

Table 24.4 Requirements of pharmaceutical solutions, with respect to their route of administration—cont'd

Route of administration	Requirements of the solution
<p>Nasal</p> <p>Nose drops, nasal sprays, used for local, e.g. decongestant effect, or for systemic drug delivery.</p>	<p>Nasal solutions are aqueous formulations.</p> <p>Solution pH is in the normal pH range of nasal fluids (pH 5.5 to 6.5).</p> <p>Solutions are usually isotonic to nasal fluids.</p> <p>Solution viscosity is similar to that of nasal mucus (which is higher than that of water).</p> <p>Flavouring or sweetening agents are sometimes used to mask taste, as a small proportion of nasal solution may be swallowed following nasal administration.</p> <p>Multidose solutions require preservatives.</p>
<p>Pulmonary</p> <p>Inhaled solutions are administered by pressurized metered-dose inhalers (pMDIs) or by nebulizers for local or systemic effect.</p>	<p>Solutions of drug and excipients dissolved in liquefied propellants, such as trifluoromonoethane, are used in pMDIs.</p> <p>Solutions used in nebulizers are aqueous formulations. As relatively large volumes may be administered by nebulizers, the solutions must be isotonic and have a pH not lower than 3 and not higher than 8.5.</p> <p>Multidose preparations containing preservatives are available, although generally, sterile, single unit doses without a preservative are used.</p>
<p>Rectal</p> <p>Solution enemas are usually administered for local or systemic drug action.</p>	<p>Enemas can be aqueous or oily solutions.</p> <p>Micro-enemas have a volume of 1 to 20 mL, while macro-enemas have volumes of 50 mL or more.</p> <p>Macro-enemas should be warmed to body temperature before administration.</p>
<p>Vaginal</p> <p>Vaginal solutions are administered for local effect, for irrigation or for diagnostic purposes.</p>	<p>Vaginal solutions are aqueous.</p> <p>Excipients to adjust pH may be included.</p>
<p>Parenteral</p> <p>'Parenteral' refers to the injectable routes of administration. Drugs are most commonly injected into the veins (intravenous), muscles (intramuscular) and into (intradermal) and under (subcutaneous) the skin, although they can also be injected into arteries, joints, joint fluid areas, spinal column, spinal fluid and the heart.</p>	<p>Parenteral solutions must be sterile and pyrogen-free.</p> <p>Preservatives, such as benzyl alcohol, are included under certain conditions such as in multidose products.</p> <p>Intravenous – the solution must be aqueous, as oil droplets can occlude the pulmonary microcirculation.</p> <p>Intramuscular and subcutaneous – The solution can be aqueous or non-aqueous.</p> <p>Ideally, a parenteral aqueous solution should have a pH close to physiological pH (which is 7.4), to avoid pain, phlebitis and tissue necrosis. A pH of 7.4 may not however be the optimum pH for drug solubility and product stability, and since a reasonably wide pH range can be tolerated, the pH of most licensed parenteral solutions is between 3 and 9. A wide pH range is tolerated as the administered solution is diluted upon administration, most notably with the intravenous route.</p> <p>Parenteral solutions must be isotonic when large volumes are administered by intravenous infusion. When smaller volumes are used, a wider range of tonicity can be tolerated as dilution with body fluids occurs.</p>