satisfactory mix of all the ingredients in order to achieve uniformity of dosage in every dosage unit, and fast and uniform powder flow in high-speed tableting and encapsulation machines. For convenience, the mixing of liquids and semi-solids is also discussed here as the basic theory is the same.

Another extremely important area that must be understood before a satisfactory dosage form can be designed and manufactured is the microbiological aspects of medicines development and production. It is necessary to eliminate viable microorganisms from the product both before and during manufacture. Microbiology is a very wide-ranging subject. This book concentrates only on those aspects of microbiology that are directly relevant to the design, production and distribution of dosage forms. This mainly involves avoiding (asepsis) and eliminating (sterilization) the presence (contamination) of microorganisms in medicines, and preventing the growth of any microorganism which might enter the product during storage and use of the medicine (preservation). Techniques for testing that these intentions have been achieved are also described. The principles and practice of sterilization are also discussed. The relevant parts of pharmaceutical microbiology and sterilization are considered in Part 3 of this book.

It is not possible to begin to design a satisfactory dosage form without knowledge and understanding of how drugs are absorbed into the body, the various routes that can be used for this purpose and the fate of the drugs once they enter the body and reach their site(s) of action. The terms 'bioavailability' and 'biopharmaceutics' are defined and explained in Part 4. The factors influencing the bioavailability of a drug and methods of its assessment are described. This is followed by a consideration of the manner in which the frequency of drug administration and the rate at which drug is released from a dosage form affect its concentration in the blood plasma at any given time. This book concentrates on the preparation, administration, release and absorption of drugs but stops short at the cellular level and leaves to other texts the detail of how drugs enter individual cells, how they act and how they are metabolized and eliminated.

Having gathered this understanding of the basics of pharmaceutics, the formulation scientist should now be equipped to begin a consideration of the design and manufacture of the most suitable dosage forms for the drug in question.

Superficially, the formulation and manufacture of dosage forms containing drugs may seem relatively straightforward. The chapters in Part 5 will demonstrate that this is not the case. Formulation scientists are able to realize the full potential as a medicine of the active pharmaceutical ingredient, whether it is a small synthetic molecule, a plant extract or a biotechnology product. Good formulation can enhance therapeutic efficacy and/or limit adverse effects. A couple of examples illustrate this:

a. Whilst an immediate-release capsule of nifedipine has a dosing frequency of three times a day, formulation as a modified-release capsule permits once-daily dosing, with an improved drug plasma profile and increased patient convenience and compliance.
b. A cream formulation of a sunscreen applied to the skin restricts the active component(s) to the skin surface, whilst a gel formulation of estradiol, also applied to the skin surface, is formulated so as to ensure effective penetration of drug through the skin and into the systemic circulation.

The first stage of designing and manufacturing a dosage form is known as preformulation. This, as the name implies, is a consideration of the steps that need to be performed before formulation proper can begin. Preformulation involves a full understanding of the physicochemical properties of drugs and other ingredients (excipients) in a dosage form and how they may interact. An early grasp of this knowledge is of great use to the formulation scientist as the data gathered in these early stages will influence strongly the design of the future dosage form. Results of tests carried out at this stage of development can give a much clearer indication of the possible (and indeed impossible) dosage forms for a new drug candidate.

Following, consideration of preformulation, the remaining chapters of Part 5 cover the formulation, small and large scale manufacture, and the advantages, disadvantages and characterization of the wide range of available dosage forms. The properties of these dosage forms can be modified dependent on the properties of the drug, excipients included, the route of drug administration and specific patient needs. Early chapters consider liquid dosage forms, namely solutions (drug dispersed as molecules or ions), suspensions (drug dispersed as particles) and emulsions (one liquid phase dispersed in another, with drug present in either phase, dependent upon its relative solubility). Appropriate formulation of emulsions results in more structured semi-solid