



TEMPLATE SOP FOR LOCAL ADAPTATION

Pharmacy Bench Top Preparation of Monoclonal Antibodies (mAbs) used in the treatment of cancer

This template SOP has been developed and approved by the NCCP, considering the input of the parenteral SACT Resilience Group. The template is developed considering best practice and supported by evidence, as referenced, where available and appropriate.

Please note that these are template SOPS are the minimum requirements to be used in ACU processes which should be adopted and adapted as appropriate to the local processes and documentation templates. If these minimum requirements cannot be met, the reason for this should be clearly documented locally.

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| **Version** | **Date** | **Amendment** | **Approved By** |
| 1a | 20/09/2021 |  | NCCP |
| 1b | 18/10/2023 | Update to footer | NCCP  |

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

# Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedure for the bench top preparation of monoclonal antibodies (mAbs) in pharmacy departments without locally available aseptic compounding facilities or where aseptic facilities are at capacity.

# Scope

The scope of this SOP describes the process to be followed for bench preparation of mAbs so that they are prepared in a safe, efficient and accountable manner.

# Definitions

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| **ACU** | Aseptic Compounding Unit |
| **CSTDs** | Closed system transfer device is a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapour concentrations outside the system |
| **mAbs** | Monoclonal antibodies |
| **PPE**  | Personal Protective equipment  |
| **SOP** | Standard Operating Procedure |

# Responsibilities

## It is the responsibility of the ACU/Pharmacy manager to ensure all staff are trained in and adhere to this procedure.

## It is the responsibility of all staff to comply with this procedure.

It is the responsibility of all staff to notify the ACU manager/Pharmacy manager of any infectious diseases or open lesions on the exposed surface of the body or if feeling unwell. The ACU manager/Pharmacy manager will decide on the fitness of the staff member to carry out activities in the preparation area or clean room and the specific protective measures that should be taken to avoid contamination of the product. If adequate protection is not possible, the person should not be allowed to be involved in preparation or compounding activities.

# Procedure

## A local risk assessment for each mAb should be performed to confirm suitability for bench top preparation. Please refer to the NCCP Guidance for Pharmacy bench top preparation of mAbs used in the treatment of cancer[[1]](#footnote-2).

## A list of mAbs eligible for preparation should be locally agreed and maintained in the pharmacy.

## All staff involved in the bench top preparation of mAbs should be trained in the following: aseptic technique, cleaning, waste management, spillage as per local hospital SOP.

## A dedicated area free of interruptions for bench top preparation of mAbs should be identified. The area should be well ventilated, clean, free of clutter and easy to maintain.

## Closed system transfer devices (CSTDs) may be used to give an additional layer of protection to both the product and operator. However, they are not essential for the bench top preparation of mAbs. If a CSTD is to be used, this does not remove the need for aseptic non-touch technique.

## mAbs prepared at bench top preparation are for immediate use only[[2]](#footnote-3).

# 5.1 Preparation of MAb steps using CTSD

* Confirmation of treatment should be given by an authorised person prior to proceeding with benchtop preparation of the mAb. A documentation check of the worksheet against the prescription should have been completed prior to tray set up
* The tray for set up for bench top preparation should be assembled as per template SOP 104 ‘Tray assembly and Checking Procedure’
* Hands should be washed as per template SOP 101 ‘Handwashing SOP’
* Based on local risk assessment, PPE should be donned as per local policy
* The bench top preparation work area should be sprayed and wiped down using 70/30 IPA solution
* The vial(s) of drug should be wiped with an alcohol wipe downwards from bung, to middle, to base, wiping in one direction only and taking care to cover all surfaces. The port of the infusion bag should also be wiped in one direction only
* The CSTD adaptor(s) should be attached to the vial(s) as per local SOP, if using
* The required volume of drug from the vial(s) should be withdrawn using aseptic technique using appropriate sized syringes
* The drug and volume should be checked against the worksheet by a second authorised checker
* Using aseptic technique, the required infusion bag should be opened and the port on the bag swabbed before attaching the bag adaptor that allows the transfer the drug to the infusion bag
* Using aseptic technique the syringe should be attached to the bag adaptor and the required volume added to the infusion bag. The syringe should be removed and placed in the appropriate disposal bin as per template SOP 106 ‘Waste Disposal’. The infusion bag should be gently inverted (not shaken) to mix the solution
* The product should be inspected for particulates or discolouration as per drug SmPC
* A label should be applied to the infusion bag with relevant patient and drug information and should include batch number, manufacture time, manufacture date, storage precautions and ‘For immediate use’
* A final check of the product against the prescription and worksheet should be completed by a pharmacist prior to release
* The finished labelled product should be placed in a dedicated storage bag with appropriate labels as per local SOP
* The product should be placed in a dedicated transport device as per local SOP
* The worksheet should be completed and signed as per local SOP
* The accumulated waste should be disposed of as per local SOP
* The preparation area should be cleaned down as per local SOP

**5.2 Preparation of mAb steps using Needles**

* The vial(s) of drug should be wiped with an alcohol wipe downwards from bung, to middle, to base, wiping in one direction only and taking care to cover all surfaces. The port of the infusion bag should also be wiped in one direction only
* Needle(s) should be attached to appropriate syringe(s) using aseptic technique
* The required volume of drug from the vial(s) should be withdrawn using aseptic technique using appropriate sized syringes
* The drug and volume should be checked against the worksheet by a second authorised checker
* The required drug volume should be added via the infusion port using aseptic technique. Needles should not be re-sheathed at any point
* The syringe and needle should be removed and placed in the appropriate sharps bin as per template SOP 106 ‘Waste Disposal’. The infusion bag should be gently inverted (not shaken) to mix the solution
* A cap should be placed on the additions port to seal the product
* The product should be inspected for particulates or discolouration as per drug SmPC
* A label should be applied to the infusion bag with relevant patient and drug information and should include batch number, manufacture time, manufacture date, storage precautions and ‘For immediate use’
* A final check of the product against the prescription and worksheet should be completed by a pharmacist prior to release
* The finished labelled product should be placed in a dedicated storage bag with appropriate labels as per local SOP
* The product should be placed in a dedicated transport device as per local SOP
* The worksheet should be completed and signed as per local SOP
* The accumulated waste should be disposed of as per local SOP
* The preparation area should be cleaned down as per local SOP

# 6. References

1. Guideline for the Preparation or Manipulation of Monoclonal Antibodies (MABs) and related compounds such as Fusion Proteins, used in the Treatment of Cancer (2012) V2. Pan Birmingham Cancer Network
2. Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. Internal Medicine Journal 44(2014)
3. National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs in health care settings 2016. Accessed March 2020 at

https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

1. NCCP Guidance: Pharmacy bench top preparation of monoclonal antibodies (mAbs) used in the treatment of cancer. V1 2020. Available at <https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/nccp%20guidance%20benchtop%20preparation%20mabs.pdf>

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| **Version** | **Date** | **Amendment** | **Approved By** |
| 1 | 10/11/2020 |  | NCCP and SACT resilence group |
| 1a | 20/09/2021 | Amended standard wording on page 1 of template  | NCCP |
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1. <https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/nccp%20guidance%20benchtop%20preparation%20mabs.pdf> [↑](#footnote-ref-2)
2. Immediate use should be defined locally in line with local risk assessment and processes [↑](#footnote-ref-3)