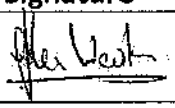
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_005

SOP Title: Storage of clinical trial medication (within pharmacy)

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**	Effective date stamp	

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	
3	1-June-2018	Reviewed to ensure content is still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for storing clinical trial medication in the pharmacy.

1.2 Covers the procedures to follow to identify areas within pharmacy that are approved for clinical trial medication storage and the steps to be taken to ensure that clinical trial medication are stored appropriately. The term clinical trial medication will cover investigational medicinal products (IMPs), and other medicinal products which may be provided by the sponsor for a specific trial (e.g. non-investigational medicinal products - nIMPs). The detailed procedure for temperature monitoring is covered in the procedure for temperature monitoring of clinical trial medication storage areas.

2. DEFINITIONS

3. PROCEDURE and RESPONSIBILITIES

3.1 Establishing the storage condition

3.1.1 As part of the trial review and set up process, ascertain the required storage condition for each clinical trial medication with reference to the protocol, investigator's brochure, Summary of Product Characteristics, pharmacy manual or other sponsor/trial specific information/documentation.

3.1.2 Contact the sponsor for further information if there is any doubt as to how the product should be stored. Print all correspondence relating to this and file in the pharmacy trial file.

3.1.3 Document in the trial specific pharmacy instructions: the storage condition and location of each clinical trial medication.

3.2 Storage of clinical trial medication within pharmacy

3.2.1 Store clinical trial medication in a secure area accessible only to pharmacy staff and other authorised members of the site team.

3.2.2 Ensure the storage location is temperature monitored in line with the standard operating procedure for *Temperature monitoring of clinical trial medication storage areas* (CP/R&D_021), and ensure *Clinical trial medication storage area assessment form* (Form 03) has previously been completed and that the area has been approved as a suitable storage area for clinical trial medication. Please note, if a new storage area is required, complete a new *Clinical trial medication storage area assessment form* (Form 03) for the proposed area to assess its suitability.

3.2.3 Ensure all areas used for clinical trial medication storage are temperature regulated, e.g. ambient temperature storage areas are temperature controlled by air conditioning systems.

3.2.4 For high risk drugs (e.g. cytotoxic, biological or otherwise high risk), assess the safe handling and storage requirements of clinical trial medication as part of the pharmacy feasibility assessment of a clinical trial. This may require additional information from the sponsor or manufacturer such as Control of substances hazardous to health (COSHH) data or material safety data sheet (MSDS) data.

3.2.5 Segregate clinical trial medication for each clinical trial in clearly marked approved areas. Be sure to carry out any actions necessary to avoid incorrect selection of clinical trial medication.

3.2.6 Consider capacity issues in fridges, freezers and ambient temperature storage areas before clinical trial medications are received on site.

3.2.7 Store quarantined and returned clinical trial medication, e.g. expired stock to be destroyed and returns from patients, in an area clearly marked for this purpose, and segregate from in use clinical trial medication to avoid its inadvertent use.

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Ensure correct procedures are followed.
2	Clinical Trials Pharmacist	Staff involved with the day to day management of IMP's	Temperature monitoring and reporting of temperature deviations.
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Clinical trial medication storage area assessment form (Form 03)

5. TRAINING

The Clinical Trial details, which are specific to each individual trial, must have been read.

6. REFERENCES

For more detailed guidance/reference, refer to:

- Section 6.14 of the MHRA Good Clinical Practice Guide, 2012.
- Professional Guidance on Pharmacy services for clinical trials, National Pharmacy Clinical Trials Advisory Group, Version1, October 2013.
- The safe and secure handling of medicines: A team approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society". March 2005.