

Abstract ECOP

Workshop « Practical stability studies for anticancer drugs : How to perform ? How to find relevant information ? »

How to find and use relevant information on stability ?

Searching for information on stability is essential for the daily practice of hospital pharmacists for the preparation of medications or for giving information to the clinical wards.

The main journal publishing articles on stability and the international databases (Handbook on injectable drugs, Trissel's stability of compounded formulations, King guide to parenteral admixtures, Stabilis) are presented. Precautions for the use of these data are recalled and detailed. Examples of the main defaults found in publications are presented : lack of stability indicating capacity, use of a non stability indicating analytical method, questionable chromatographic conditions, bad repeatability, insufficient number of samples, degradation products not taken into account, discordance between abstract and article, great variation in the results, biological stability but without physical and chemical evaluation, bad interpretation or discussion, surprising results not discussed.

Criteria for the extrapolation of the results presented in publications for our specific daily practice are discussed. Galenic form, generics, container, solvent, concentration, temperature are critical factors that influence the decision.

As Lawrence Trissel recalls in the preface of his handbook, databases are a tool and a guide to the research that has been conducted and published. It is not a replacement for thoughtfully considered professional judgment.

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How to perform stability study ?

Carrying out a stability study is one of the scientific missions of the hospital pharmacist. If stability data are not available in the literature, the pharmacist should perform stability studies.

The realisation of a stability study is a complex work which requires the study of several elements such as physical stability (visual and subvisual examination), chemical stability by a validated separative analytical method.

To help the hospital pharmacist and the researchers to carry out a stability study, ValiStab[®] is a tool created to validate all the steps of a stability study (linearity, precision, stressed degradation). It makes it possible to study the stability of a classic molecule, under different conditions (concentrations, solvents, containers, temperature).

All the steps necessary to carry out a stability study are integrated into the same file, ValiStab[®]. Each researcher can adapt the data of the file according to his stability study, respecting all the necessary steps. This software must allow each researcher to open an account with an identifier and a password, to access these stability studies in progress, finished, or to start a new stability study.

ValiStab[®] will soon be available for free on the Stabilis database.