

Stability-Indicating HPLC Methods for Drug Analysis.

Xu QA, Trissel LA. American Pharmaceutical Association, Washington, DC, 1999.

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Stability-Indicating HPLC Methods for Drug Analysis is the first compilation of proven stability-indicating high-performance liquid chromatographic (HPLC) methods. The information in this book is for busy analytical chemists who evaluate drug stability in various dosage forms, and for those involved in quality control and drug regulation. It is a quick reference for determining if a stability-indicating HPLC method is available in the literature. A variety of other important chemical information, such as chemical name, molecular weight, solubility and pKa, is also given.

Stability-indicating methods are only a small subset of the HPLC methods reported in the literature. This reference lists more than 500 stability-indicating methods, covering 250 different drug entities. Each monograph is presented in a structured format consisting of 4 sections, which cover a total of 27 different elements. The first section lists the basic chemical information an analyst would find useful. The second section gives a summary of the method, which describes the information an analyst requires to reproduce the method. The third section describes the procedure used to prepare the degradation samples and the results of analyzing these samples. The final section summarizes the information assuring that the method adequately demonstrates specificity, precision, reproducibility, and sensitivity.

By compiling most of the known methods in one volume, this book greatly reduces the time-consuming task of finding stability-indicating assays. It is set up

alphabetically for easy retrieval of the information, and drug and brand names are cross-referenced in the index. It provides enough information to allow methods to be sufficiently reproduced, as well as guidance for preparing degradation samples and validating methods. Other pertinent information is also consolidated into one concise source. The authors stress that even though these methods are stability-indicating, each analyst must validate this in his or her own laboratory.

One shortcoming of this and any other similar textbook is that the information becomes outdated as soon as it is published. The references listed cover the literature as of 1998; therefore, a literature search would still be needed to capture the most recent methods. However, the search could be restricted to the most recent years, which would save some time. A spot check of some of the monographs indicated that a few were missing relevant stability-indicating methods.

Overall, this is a concise, well-written reference that consolidates most of the stability-indicating HPLC methods into one source. If it is borne in mind that this is not an all-encompassing reference list, experienced analysts will find it a useful starting point to determine the methods reported in the literature up to 1998.

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