Good Laboratory Practice

Buffer Preparation Exercise Workbook

Copyright statement

Preface

This workbook and the accompanying video have been commissioned by Skills Development Scotland and prepared by Edinburgh Napier University with support from a member of the Life and Chemical Sciences Skills Group. The aim is to help you understand Good Laboratory Practice (GLP) by showing you the process and documentation that apply to a simple example: making a blocking buffer.

Any industry laboratory that carries out studies related to medicines will have to follow the GLP set of quality standards by law, and awareness of this is very helpful for anyone wanting to get a job in the life and chemical sciences sector, e.g. in the pharmaceutical industry.

Please bear in mind that most modern companies use a computer system to log all the data and documentation related to GLP. This exercise shows you the process in a simplified paper-based way to aid understanding.

Learning Outcomes/ Intentions

By the end of the exercise, you should be able to:

1. Explain why Good Laboratory Practice is needed
2. Understand the principles of Good Laboratory Practice
3. Give examples of how Good Laboratory Practice is documented

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Background

What is Good Laboratory Practice?

'The principles of Good Laboratory Practice (GLP) define a set of rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived' (European Medicines Agency 2025)[1]. This means that any laboratory (or 'test facility') testing medicines and chemicals must, by law, follow a set of quality standards for their organisation and management, and any studies they undertake must be carried out and reported in a certain way, called GLP.

In the UK GLP compliance is overseen by the Medicines and Healthcare Products Regulatory Agency (MHRA) and any test facility that carries out regulatory studies must be registered with them. Other countries will have their own regulatory authorities.

In order to show they are following GLP, test facilities must follow a process of documentation. Those documents are usually made electronically on a computer using a Quality Assurance system, but we use a paper-based process in this exercise to show you the main points.

Data Integrity

Data integrity is an important part of the quality assurance process that documents that GLP has been followed correctly. This means that every step of every part of every study will be secure, of high quality and traceable because it follows ALCOA++ principles in all the documentation. All GLP data contained within the documents should therefore be:

- **A**ttributable: show who or what did the activity
- **L**egible: always readable
- **C**ontemporaneous: documented at the time of the activity
- **O**riginal: the record is original or a certified true copy
- **A**ccurate: errors and changes are documented

Data should also be (++)

- Complete: *all* data and tests, including repetitions and reanalysis must be documented
- Consistent: all components of the analysis, including the sequence of events should be carried out the same way
- Enduring: a systematic, sustainable record on a valid system
- Available: data can be accessed for review, audit or inspection
- Traceable: data can be found throughout the process, including changes

How does GLP work?

This practical exercise will show you how GLP is documented using a simple process of making a blocking buffer.

When you are completing the documentation yourself, or looking at the documentation for the exercise, think about how it follows the ALCOA++ principles.

Making a Buffer using Good Laboratory Practice (GLP)

Documentation

Two main documents are needed to complete the preparation of the blocking buffer according to GLP principles in this exercise. They are:

1. Reagent instructions
2. Reagent preparation form

Reagent Instructions

In a GLP lab every reagent will have its own set of instructions that explain how to make it (the method), what to make it from (components) and how to store it. This looks like a normal protocol you might see in any lab, except each set of instructions should be signed and dated by the person who wrote them, and then quality control checked (QC'd) by a second person to make sure they are right, who also signs and dates the document. The ***same*** instructions are used every time the reagent is made.

In our example the reagent instructions explain how to make and store the blocking buffer.

The reagent instructions also give details of the ingredients (BSA = Bovine Serum Albumin, PBS (1x) = Phosphate Buffered Saline and Tween 20), their manufacturer catalogue numbers and where they are stored so that the right ones are used every time.

REAGENT PREPARATION

Blocking Buffer (5% BSA in 1x PBS with 0.1 % Tween 20)

Instructions

Add 25.0 g (±0.01g) of BSA to 500mL of PBS pH 7.4 (1x) and dissolve with a magnetic stirrer until fully dissolved.

Once dissolved, add 0.5 mL Tween-20® to the solution and mix well using a magnetic stirrer.

After dissolving, measure the solution pH.

Store in a refrigerator set to maintain 4°C for up to one month after preparation.

BSA
Sigma Cat No.: A7030
Stored in: Cold Room 52

PBS (1X)
Gibco Cat No.: 10010
Stored in: Dry Store 54

Tween-20®
Sigma Cat No.: P1379
Stored in: Dry Store 54

Reagent Preparation sheet prepared by:

Sign: _____ Date: 24/07/2025

Reagent Preparation sheet QC'd by:

Sign: _____ Date: 24/07/2025

Reagent Preparation form

In addition to the set of instructions, GLP requires that a reagent preparation form is completed ***during the process*** of preparing ***every*** reagent. This is probably different to what you are used to at school, college or university, where the rules are less strict, but this is a requirement for GLP.

ACTIVITY Take a look at the form below and think about why it is needed to ensure that ALCOA++ principles are followed.

REAGENT PREPARATION FORM

Reagent Name: _____

Concentration: _____

Reagent ID: _____

Hazard Assignment: _____

Expiry Date: _____

Component A:	_____	Supplier:	_____
Cat. No:	_____	Batch/Lot:	_____
Wt/Vol Used:	_____	Expiry Date:	_____
Component B:	_____	Supplier:	_____
Cat. No:	_____	Batch/Lot:	_____
Wt/Vol Used:	_____	Expiry Date:	_____
Component C:	_____	Supplier:	_____
Cat. No:	_____	Batch/Lot:	_____
Wt/Vol Used:	_____	Expiry Date:	_____
Component D:	_____	Supplier:	_____
Cat. No:	_____	Batch/Lot:	_____
Wt/Vol Used:	_____	Expiry Date:	_____
Component E:	_____	Supplier:	_____
Cat. No:	_____	Batch/Lot:	_____
Wt/Vol Used:	_____	Expiry Date:	_____

Final Vol: _____ Storage Conditions: _____

No. of aliquots prepared: _____ Aliquot volume: _____

Balance ID: _____ pH Meter ID: _____

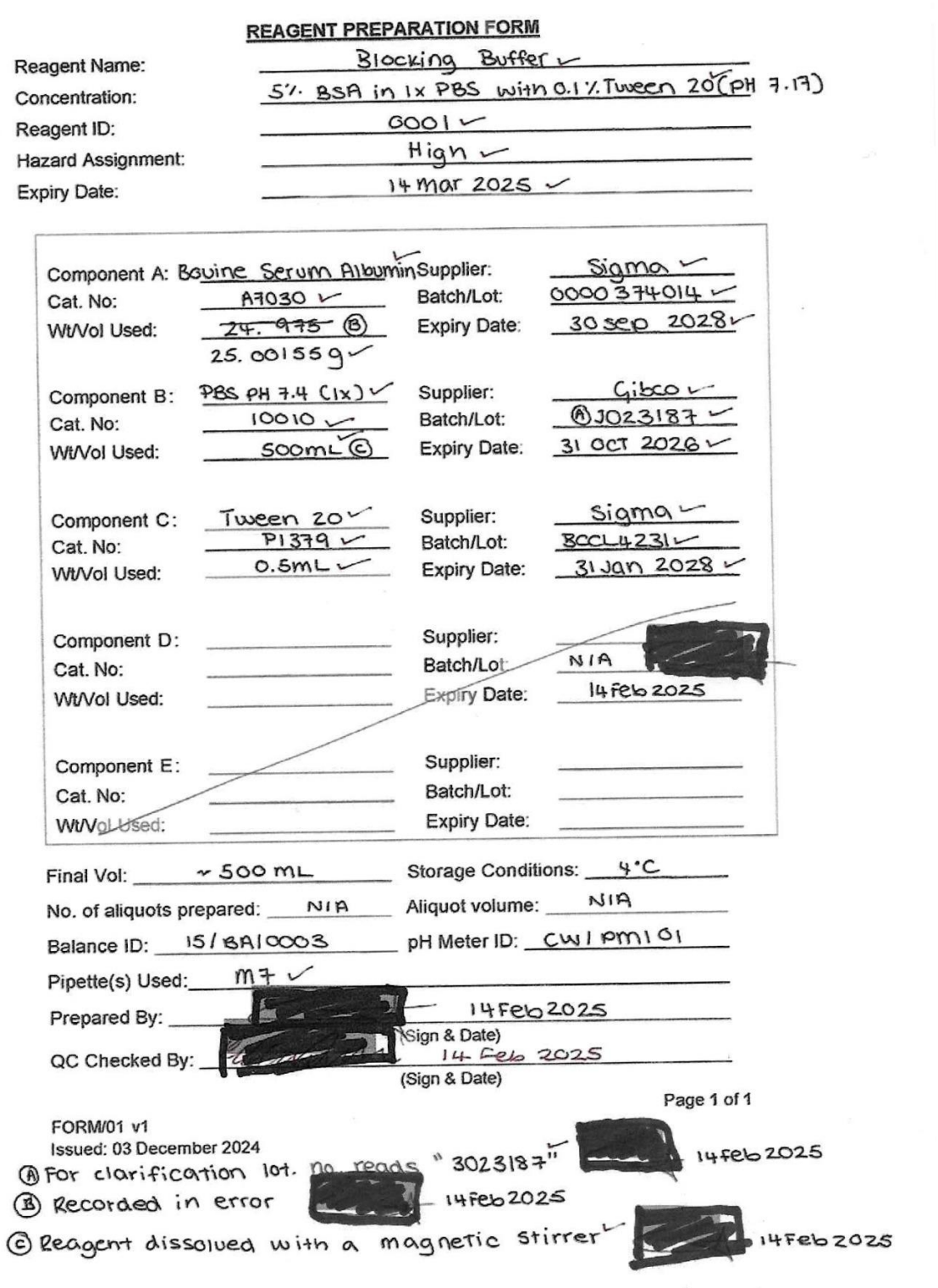
Pipette(s) Used: _____

Prepared By: _____
(Sign & Date)

QC Checked By: _____
(Sign & Date)

Completed Reagent preparation form

Every time a reagent is made, a new form is completed by the person making it, who signs and dates it once the reagent is complete. In this exercise you have been given a completed reagent preparation form. Signatures have been obscured for privacy.



REAGENT PREPARATION FORM

Reagent Name: Blocking Buffer
Concentration: 5% BSA in 1x PBS with 0.1% Tween 20 (pH 7.17)
Reagent ID: 0001
Hazard Assignment: High
Expiry Date: 14 Mar 2025

Component A: Bovine Serum Albumin		Supplier:	Sigma
Cat. No:	A7030	Batch/Lot:	0000374014
Wt/Vol Used:	~~24.975~~ (B) 25.00155g	Expiry Date:	30 Sep 2028
Component B:	PBS pH 7.4 (1x)	Supplier:	Gibco
Cat. No:	10010	Batch/Lot:	(A) J023187
Wt/Vol Used:	500mL (C)	Expiry Date:	31 OCT 2026
Component C:	Tween 20	Supplier:	Sigma
Cat. No:	P1379	Batch/Lot:	BCCL4231
Wt/Vol Used:	0.5mL	Expiry Date:	31 Jan 2028
Component D:		Supplier:	[redacted]
Cat. No:		Batch/Lot:	N/A
Wt/Vol Used:		Expiry Date:	14 Feb 2025
Component E:		Supplier:	
Cat. No:		Batch/Lot:	
Wt/Vol Used:		Expiry Date:	

Final Vol: ~500 mL
Storage Conditions: 4°C
No. of aliquots prepared: N/A
Aliquot volume: N/A
Balance ID: 15/BA10003
pH Meter ID: CW/PM101
Pipette(s) Used: M7
Prepared By: [redacted] 14 Feb 2025 (Sign & Date)
QC Checked By: [redacted] 14 Feb 2025 (Sign & Date)

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FORM/01 v1
Issued: 03 December 2024

(A) For clarification lot. no reads "3023187" [redacted] 14 Feb 2025
(B) Recorded in error [redacted] 14 Feb 2025
(C) Reagent dissolved with a magnetic stirrer [redacted] 14 Feb 2025

Quality control and the reagent preparation form

The quality control check (QC) is an important part of GLP to verify that the correct process has been followed, and the data has been recorded properly. Once a scientist has finished making a reagent, the form and the reagent are quality control checked (QC'd) by someone else who also signs and dates it.

ACTIVITY Use the information below to quality control check the completed reagent preparation form. You can see the QC process in this video: https://www.youtube.com/watch?v=BqYe19XDdhA

Reagent name: *see reagent instructions- is this correct?* **YES/ NO**

Concentration: *see reagent instructions – is this correct?* **YES/ NO**

Regent ID: *in our example this is 1, but for any real studies the study book will tell you which number to put down – the next number in the series for that reagent*.

Hazard Assignment: *this is the highest hazard of all the ingredients and is completed at the end when a hazard label is attached to the prepared buffer. See ingredient labels below. Is this correct?* **YES/ NO**

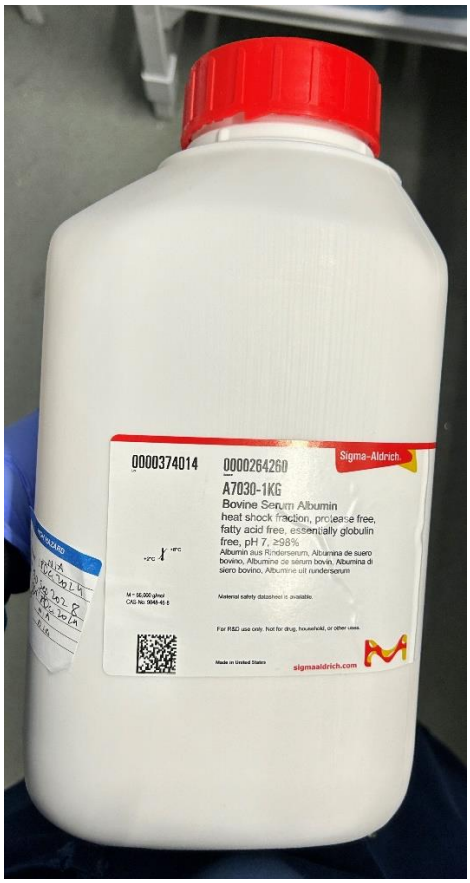
Expiry Date: *see reagent instructions. Is this correct? Note that the expiry date for the reagent cannot be after the expiry date of any of the reagents, so the component labels should also be checked at this step.* **YES/ NO**

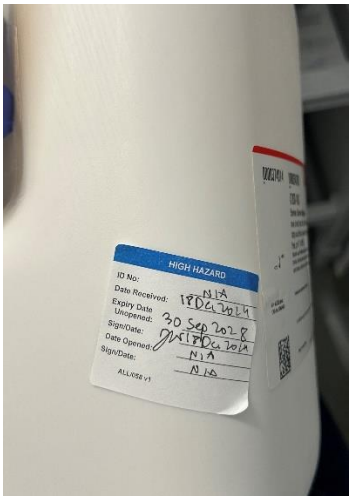
Component details*: see labels on the containers provided below for details of the supplier, catalogue number, batch/ lot number and expiry date. Wt/ Vol used is completed using the actual weight or volume while the reagent is prepared according to the reagent instructions. You need to check that these are acceptable by referring to the reagent instructions. Are they correct?* **YES/ NO**

Equipment ID: *should match the labels of the equipment used. Are they correct?* **YES/ NO**

Component and equipment details

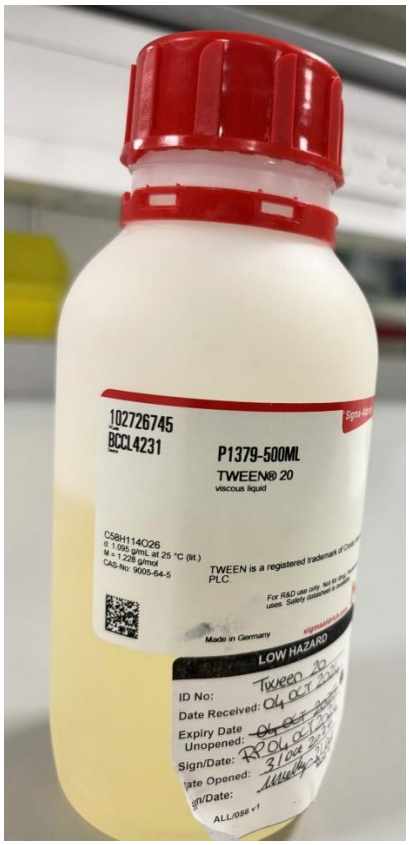
Component A: BSA





Component B: PBS (1x)

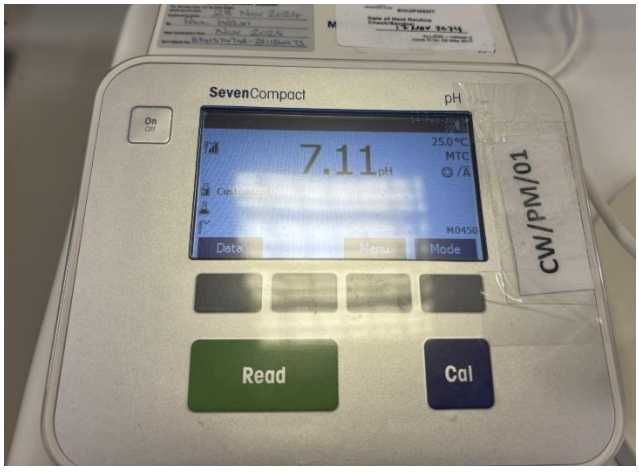
Component C: Tween 20



Balance ID

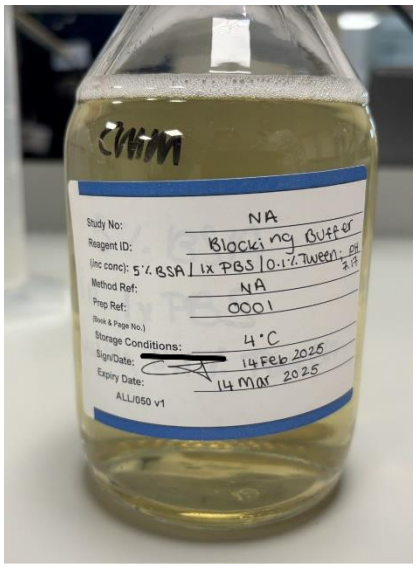
15/BA/0003

pH meter ID



Pipette ID – it is difficult to read the label from a photograph, the ID reads: M7

Completed buffer label



Annotations

Annotations can be added to GLP documentation any time clarification is needed. In the reagent preparation form example above, three annotations have been made:

1. Clarification at the bottom of the sheet for PBS lot number as it was not clear when first written.
2. A note that the BSA weight was first noted before the scales had settled, after a wait the balance settled and the correct, final weight was noted.
3. Confirmation that the magnetic stirrer had been used at the bottom of the sheet.

ACTIVITY Take a look at the annotations on the completed reagent preparation form, what do you notice about them?

ALCOA++ Principles in the documentation

ACTIVITY Look at the completed reagent preparation form and the reagent instructions and note where in the documentation you found the following principles:

- **A**ttributable: show who or what did the activity
- **L**egible: always readable
- **C**ontemporaneous: documented at the time of the activity
- **O**riginal: the record is original or a certified true copy
- **A**ccurate: errors and changes are documented

Data should also be (++)

- Complete: *all* data and tests, including repetitions and reanalysis must be documented
- Consistent: all components of the analysis, including the sequence of events should be carried out the same way
- Enduring: a systematic, sustainable record on a valid system
- Available: data can be accessed for review, audit or inspection
- Traceable: data can be found throughout the process, including changes

Answer

- ***A**ttributable*: the instructions and the preparation form are signed by the person completing them and also by someone else who quality checks them.
- ***L**egible*: records are either type written or completed by hand. Annotations help to clarify where entries are not clear e.g. annotation a on the reagent preparation form.
- ***C**ontemporaneous*: the documents are dated whenever they are signed and the the preparation form was filled in at the same time the preparation was taking place.
- ***O**riginal*: the preparation form is the one that was completed at the time.
- ***A**ccurate*: errors and changes are documented in the annotations e.g. the BSA weighing error in the reagent preparation form.

Data should also be (++)

- *Complete*: every step of the reagent preparation was documented, and annotations added to make sure it is clear that the instructions were followed e.g. annotation c confirms that a magnetic stirrer was used for the preparation.
- *Consistent*: the instructions were followed in the correct sequence and recorded in the preparation form.
- *Traceable*: we know which chemicals and equipment were used to make the blocking buffer because these were logged on the preparation form.

Because we don't show you what happens to these records after they are created it is difficult for you to assess whether they are enduring and available. However the following should be the case if GLP is being followed correctly:

- *Enduring*: these records should be logged in the system once completed. Most laboratories would log electronic data in a quality control system and software to ensure this is the case.
- *Available*: these records should be easy to find in the system.

Feedback

We would love it if you left us some feedback, please scan the QR code below or use this link https://forms.microsoft.com/e/qE27bayJDd to be taken to a brief survey:

Further Information

OECD Good Laboratory Practice and Compliance Monitoring topic: https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html

Information about jobs in the Life Sciences – lab-based roles in industry will require GLP and quality control:

Life sciences | My World of Work