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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Packaging and labelling IMP** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose/scope**

To describe the procedure for facilitating the generation of labels for, and packaging, investigational medicinal product (IMP) where necessary for a clinical trial conducted by the [group/institution]. This procedure may be supplemented with a trial-specific pharmacy manual or process document(s).

1. **Templates/forms**

IMP02.1 Label requisition form and printing request

IMP02.2 IMP label

IMP02.3 Packing of IMP form

1. **Glossary/definitions**

See also: South African Good Clinical Practice (SAGCP) Guideline; ICH Guideline for Good Clinical Practice E6; South African Guide to Good Manufacturing Practice and Good Pharmacy Practice

**Essential Documents**

Documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced (See South African Good Clinical Practice Guideline, Second Edition. 2006. Appendix C).

**Good Manufacturing Practice**

That part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the medicine registration or product specification

**Good Pharmacy Practice**

Standards developed to ensure that all practising pharmacists and other health care professionals providing medicines provide a service of high quality for the public and private sector alike.

**Investigational Medicinal Product (IMP)**

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Investigator Site File (ISF)**

Files of Essential Documents held by the Investigator. NB on occasion the [group/institution] may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role.

1. **Responsibilities and procedure**

If the trial is conducted outside of [group/institution] facilities the place where IMP is to be stored (pharmacy or otherwise) should, similarly, be suitable in terms of access control, capacity and equipment (e.g. for temperature monitoring).

Should the IMP involve re-packaging of bulk supplies for individual participants, contact the CRC for advice about whether there is a requirement to comply with regulations over and above Good Pharmacy Practice (e.g. Good Manufacturing Practice).

* 1. **Label printing**
     1. The investigational team member given such responsibility completes a Label requisition form and printing request (IMP02.1) adhering to the protocol and South African GCP/GMP requirements. The completed form(s) is checked by another appropriately trained member of the team before a draft set of labels (IMP02.2) is prepared. This should be approved by the PI or trial pharmacist.
  2. **IMP packaging and labelling** *When the IMP is already packaged then only the labelling instructions are relevant. This procedure may also be adapted according to the trial design and IMP formulation etc., though the concepts should remain - procedures may alternatively be described in a trial-specific pharmacy manual.* 
     1. The packing area is appropriately cleaned, windows and doors closed, and extraneous materials removed.
     2. The bulk IMP, required number of appropriately labelled containers, randomisation list, and the Packing of IMP form (IMP02.3) are introduced into the packing area.
     3. Treatment dose units are packed per participant (including back-up dose units if required) starting with the first participant number:
        1. Dose units are selected from the bulk supply and transferred to the labelled containers according to protocol requirements;
        2. A protocol-specific identifier is manually completed on the pre-printed label of the participant-specific container;
        3. The information on the label is checked with the randomisation list, if applicable;
        4. After all dose units have been packed, the pharmacist and another appropriately trained person must check the packed IMP containers and labels and initial the Packing of IMP form to confirm that containers have been correctly packed and correlate with the randomisation list.
     4. The packed IMP containers and back-up dose units (if any) are separately and securely stored.
     5. The Pharmacy accountability form (IMP01.2) is updated to indicate the number of packed and unpacked IPs.
  3. Should members of the trial team need to be blinded to any of the above procedures, this should be documented in detail in a Pharmacy Manual or other trial-specific document.

1. **Document history:**

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| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
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