

## **1 Purpose**

The purpose of this Guideline is to outline the requirements in the expiration dating of all analytical reagents and solutions prepared from these reagents. Recommendations are also included on how to achieve compliance.

## **2 Scope and Applicability**

This Guideline is applicable to all manufacturing Operations sites operating laboratories required to meet GMP and/or ISO standards. It applies to all analytical reagents used in analytical work, excluding those associated with Biological Drug Products.

## **3 Definitions**

None.

## **4 Responsibilities**

It is the responsibility of each laboratory manager to establish, document and operate procedures to assign expiry dates to reagents, and solutions prepared from reagents, and record these on each container at the time of receipt (reagents) or preparation (solutions).

## **5 Guideline**

### **5.1 Purchased Reagents**

**5.1.1** On receipt of purchased reagents the date should be recorded on each container so that it's approximate age is subsequently known. An expiry date as well as the opening date must be added when the reagent is taken into use in the laboratory.

**5.1.2** Where the supplier's label or catalogue indicates specific storage conditions then these must be strictly observed.

**5.1.3** Where no conditions are specified then material must be stored in sealed containers at room temperature, in an area preventing exposure to excessive heat and humidity, and commensurate with the potential hazard of the material. Example: Flammable reagents and solvents must be stored in fire resistant cupboards. Large packages and hazardous material must be stored in fire resistant cupboards and near the ground. Material producing toxic fumes must be stored in a fume cupboard or ventilated area.

**5.1.4** During their life in the laboratory, care should be taken that in-use contamination is avoided.

**5.1.5** If there is any doubt about the acceptability of a reagent it must be either re-tested before use, or if this is not possible, it must be discarded and a new supply obtained.