



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

***This page of Chapter 4 of the Australian Regulatory Guidelines for OTC Medicines (ARGOM) was replaced on 28 June 2006. The information below is provided for historical reference only. Please refer to the ARGOM for the most current information.***

## Stability testing

Full details of stability testing conducted on the product together with associated validation must be included in the submission. This section provides guidance as to the design, conduct and reporting of stability studies for OTC medicines.

The guidelines are based on the principles and requirements set out in *Guidelines on the stability testing of pharmaceuticals*, included as Appendix 9 to the *Australian guidelines for registration of drugs Volume 1 (AGRD1)*<sup>1</sup>.

Departure from the principles set out in this document will only be considered when adequately justified.

### General principles

The objective of a stability study is to determine the time during which a pharmaceutical product meets appropriate standards when stored under defined conditions. The product must be shown to remain, or is likely to remain, within its expiry specifications throughout the proposed shelf life when stored under the proposed storage conditions. Thus the difference between release and expiry specifications must take into account the results of stability testing.

### Critical summary of the stability studies

In addition to providing full details of the stability studies undertaken in support of registration of a product, a separate critical analysis of each study should be provided. Each of the points listed below should be addressed separately for each stability study.

A table giving batch numbers, batch types (pilot or production), batch size or scale, storage conditions (temperature, humidity, lighting conditions, and storage upright or inverted for liquids), and storage durations. If the storage conditions were not controlled, this should be stated.

A statement whether all (or some) of the batches tested were identical with the product intended for marketing in terms of formulation and container (if not, the differences should be justified and full details provided).

A statement whether the method of manufacture and manufacturing equipment for the batches tested were identical with the product intended for marketing (If not, the differences should be justified and full details provided).

<sup>1</sup> [www.tga.gov.au/docs/html/agrd1.htm](http://www.tga.gov.au/docs/html/agrd1.htm)