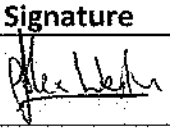
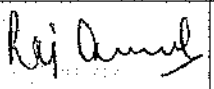
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_012

SOP Title: Quarantining of Investigational Medicinal Products

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-Dec-2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 – Reviewed to check that SOP is still current	
3	1-June-2018	Reviewed to check that content still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

- Provide clear procedures for the quarantining of Investigational Medicinal Products (IMPs). Reasons may include temperature deviations, damage to IMPs or due to lack of QP certification.

2. DEFINITIONS

- Temperature deviation – any deviation from the recommended temperature range.

3. PROCEDURE and RESPONSIBILITIES

3.1 If any IMPs have been stored outside the recommended range of temperatures, or are thought to be faulty for any reason then they must be quarantined until it is confirmed whether or not they can be used.

3.2 When a shipment has been received, unpack the shipment and store the contents in the appropriate condition under quarantine and follow CP/R&D_004

3.2 Separate any IMPs to be quarantined clearly from other products (for example in a plastic bag, cardboard box, or, if needed, an entire cupboard/fridge), and attach a "quarantined" sign to the affected IMPs or fridge/cupboard door.

3.3 Contact the study monitor to request advice (or QP certificate if this is missing).

3.4 Follow procedures given by study monitor / protocol / IMP manager.

3.5 If the IMPs are approved for use then remove the quarantine sign and store as normal.

3.6 If the IMPs are not suitable for use then transfer them to the returns cupboard.

3.7 File any documentation from the monitor or sponsor in the appropriate section of the pharmacy working documents file.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensures that procedures are in place to confirm the integrity of IMPs
2	Clinical trials pharmacist	All staff who receive deliveries and/or monitor storage	Dealing with temperature deviations and damaged IMP
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 1 Medicines Control, Administration and Prescribing Policy
- CP/R&D_004 Receipt of clinical trial medication
- CP/R&D_021 Room temperature monitoring of clinical trials medication storage area
- CP/R&D_025 Refrigerated clinical trials
- CP/R&D_027 Fridge temperature deviations

5. TRAINING

- ICH-GCP guidelines
- Specific protocol training for managing quarantined product

6. REFERENCES