creams, most frequently used for application to the skin. These dosage forms may be administered by a number of routes, and their formulation requirements will vary dependent on the route of administration.

Whilst drugs in the solid state can be administered as simple powders, they are more usually formulated as solid dosage forms, namely tablets (currently the most commonly encountered solid dosage form) and capsules. Several chapters in this Part describe the various stages in the processing of a powder required to manufacture tablets: granulation (formation of drug-excipient aggregates), drying, compaction and coating. Tablet formulation and manufacture requires inclusion of several excipients, including fillers, disintegrants, binders, glidants, lubricants and antiadherents. The purposes of these are described, together with their impact on product quality and performance. The strategies to modify the release of drug from solid dosage forms include: production of monolithic matrix systems, the use of a rate-controlling membrane or osmotic pump systems. These are described in a separate chapter, as are other solid dosage forms: hard and soft gelatin capsules. For all dosage forms, drug must be released at an appropriate rate at the appropriate site for drug action and/or absorption to occur. This is particularly pertinent for solid peroral dosage forms, which must permit dissolution of drug at an appropriate rate and at an appropriate site within the gastrointestinal tract. Bioavailability (i.e. the amount of drug that is absorbed into the bloodstream) may be limited by the rate of drug dissolution, whilst the pH range in the gastrointestinal tract (pH 1–8) may adversely affect the absorption of ionizable drugs. Consequently, dissolution testing is a key quality control test and is considered in detail here.

Solid dosage forms are administered predominantly (though not exclusively) by the oral route. Whilst the oral route is the most common way of administering drugs, many other routes for administration exist and these are each considered in detail. Such routes include parenteral administration (injections, infusions, implants), pulmonary (aerosols), nasal (sprays, drops, semisolids, powders), topical and transdermal (semisolids, patches, liquids, powders, wound dressings), ungual (nail lacquers, liquids), ocular (drops, semisolids, injection, implants), rectal (suppositories, tablets, capsules, semisolids, liquids, foams) and vaginal (pessaries, semisolids, liquids, tampons). For each route, consideration is given to the nature of the administration site and the formulation requirements to localize drug action, or to control absorption, either to enhance systemic drug efficacy or minimize systemic adverse effects. The dosage forms available for delivering drugs by each route are outlined and particular aspects regarding their formulation and manufacture are highlighted. The methods used to characterize and test these dosage forms, for formulation development and quality assurance purposes are also detailed.

The final chapters of Part 5 reflect special considerations in dosage form design and manufacture that result from the needs of specific patient groups (in particular the elderly and young children), drugs of natural (plant) origin (which may comprise extracts having many complex components, potentially of variable composition) and biopharmaceutical products. Some of the latter products, for instance insulin, are long established, whilst others, such as nucleic acids for gene therapy, offer exciting therapeutic possibilities for the future. All are relatively large macromolecules and present particular formulation and drug delivery challenges. To meet some of these and indeed other challenges, pharmaceutical nanotechnology has become established in recent years as a means of improving solubility and dissolution rate, protecting drugs from hostile environments, minimizing adverse effects and delivering drugs to specific therapeutic targets. The preparation and properties of various nanomedicines, including antibodies, polymer-drug conjugates, liposomes, nanoparticles and dendrimers are considered.

Before finalizing the formulation and packaging of the dosage form, there must be a clear understanding of the stability of the drug(s) and other additives in a pharmaceutical product with respect to the reasons why, and the rates at which, they may degrade during storage. Aspects of product stability, stability testing and the selection of appropriate packaging to minimize deterioration during storage are considered in Part 6. No product will be stable indefinitely, and so mechanisms (i.e. the fundamental chemistry) and kinetics of degradation must be understood so that a safe and realistic shelf-life for every product can be determined.

The product pack and any possible interactions between it and the drug or medicine it contains are so vitally linked that the final pack should not be considered as an afterthought. Instead, packaging considerations should be uppermost in the minds of