

# Policy for Publication of Chemical Stability Study Manuscripts

To keep pace with current science and technology and to ensure that stability studies published in the *Canadian Journal of Hospital Pharmacy* provide reliable and accurate data, the editors of *CJHP* have adopted a policy concerning stability study manuscripts. The editorial by Trissel<sup>1</sup> and the commentary by Trissel and Flora<sup>2</sup> form the basis of this policy. *CJHP* requires that all manuscripts reporting drug stability must include the following:

## I. A complete description of the materials, methods and test conditions

## II. A complete description of procedures used to validate the analytical method

Methods and results must provide documentation verifying that the analytical method used is stability-indicating. Investigators must demonstrate that their method can discriminate between the parent compound and degradation products. This can be done in one of two ways:<sup>1</sup> (a) indicate that pure standards of each degradation product were obtained and in the presence of these degradation compounds, parent compound was measured specifically, without interference; or (b)

indicate that degradation product(s) were created by intentionally degrading the parent drug using heat and, if necessary, acid or base. Investigators using a previously published method should also provide similar information verifying that, in their hands, the method is also stability-indicating. Each investigator is also encouraged to provide additional proof of assay validation which may include ultraviolet spectroscopy, mass spectral identification and/or mass balance of parent compound and degradation product(s).

## III. Complete disclosure of testing times including baseline or control measurements

A characteristic of good research is the presence of a control, baseline or initial measurement. In stability studies if an initial (time zero) measurement is not reported, then conclusions concerning the stability of the compound cannot be made with any confidence. For example, if it is reported that after 30 days storage the potency of parent drug is 85 percent of label claim, in the absence of data reporting analysis from day zero, it cannot be determined whether the product has degraded, or was initially below label claim.

## IV. Documentation of analytical reproducibility

In general, the more reproducible sample concentrations are from day-to-day, the greater the level of confidence in the results. Investigators should provide documentation indicating the reproducibility of their method and are encouraged to ensure that their method can confidently detect at least a 10 percent change in concentration, if such a change did occur.

## V. Appropriate conclusions

Ensure that conclusions accurately reflect the observed results of the paper.

Failure to meet these minimum standards, could result in lengthy delays prior to publication or rejection of the paper.

By requiring that all manuscripts comply with these standards, stability studies published in this journal will provide accurate and valid data which pharmacists can use confidently in practice. ☐

## REFERENCES

1. Trissel LA. Avoiding common flaws in stability and compatibility studies of injectable drugs. *Am J Hosp Pharm* 1983;40:1159-60.
2. Trissel LA, Flora KP. Stability studies: Five years later. *Am J Hosp Pharm* 1988;45:1569-71.