



**SCHEME 8.3** Decision tree for the disposition of degradation products. (Courtesy of Pharmquest Corporation, Mountain View, CA.)

define the degradation products and their limits. Scheme 8.3 shows a decision tree for handling the degradation products in the drug substance.

### 8.2.2.1 Impurities

Organic and inorganic impurities and residual solvents are included in this category. Scheme 8.4 shows a decision tree that can be used to decide the disposition of impurities in the drug substance.

### 8.2.3 Physicochemical Properties

Physicochemical properties are properties, such as the pH of an aqueous solution, melting point/range, and refractive index. The procedures used for the measurement of these properties are usually unique and do not need much elaboration, for example, capillary melting point and Abbe refractometry. The tests performed in this