- Fewer steps in synthesis
- Passes carcinogenicity, mutagenicity, and lethal dose 50 (LD50) level testing
- Nonhygroscopic
- Crystalline with sufficient solid-state stability
- Possible to be administered orally, with sufficient bioavailability
- No strong colors or odors
- Compatible with standard excipients

Obviously, not all conditions are met, but by every compound we keep this direction in mind, it is easier to sift through many possibilities offered. It requires testing a range of selected compounds in in vitro and in vivo animal studies, and thus, preformulation work gets combined with biopharmaceutic studies to identify product design issues.

One of the major factors that often slows down the preformulation studies is the availability of a sufficient quantity of a compound at this stage, especially if biopharmaceutic studies are conducted; as a result, methods that would utilize the smallest quantity of the substance need to be devised; this is amply emphasized throughout the testing phases in this book. Another factor that often slows down the work at this stage is the often-misplaced importance on validated test methods and documentation; while this is desired, the perennial shortage of manpower requires that some things take secondary importance.

1.3.4 Stage 4: Preclinical Studies (1–2 Years)

Preclinical trials (4–6 years):

- Pre-IND meetings with the FDA
- *Preclinical trials stage I*: Acute toxicity, detailed pharmacological studies (main effect, side effect, and the duration of effect), analytical methods for active substance, and stability studies
- *Preclinical trials stage II*: Pharmacokinetics (absorption, distribution, metabolism, and excretion), subchronic toxicity, teratogenicity, mutagenicity, the scale-up of synthesis, the development of the final dosage form, and the production of clinical samples (Chemistry, Manufacturing, and Control [CMC] section for the FDA)

1.3.5 Stage 5: Phase I Clinical Studies (1–2 Years)

This is the stage of proof of concept or phase I testing to understand how the candidate drug is absorbed and metabolized in healthy human volunteers before testing it in patients. Often small-scale studies are done in patients when the cost factors are high, to make sure that there is sufficient indication for the drug's utility. There are significant differences in regulatory filings at this stage; in the United States, a fully approved IND is required, whereas in Europe, these filings are not required. Also, once an IND has been filed with the U.S. FDA, any study conducted overseas comes under the purview of this IND. Some companies may therefore decide to conduct their phase I studies prior to filing INDs in the United States to circumvent the issue