PROCEDURE

Preparation and Storage of Retained Samples

AUTHOR

Quality Control Assistant	Signature……

VERIFICATION

Quality Control Manager	Signature …….

AUTHORIZATION

Quality Assurance Manager	Signature ……. Date 22.04.2013

Expiry Date **22/04/2015**

Re-Approvals Form

RE-APPROVED ON _____

EXPIRES ON _____

QUALITY ASSURANCE _____

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Revision Matrix

REVISION	DATE	UPDATE CARRIED OUT AND REASON FOR UPDATE
01		. Date Rev. 00 Withdrawn
02		Date Rev. 01 Withdrawn
03		Date Rev. 02 Withdrawn
04		Date Rev. 03 Withdrawn
05		Date Rev. 04 Withdrawn
06		Date Rev. 05 Withdrawn
07		Date Rev. 06 Withdrawn
08		Date Rev. 07 Withdrawn
09		Date Rev. 08 Withdrawn

REVISION	DATE	UPDATE CARRIED OUT AND REASON FOR UPDATE
10		Date Rev. 09 Withdrawn
11		Date Rev. 10 Withdrawn
12		Date Rev. 11 Withdrawn
13		Date Rev. 12 Withdrawn
14		Date Rev. 13 Withdrawn
15		Date Rev. 14 Withdrawn
16		Date Rev. 15 Withdrawn
17		Date Rev. 16 Withdrawn
18		Date Rev. 17 Withdrawn

1. Scope and Application

To standardize the operations for the preparation, management and storage of retained samples of pharmacologically active raw materials, intermediates and finished products.

2. Responsibility

The Head of Quality Control is responsible for defining the operations.

The Laboratory analyst is responsible for carrying out the operations.

3. Procedure

Retained samples should be prepared and managed according to the general instructions as follows:

- The quantity should be sufficient enough to carry out at least two complete analysis.

- Finished Products are generally stored in containers which are well sealed and stored away from light.

- The storage conditions are the same as for products from which they originate, and in any case are stored in locked cabinets, which are dedicated to them, and their access is controlled by the head of Quality Control, and the key is the possession of Quality Control.

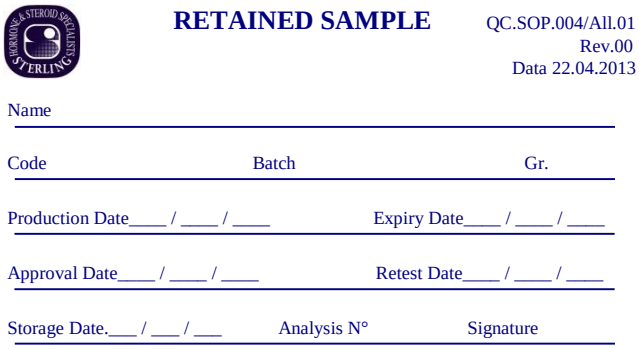
- In the cabinet designated for the storage of retained samples, there is a data logger for the monitoring of temperature and relative humidity. Each week, the data should be downloaded onto a computer and data must be checked.
  The Quality Control Lab must check, putting date and signature, that the temperature has not exceeded 40°C and that the humidity has not exceeded 75%. The choice of limits is justified on the basis of available stability data. Quality Assurance are responsible to communicate any different conditions.
  In the case of any deviations, in which the temperature and/or humidity results outside the limits provided, this should be documented and treated according to G.SOP.018, and the material/product involved should be re-analysed, verifying whether it has been degraded or can remain in use.
  During holidays, the Quality Control Laboratory is not required to download data.

- Finished Products must be stored for one year after the stability program has finished; the starting materials and intermediates must be stored for one year after the stability program has finished of the batch of finished product from which they were used.

- Once the storage time has ended, the retained samples should be discarded according to the current regulations regarding the management of waste.

- The labels of the retained samples must contain the following information:

  - Identification data: name, code, and batch number;
  - Quantity;
  - Analysis Number;
  - Date of Production;
  - Expiry Date (stability on the basis of the stability information available at the moment of storage);
  - Date of Approval;
  - Retest Date;
  - Storage Date;
  - Analysts Signature.


RETAINED SAMPLE QC.SOP.004/All.01 Rev.00 Data 22.04.2013

Name

Code Batch Gr.

Production Date____ / ____ / ____ Expiry Date____ / ____ / ____

Approval Date____ / ____ / ____ Retest Date____ / ____ / ____

Storage Date.___ / ___ / ___ Analysis N° Signature

For each update of the stability information, Quality Control must update, by signing the date and signature, the table of retained samples (QC.SOP.004/All.03), situated in the cabinet used for storage of retained samples, on which the following information is recorded:

- Name of Product;
- Batches in stability reported for process validation;
- Expiry date updated on the basis of stability information available.

4. Documentation

The management of retained samples is documented in the Register Retained Samples (QC.SOP.004/All.02) reporting for each of them the following information:

- Prooduct
- Batch
- Code
- Micronisation code (refers to the micronisation batch number),
- Quantity
- Date of Production
- Expiry Date
- Date of Approval
- Date of Storage

- Signature
- Registration of withdrawal: eventual withdrawals carried out during the storage period, indicating the amount withdrawn (*Quantity Withdrawn*), the reason (*Reason for Withdrawal*) and the date of withdrawal together with the signature of who withdrew the sample (*Signature*)
- Notes.

This documentation must be kept by Quality Control for at least 10 years from the storage date of each batch.