for warehousing and distribution of the product and storage at the pharmacy without degradation. Once it is reconstituted, the patient must be warned of the short shelf-life. A shelf-life of 1–2 weeks for the reconstituted antibiotic syrup should not be a serious problem for the patient as the dosing would normally be complete by then. Examples are Amoxicillin Oral Suspension and Erythromycin Ethylsuccinate Oral Suspension.

Powders for oral drops

Oral drops are solutions, emulsions or suspensions that are administered in small volumes, such as in drops, by the means of a suitable device. Powders for the preparation of oral drops would have to conform to requirements of all other oral powders. They may contain excipients to facilitate dissolution or suspension in the prescribed liquid, or to prevent caking.

After dissolution or suspension, they comply with the specific pharmacopoeial requirements for preprepared oral drops. If the dose is measured in drops, the label should also state the number of drops per millilitre or per gram of preparation.

Powders for injection

Injections of medicaments that are unstable in aqueous solution must be made immediately prior to use. The ingredients are presented as sterile powders in ampoules or vials. Sufficient diluent, e.g. sterile Water for Injections, is added from a second container to produce the required drug concentration and the injection is used immediately. The powder may contain suitable excipients in addition to the drug, e.g. sufficient additive to produce an isotonic solution when the injection is reconstituted.

Powders for injection are most often manufactured by a freeze drying process (Chapter 29). The sterilization of these 'lyophilized powders' is described in Chapter 17 and their use as parenteral products is discussed in more detail in Chapter 36.

The label for powders for injection should state i) the amount of active ingredient contained in the sealed container, ii) the directions for preparing the injection or intravenous infusion from the powder and iii) that when dissolved or suspended, the preparation is intended for parenteral use.