

Safety Assessment of Inhalant and Dermal Route Drugs

While the two most common routes for administering a drug are either orally or parenterally (by injection), there are many other routes that can be used. The two next most common are inhalation (with all its variations) and dermally.

Each route has special considerations as to the evaluation of their safety—both regulatory and technological—which this chapter will consider in turn.

1 INHALED THERAPEUTICS

Drugs and medicinal agents administered by the inhalation route include the gaseous and vaporous anesthetics, coronary vasodilators, the aerosols of bronchodilators, corticosteroids, mucolytics, expectorants, antibiotics, and peptides and proteins where there is significant nasal absorption (Cox et al., 1970; Williams, 1974; Paterson et al., 1979; Hodson et al., 1981; Lourenco and Cotromanes, 1982). Concerns with the environmental effects of chlorofluorocarbons has also led to renewed interest in dry-powder inhalers, which have additionally shown promise for better tolerance and absorption for some new drugs. Excessive inhalation of a drug into the pulmonary system during therapy or manufacturing may result in adverse local and/or systemic effects. Consequently, safety assessment of inhaled medicinal preparations with respect to