

Standard Operating Procedure

Title: Management of Reference Substances

1.3.4. Write on the actual label of the bottle of Reference Substance itself the information below. Use a permanent ink pen and ensure information is clear.

- Assigned Reference Number
- Date received
- Storage location
- Expiry/ Retest dates are not straightforward for some products, but for Primary reference reagent solutions these can also be written on the bottles.

Place a protective layer of sticky tape on the information especially when written on the larger bottles.

1.3.5. Place some "masking tape" around the lid of the bottle for bottles that do not have a seal to break when first opened. This tape will serve as a reminder for the analyst to write down a "Date bottle opened" date for the bottle and advise Authorised lab. person to update information on the Summary Sheet (Form-330) and on Reference Substances Log.

1.5.11 Place the bottle in the appropriate locations as instructed by the manufacturer:

- The Laboratory Desiccator.
- The Laboratory Freezer
- The Laboratory Fridge
- The Laboratory Safe

1.4. Coding of Primary and Impurity Reference Substances

The reference number is issued to each bottle of Reference Substance received to individually identify each bottle to its Certificate of Analysis and to correlate them to a controlled standards referencing system. The reference number is generated using the following format:

- e.g. P\ ISO\ XXX\ 2, Standard (ISO) here being Isosorbide-5-mononitrate
- The first section indicates whether the Reference Substance is either Primary (P), or Impurity (I). Note Impurities are also referred to as break down product (BDP) to avoid confusion in naming.
- The second section indicates the first three letters of the Active family of the Reference Substance.
- The third section is the manufacturer's batch number of the Reference Substance collected from the C of A.
- The fourth section is the bottle number of the batch received.

2. Primary Reagent Reference Solutions (PRRS)

Analytical standards supplied as a solution for direct use or accurate dilution, for example commercially prepared volumetric reagents are also be considered for use as PRS. A reputable supplier should be used and a Certificate of Analysis for the substances should be attained. These are referred to as Primary Reagent Reference Solutions (PRRS).

Note: Purchased volumetric solution for titrimetric use are not subject to the procedures described in this SOP. Laboratory analyst using these must refer to SOP LAB-035.

2.1. Ordering of Primary Reagent Reference Solution.

2.1.1. Ordering of these PRRS is assigned to Laboratory staff doing Reference Substance maintenance. The PRRS should be ordered through a reputable supplier, and a Certificate of Analysis should be attained.

2.2. Registration of the Primary Reagent Reference Solutions