

## 5.2 Laboratory Prepared Reagents

5.2.1 These are normally solutions, for example, volumetric, buffers, indicators, reference standards and general reagents. They must be stored in suitable glass or plastic containers and labeled with:

The name of the reagent  
Strength and/or factor  
Date of preparation and/or standardization  
Initials of person preparing the reagent  
Expiry date  
Storage conditions  
Reference to the source of raw data (if possible)

5.2.2 The Chemistry Manufacturing Control (CMC) Dossier may contain comments such as 'prepare fresh,' 'standardise immediately before use,' 'protect from light,' 'store in a plastic container' etc. these conditions where specified must be strictly adhered to.

## 5.3 Test of Reagent

When necessary, tests should be performed to confirm that reagents are suitable for their intended purpose, e.g. positive or negative controls to verify the suitability of microbiological culture media. Tests on reagents should be recorded.

## 5.4 Storage Lives

### 5.4.1 Specific Recommendations

- Unless stated on the container or experience dictates otherwise, solid reagents will normally be stable for a period of 5 years if correctly stored.
- Buffer solutions must be discarded after 3 months unless otherwise specified.
- Solutions used, as reference standards for limit tests must be prepared immediately before use and discarded after use.
- Volumetric solutions of Molarity less than 0.01 M must be prepared immediately before use and then discarded after use.

### 5.4.2 General Recommendations

A storage life of 12 months should generally be adopted for all solutions of reagents or indicators unless otherwise stated above or in the CMC Dossier or if experience indicates otherwise. Volumetric solutions must be re-standardized at least monthly.