Consideration should be given to differences in the bioavailability of drugs and their bio-fate in patients between apparently similar formulations and possible causative reasons. In recent years, increasing attention has therefore been directed towards eliminating variation in bioavailability characteristics, particularly for medicinal products containing an equivalent dose of a drug substance, as it is recognized that formulation factors can influence their therapeutic performance. To optimize the bioavailability of drug substances, it is often necessary to carefully select the most appropriate chemical form of the drug. For example, such selection should address solubility requirements, drug particle size and physical form and consider appropriate additives and manufacturing aids coupled to selecting the most appropriate administration route(s) and dosage form(s). Additionally, suitable manufacturing processes, labelling and packaging are required.

There are numerous dosage forms into which a drug substance can be incorporated for the convenient and efficacious treatment of a disease. Dosage forms can be designed for administration by alternative delivery routes to maximize therapeutic response. Preparations can be taken orally or injected, as well as being applied to the skin or inhaled, and Table 1.1 lists the range of dosage forms which can be used to deliver drugs by the various administration routes. However, it is necessary to relate the drug substance to the clinical indication being treated before the correct combination of drug and dosage form can be made, since each disease or illness often requires a specific type of drug therapy. In addition, factors governing choice of administration route and the specific requirements of that route which affect drug absorption need to be taken into account when designing dosage forms.

Many drugs are formulated into several dosage forms of varying strengths, each having selected pharmaceutical characteristics which are suitable for a specific application. One such drug is the glucocorticoid prednisolone used in the suppression of inflammatory and allergic disorders. Through the use of different chemical forms and formulation additives, a range of effective anti-inflammatory preparations is available, including tablet, enteric-coated tablet, injections, eye drops and enema. The extremely low aqueous solubility of the base prednisolone and acetate salt makes these forms useful in tablet and slowly absorbed intramuscular suspension injection forms, whilst the soluble sodium phosphate salt enables a soluble tablet form and solutions for eye and ear drops, enema and intravenous injection to be prepared. The analgesic paracetamol is also available in a range of dosage forms and strengths to meet the specific needs of the user, including tablets, dispersible tablets, paediatric soluble tablets, paediatric oral solution, sugar-free oral solution, oral suspension, double-strength oral suspension and suppositories.

In addition, whilst many new drugs based on low molecular weight organic compounds continue to be discovered and transformed into medicinal products, the development of drugs from biotechnology is increasing and the importance of these therapeutic agents is growing. Such active compounds are macromolecular and of relatively large molecular weight, and these include materials such as peptides, proteins and viral components. These drug substances present different and complex challenges in their formulation and processing into medicines due to their alternative biological, chemical and structural properties. Nevertheless, the underlying principles of dosage form design remain applicable.

Table 1.1 Dosage forms available for different administration routes

Administration route	Dosage forms
Oral	Solutions, syrups, suspensions, emulsions, gels, powders, granules, capsules, tablets
Rectal	Suppositories, ointments, creams, powders, solutions
Topical	Ointments, creams, pastes, lotions, gels, solutions, topical aerosols, foams, transdermal patches
Parenteral	Injections (solution, suspension, emulsion forms), implants, irrigation and dialysis solutions
Respiratory	Aerosols (solution, suspension, emulsion, powder forms), inhalations, sprays, gases
Nasal	Solutions, inhalations
Eye	Solutions, ointments, creams
Ear	Solutions, suspensions, ointments, creams