



STANDARD OPERATING PROCEDURE FOR MANUFACTURE, ASSEMBLY, PACKAGING AND LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

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1. PURPOSE

This document describes the definitions and procedures for the manufacture, assembly, packaging and labelling of Investigational Medicinal Products (IMPs). This Standard Operating Procedure (SOP) complies with the principles of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) (Annexe 13) and the UK Medicines for Human Use (Clinical Trials) Regulations.

2. SCOPE

This SOP applies to all University of Dundee or NHS Tayside personnel (including Clinical Trial Pharmacy staff and research personnel) involved in the processes of assembly, packaging and labelling of IMPs.

3. RESPONSIBILITIES

It is the responsibility of the Sponsor to ensure that the IMP, including any active comparator and placebo, is manufactured in accordance with any applicable GMP. The labelling must comply with applicable regulatory requirements and be coded in a manner that protects the blinding, if applicable. The IMP must be packaged to prevent contamination and deterioration during transport and storage.

4. PROCEDURE

4.1 Introduction

This SOP should be consulted by Clinical Trial Pharmacy Staff and trial personnel at the Clinical Trial of Investigational Medicinal Product (CTIMP) planning stage (preferably before submission of a grant) to ensure early consideration of all issues pertaining to the manufacture, assembly, packaging and labelling of the IMPs and that the appropriate actions are taken.

4.2 Early-stage planning

The Chief Investigator or delegate should consider the following issues relating to IMP management:

- Names of IMPs to be used in study
- Is the CTIMP blinded? Establish how 24-hour emergency unblinding cover will be provided
- Manufacturer/supplier of both active drug and any placebo
- Storage conditions/stability issues/special handling restrictions. See TASC SOP39
- Will the IMP be required at multiple trial locations? See TASC SOP39
- An Investigator Brochure (IB) or Summary of Medicinal Product Characteristics (SmPC) should be obtained
- Who will place the order for the IMP, what quantity will be required and who is funding this? See TASC SOP39
- Will IMP be stored, supplied and/or dispensed from pharmacy or will this be managed, in a local IMP Storage and Supply Site by the investigator? See TASC SOP39. **Note: IMP Storage and Supply Sites are subject to annual audit by the Clinical Trial Section of Ninewells Hospital Pharmacy**
- Will any re-labelling, re-packaging or re-assembly be required at the trial location?
- Will a trial-specific Qualified Person (QP) release be provided by the manufacturer?

For licensed drugs where the IMP is used in the original packaged or presented form, quality assurance is provided by the Marketing Authorisation and the accompanying Product License.

If a licensed drug is re-packaged or presented differently for use in a CTIMP, or an un-licensed drug is being used, a trial-specific QP release must be provided by the manufacturer. The QP is the Quality Control expert at the manufacturing company who confirms the quality of the IMP for use in the CTIMP.

Suppliers of IMPs must have a specific Manufacturing Authorisation issued by the licensing authority before they can manufacture, assemble or import an IMP for use in a clinical trial.

An exemption exists in the UK Clinical Trials Regulations (section 37) which permits the assembly of an IMP in the pharmacy or locally within the trial location by a doctor, pharmacist or person acting under the supervision of a pharmacist. The term assembly includes the reconstitution of a product and the re-packaging and/or re-labelling of a product into its final form. This exemption only applies when the IMP is assembled exclusively for use in that hospital or health centre trial location or any other hospital or health centre which is a trial location for the clinical trial in which the IMP is to be used.

This exemption means that Pharmacy can re-package, re-label or dispense batches of IMPs after they have been sourced and obtained for use in a CTIMP.

Members of the study team delegated to do so may issue pre-packaged, pre-labelled IMP to

which they have attached the participant's ID and date of supply.

The Clinical Trials Pharmacy Staff may assist the Chief Investigator in answering the above questions. The information should be documented and filed in the Pharmacy Site File and the Trial Master File and/or Investigator Site File, as appropriate. The information should also be added to the IMP handling guidelines or the IMP section of the protocol.

4.3 Assembly, packaging, and labelling issues identified

If the IMP for a clinical trial will require some form of assembly at the clinical trial location (e.g. reconstitution, re-packaging or re-labelling other than solely the application of a label containing participant's name and date of supply), the Clinical Trials Pharmacist must be contacted and the following procedures implemented:

4.3.1 Procedures for assembly, packaging, and labelling at clinical trial location

Exemption 37

Ensure that any activities lie within exemption 37 of the UK Clinical Trial Statutory Instrument. If the activities lie outwith the exemption, they will be classed as manufacturing and the trial team must employ an organisation with a manufacturing license to conduct the activities.

Documentation required

Ensure that the manufacturer, supplier or manufacturing organisation provides the required documentation (IB or SmPC, batch analysis certificates and QP release/shipping documentation).

Document names and signatures of personnel who will perform the assembly activities on the Delegation log.

Document details of the IMP assembled, i.e. name of IMP, quantities assembled, details of re-labelling and/or re-packaging and other pertinent details. This information should be filed in the Pharmacy Site File, Trial Master File and/or Investigator Site File, as appropriate.

Assembly will take place in pharmacy.

Labelling/re-labelling

The Clinical trials pharmacist will ensure that labelling/re-labelling complies with GMP Annexe 13 revision.

Clinical trial drugs must be labelled in a way that allows for their proper use and identification of the product, the trial and the trial participant. A record of the manufacturer/supplier and batch number must be kept to identify and trace any IMP supplied to a trial participant. This is an important safety issue in the event of unblinding or

a drug recall during the course of the trial.

For trials in which the IMP is supplied by an outside agency (pharmaceutical company or other licensed manufacturer), the IMP should be provided with the necessary labelling in place. In an open-label study, the manufacturer's original label might suffice with the addition of a label that includes the following:

- The words 'For Clinical Trials Use Only'
- Trial participant name/initials/trial number
- Trial reference code (e.g., NHS R&D number) to allow identification of the clinical trial location, the Chief Investigator/Investigator and Sponsor
- Directions for use. If directions are lengthy or variable, these may be written on an accompanying leaflet and the words 'As directed, see accompanying leaflet' added to the label
- Specific storage information and any relevant expiry date
- Date of issue
- Name/address of hospital/primary care supplier
- The words 'Keep out of the reach and sight of children'
- Any additional cautionary label recommended by the British National Formulary.

The above also applies to a blinded trial, irrespective of whether the IMP is the test drug, comparator or placebo.

It does not apply to IMPs prescribed in accordance with their marketing authorisation in an open-label trial or an observational study where this is effectively carried out as part of usual care.

The same labeling requirements apply to Non-IMP (NIMP) but most NIMPs will be licensed so exemptions will apply. NIMPs used in clinical areas should be labeled for the patient and the trial. If appropriate, the sponsor can apply to MHRA to "disapply" the NIMP labeling requirement.

5. ABBREVIATIONS & DEFINITIONS

CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator Brochure
IMP	Investigational Medicinal Product
NIMP	Non-Investigational Medicinal Product
QP	Qualified Person
SmPC	Summary of Medicinal Product Characteristics
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

TASC SOP39: For Supply, Transport and Storage of Investigational Medicinal Products in Clinical Trials of Investigational Medicinal Products

7. Document History

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
7	Tracy Petrie (Quality Assurance Support Officer)	01/02/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
8	Shona Carson (Clinical Trials Pharmacist)	08/04/2021	Scheduled review, no changes to procedure required.
9	Shona Carson (Clinical Trials Pharmacist)	08/04/2023	Scheduled review, no changes to procedure required.
10	Shona Carson (Clinical Trials Pharmacist)	08/04/2025	Scheduled review, no changes to procedure required.
11	Neil Reynolds (Clinical Trials Pharmacist)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	13 Apr 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	13 Apr 2026