PROCEDURE

Storage of Reagents

AUTHOR

Quality Control Assistant	Signature……

VERIFICATION

Quality Control Manager	Signature……

AUTHORIZATION

Quality Assurance Manager	Signature …… Date 29.08.2013

Expiry Date **29/08/2015**

Re-Approvals Form

RE-APPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

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0. Revision Matrix

REVISION	DATE	UPDATE CARRIED OUT AND REASON FOR UPDATE
01	29/08/2013	The monitoring of temperature and humidity by data logger of the reagents storage area was added in order to acquire information of the daily storage conditions of these reagents. Date Rev. 00 Withdrawn: 02/09/2013
02		Date Rev. 01 Withdrawn
03		Date Rev. 02 Withdrawn
04		Date Rev. 03 Withdrawn
05		Date Rev. 04 Withdrawn
06		Date Rev. 05 Withdrawn
07		Date Rev. 06 Withdrawn
08		Date Rev. 07 Withdrawn
09		Date Rev. 08 Withdrawn

1. Scope and Application

To standardize the criteria for management of Laboratory Reagents used for carrying out analysis. The term reagent also refers to products which do not directly participate in the chemical reaction.

2. Responsibility

The person responsible for the Laboratory must ensure that the correct management of Reagents is being carried out.

3. Procedure

1. General Information

- Reagents must meet requirements according to a pre-defined quality which depends on their specific use and their critical parameters must be known.

- Reagents prepared in the Laboratory and their laboratory checks must be carried out according to dedicated Methods which have been written by and/or verified by the Head of Quality Control or derived from a qualified publication or from supplier instructions.

- The availability of reagents must be such as not to cause delays or interruptions in the Control analysis: each item must be managed according to its minimum stock defined, which is based on the known availability time and procurement time.

- All the stock must be kept in the defined conditions, adequate room or adequate area, which is requested by the Security Standards.

- The Quality Control Laboratory must draw-up a table for each reagent (excluding those prepared freshly) which contains the following information:

    - Product Name
    - Product Code
    - Minimum stock
    - Material Safety Data
    - Supplier
    - Supplier code
    - Batch number
    - Date of arrival
    - Quantity
    - Storage location

- Signature

- The Quality Control Laboratory must register in real time the preparation of each Internal Reagent in a notebook dedicated and in FORM 41 "Logbook Internal Reagents".
  In the said Form the following information is registered:
  - Identification data of the Internal Reagent: Name, Code;
  - Batch Number
  - Preparation (Date and Signature);
  - Quantity;
  - Storage location;
  - Expiry date;

The batch number is assigned by Quality Control as described below:
QC 00X/YZ, where 00X is a progressive number made up of 3 numbers and YZ represent the year in which the internal reagent is prepared.
The "Logbook for Internal Reagents" (FORM 41) is made up of 10 pages (Page X of Y) and is issued by Quality Assurance reporting the date of emission and assigning the appropriate signature on all the pages of the Logbook. Quality Assurance also report the year of reference and assign a progressive number in the same year.
At the end of logbook compilation, the successive logbook issued by Quality Assurance must be compiled continuing to assign a progressive batch number for Internal Reagents when in the same year.

2. Technical Management

- When receiving a solvent, its quality, storage conditions and expiry date should be verified against its certificate of analysis after which the certificate should be appropriately archived. All certificates should be signed and dated for approval. If the solvents arrive without a corresponding certificate, it is the duty of the lab analyst to search for it on the suppliers' website or contact the supplier. It is the analyst's duty also, to write on the solvents original label, its internal code and the expiry date according to the guidelines provided in the section named 'Stability'.

- The reagents should be handled in an appropriate manner so as to leave unchanged their physico-chemical characteristics throughout their Validity Time:
  - ✓ when stored in containers different to their original, the said containers should be made up of material which is compatible with the reagents itself, and should contain adequate closures;
  - ✓ all precautions relating to hazards and stability of the reagent should be adopted;

- ✓ reagents which require special storage conditions should be immediately stored in a suitable place, and should be placed back in their adequate storage immediately after use.
- ✓ The area in the Quality Control Laboratory dedicated to storing reagents that can be stored at room temperature is monitored by a data logger which is set to record temperature and humidity every ten minutes. Quality Control is required to unload this data every Monday morning. A tolerance period of one week is given to this activity since the data logger can store temperature and relative humidity data from two weeks. Quality Control is permitted to not unload the data loggers during the holidays.

- All the reagents should be labeled as follows:

A. Reagents in their original containers:

- ✓ On arrival, the internal code and the expiry date (as defined in the 'Stability' section of this procedure) should be written on the original label;
- ✓ When opened, the opening date and expiry date (as defined in the 'Stability' section of this procedure) should be written on the original label;

B. Reagents in containers different to the original ones and reagents prepared in the laboratory:

- ✓ On every container, a label should be applied (shown below) showing,
  - Information which identifies the Reagent: Name, Code, Batch number;
  - Initial quantity (Gr.)
  - Opening date of original container or date of preparation
  - Expiry date (as defined in the 'Stability' paragraph of this procedure)
  - Signature

REAGENT

QC.SOP.005/All.02
Rev.01
Data 29.08.2013

Name _____

Code _____

Batch _____

Gr. _____

Prepared ____/____/____ Expires ____/____/____ Signature _____

3. Stability

Based on the information provided by the manufacturer and the product literature, a Validity Time is established by the head of quality control, for each reagent and is approved by the Head of Quality Control. The Validity Time is the period of time during which the critical parameters of the reagent remain constant and fall within an expected tolerance range.

In the case of reagents and solvents known to be stable, or in which their characteristics are not critical for their work, the supplier's expiry date is considered valid, even after opening, until a Validity Time of **3 years**.

Distilled water and Water for HPLC have an established Validity Time of **6 months**.

Methanol dry and has an established Validity Time of **3 months**.

Buffers have an established Validity Time of **6 months**.

In the case or titrants, the expiry date of the supplier is considered valid for unopened substances; after opening, the Validity Time is **three months** for the Redox titrants and **6 months** for acid-base titrants. For this reason, all titrants should be acquired in the smallest possible size available.

The Validity Time is assumed to be the reference for the expiry date, and is calculated from the opening date of the item in the case of bought reagents, or from the date of preparation in the case of reagents prepared in the Lab.

Reagents which have expired must not be used anymore. Any exceptions must be immediately authorized by the head of quality control and any exceptions must still be supported by experimental data demonstrating the usability of the reagent, by checking the stability or providing updated values of its critical parameters.

In these cases, the label must be updated, particularly the new expiry date, and applied to the said reagent. The new expiry date and any other corrections should be approved by the head of quality control or by a designated person. Therefore, on the basis of what has been defined and unless there are different requirements by the manufacturer, the Validity Time is defined as:

- ✓ **3 years** for solvents and reagents whose characteristics are not critical for their intended use;
- ✓ **6 months** for distilled water and water for HPLC;
- ✓ **6 months** for acid-base titrants;
- ✓ **6 months** for buffers;
- ✓ **3 months** for Methanol dry;
- ✓ **3 months** for Redox titrants;

4. Documentation

Attached is the Reagent Table, QC.SOP.005/All.01
The certificate of analysis released by the supplier must be archived until the relative batch ends.