laboratory to avoid any confusing test results over time. An interesting practice that can serve the purpose of confirming the consistency of the physical form of the API is to employ optical microscopy as a routine inspectional test for individual batches of the API. The key in such a test is to assure that representative samples of the API batch must be examined in using the test to confirm the comparability of the product, batch after batch.

SPECIFICATIONS

The specifications developed for a new generic API must meet all USP monograph requirements, if a USP monograph exists for the API, as well as to satisfy all the current FDA/International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidances concerning impurities, residual solvents, and other specified attributes. The scope of specifications for an API will typically include

- Identity testing
  - Active moiety (IR preferred as well as specific chromatographic procedures)
  - Identification of specific counter-ions if API is a salt
- Impurity testing (includes degradants formed post-manufacture of the material)
  - Specified identified and specified but unidentified, individual, and total
  - Residual solvents (including USP organic volatile impurities)
  - Heavy metals (elemental impurities and/or other specific elements)
- Other specified tests
  - Morphic form, including particle size
  - Others (such as water, pH, and assay)

The USP has recently posted on its website a guideline for describing the content of a typical USP monograph. The terminology in the guideline is consistent with all current ICH practices and descriptors [8].

All test procedures should be validated in accordance with standard practices. It is important to note that, in the absence of any waiver, all specifications must be met through the designated shelf life or expiry dating or re-test date for the material. Part of the development of final specifications is the performance of stability studies for the material in the final container closure system in which the material is sold to the API consumer. An important part of the API process is to establish user-friendly "Certificates of Analysis." To the extent possible, all test results should be reported with actual findings and not left to the end point of "Complies." The test method employed should be easily identified if compendial methods are used, that is, specify the exact test method used. A critical factor in developing specifications is to have available well-defined reference standards for all tests that require a standard. In the absence of a USP monograph (or any other major compendia, such as the European Pharmacopeia, British Pharmacopeia, Japanese Pharmacopeia, and the World Health Organization), which typically defines which tests need a reference standard, the API supplier needs to follow established practices to develop and