1. **Purpose**

This SOP describes the process for preparation of ready to administer **0.2mL** syringes of Comirnaty Omicron XBB.1.5 (3 micrograms/dose) concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) raxtozinameran (**Comirnaty 3 (THREE) (XBB.1.5) Concentrate).**

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| Different strengths / formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength / formulation required. This SOP is for use with Comirnaty3 (THREE) (XBB.1.5) concentratewith the label format: |  |

1. **Scope**

This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning a room temperature expiry, the dilution of the concentrate vial, and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

* One person performing dilution, and drawing up of syringes to administer by themselves.
* One person performing dilution, who passes the diluted vial to a vaccinator to draw up individual doses into syringes.
* One person both diluting the vial and drawing up individual doses into syringes and passing the syringe to the vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

1. **Responsibility**

Staff performing any stage of the preparation of the vaccine are responsible for following this procedure.

The [insert lead Clinician title / responsible Pharmacist] must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction (PGD), National Protocol, Patient Specific Direction (PSD) or other appropriate legal mechanism. In addition, the lead Clinician / responsible Pharmacist must ensure that the staff groups who are undertaking the processes are those defined as eligible to do so.

Sites are responsible for sourcing their own grip lock bags, labels (as per appendix 1 template) and lidded boxes labelled ‘CONCENTRATE VACCINE VIALS’.

1. **Procedure**

N.B. If removing a single vial from a cool box proceed directly to step 4.9.

* 1. Remove sufficient thawed concentrate vaccine vials from the original carton in the refrigerator.
     + - To reduce waste, the number of vials removed should be enough to cover no more than approximately 1 hour of anticipated usage.
       - If there is more than one carton, use the one with the shortest post-thaw expiry.
  2. Check you have selected the correct presentation of the Comirnaty vaccine. This procedure is intended for use with the **Comirnaty 3 (THREE) (XBB.1.5) concentrate** presentation. Check label format on the vial selected matches the picture below:



* 1. Check the vial is within the post-thaw expiry date printed on the carton thaw label.
  2. Seal the concentrate vaccine vials into a grip lock bag.
  3. Complete a “*Concentrate room temperature bag expiry label*” (see Appendix 1) with
* Time and date removed from the refrigerator. Use 24-hour clock format.
* Time and date of room temperature expiry. The vials must be diluted within 12 hours from the point the concentrate vaccine vials are removed from the fridge. Use 24-hour clock format.
* Batch number of the concentrate vaccine vials
* Signature of person completing the label

NB. Once removed from a refrigerator and prior to dilution the vials may be stored up to 12 hours at up to 30°C

* 1. Attach the label to the bag containing the concentrate vaccine vials.
  2. Ask a second person to:
* Check that all details on the label are correct.
* Check that the correct vaccine has been selected by confirming the product name on the vial(s).
* sign the label to confirm that the above checks have be made.
  1. Take the bag to the vaccine preparation station and place it in the empty lidded box labelled ‘CONCENTRATE VACCINE VIALS’. Confirm this box is empty before adding the new bag of vials. Close the lid on the box.
  2. Prepare the workstation for use:
     + - ensure the preparation workstation is clear and free from any other vials of vaccine.
       - ensure a yellow lidded sharps bin with sufficient free capacity and an indelible pen are available
       - clean workstation with a disinfectant wipe and discard into a clinical waste bin.
  3. [Insert statement on local practice for wearing of aprons and other PPE / sanitising hands / donning gloves for preparing injectable medicines]
  4. Assemble the following materials required to perform dilution:
     + Sodium chloride 0.9% solution for injection ampoule 5mL X 1
     + 3mL Syringe and 21g or finer needle X 1
     + Sterile single use 70% alcohol swab x2
  5. When ready to begin the dilution process, bring a single vial of **Comirnaty 3 (THREE) (XBB.1.5) concentrate** vaccine into the centre of the workstation.

**N.B. Only one vaccine vial may be in use in the preparation workstation at any one time.**

* + 1. If working with room temperature vials from lidded box labelled ‘CONCENTRATE VACCINE VIALS’ that have been assigned a room temperature expiry (see 4.1 – 4.8 above):
* check the assigned room temperature expiry on the grip lock bag of concentrate vaccine vials has not been exceeded.
* Remove a single vial and close the lid of the vial box.
  + 1. If working with vials from a cool box at 2-8OC
       - Check the vial is within the post-thaw expiry date by checking the label on the vial transport container. Refer to SOP HCV 6: *Use of cool boxes to transport Covid-19 vaccines to end user locations.*
       - Remove a single vial and close the lid of the cool box.
    2. Check the identity of the vial. This procedure is intended for use with the **Comirnaty 3 (THREE) (XBB.1.5) concentrate** presentation.

• Check the vial has a maroon cap and the label states Comirnaty ‘***10 doses of 3mcg’***

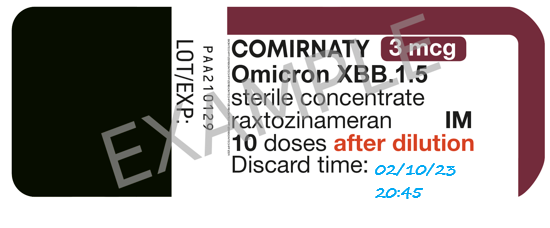
• Check label on the vial selected matches the picture below:



* 1. **Dilute the vial**
     1. Slowly invert the vial 10 times to thoroughly mix the concentrate suspension, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position. Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
     2. Remove the maroon vial dust cover and cleanse the vaccine vial stopper with a single use 70% alcohol swab Discard the swab into a clinical waste bin. Set the concentrate vaccine vial to one side.
     3. Draw up **2.2 mL** of sodium chloride 0.9% solution for injection:
        + Cleanse the top and shoulders of 5mL ampoule of sodium chloride 0.9% solution for injection with a single use 70% alcohol swab and discard the swab into a clinical waste bin.
        + Using aseptic technique, snap the top off the ampoule and use a 3mL syringe and 21g or finer needle to draw up **2.2 mL** of sodium chloride 0.9% solution for injection.
        + Check the volume of sodium chloride 0.9% solution for injection drawn up is **2.2mL. [May require independent 2nd check depending on local policy]**
        + Dispose of the remainder of the 5mL sodium chloride 0.9% solution for injection ampoule into a yellow lidded sharps bin.
     4. Dilute the concentrate vaccine vial by adding the **2.2 mL** of sodium chloride 0.9% solution for injection to the vial:
* To minimise the risk of stopper coring and particles entering the vial:
* Insert the needle vertically through the centre ring of the vial stopper.
* Do not twist or rotate the needle once inserted
* During the addition, keep the needle tip in the air space of the vial at all times. Equalise the pressure by adding the sodium chloride 0.9% solution for injection in gradual steps and allowing air to vent back into the syringe repeatedly until all of the sodium chloride 0.9% solution for injection has been added and there is 2.2mL air in the syringe.

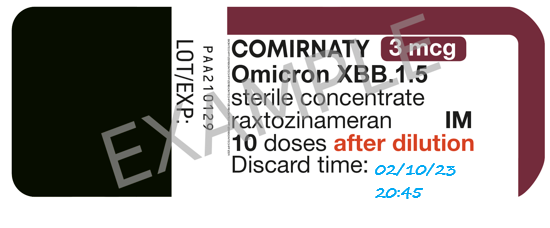
N.B. If using a syringe with an auto retracting needle depressing the plunger fully will cause the needle to retract prematurely. If the above technique is not used the full 2.2mL may therefore not be added to the vial.

* + 1. Dispose of syringe and needle into a yellow lidded sharps bin.
    2. Slowly invert the diluted vial 10 times to mix contents thoroughly. DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position.
    3. Inspect the vial. The diluted vaccine should present as an off-white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.
    4. Calculate and write the time / date of post-dilution **expiry** on the vial label as shown below in blue below. Use 24-hour clock format.



N.B. The expiry is 12 hours from the point of dilution, but the vial should still be used as soon as practically possible.

* 1. **Withdraw doses into syringes**
     1. Assemble the following materials required to prepare syringes:
        + Diluted **Comirnaty 3 (THREE) (XBB.1.5) concentrate** vial X 1
        + 1mL syringe with integrated 23g (or finer) x 25mm needle X 10
        + Sterile single use 70% alcohol swab x 10
     2. Check the vial is within the hand-written post-dilution expiry time on the label.
     3. Check the identity of the vial. This procedure is intended for use with the **Comirnaty 3 (THREE) (XBB.1.5) concentrate** presentation.
* Check label on the vial selected matches the picture below:



* + 1. Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.
    2. Using aseptic technique, draw up **0.2mL** of the diluted vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B. If using a syringe with an auto retracting needle depressing the plunger will cause the needle to retract prematurely.

* + 1. Adjust to remove air bubbles with the needle still in the vial to avoid loss of diluted vaccine.
    2. Check volume withdrawn is **0.2mL. [May require independent 2nd check depending on local policy]**
    3. Visually inspect the syringes for particles and leaks. Discard if these are observed.
    4. The newly filled syringe must be used for immediate administration. **[Local risk assessment may be required to manage risk of needle stick injury when handling unsheathed needles]**
    5. Steps 4.14.2 to 4.14.9 may be repeated a further nine times to produce a total of ten syringes from each diluted vaccine vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.
    6. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
  1. Once empty, or no longer needed, immediately discard the used vaccine vial into a yellow lidded sharps bin.

N.B. Vials should not be stored between sessions:

* During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 30°C). This may include the time it takes to move short distances between patients e.g. in a care home, or the time between patients in a clinic (up to 6 hours transportation time post dilution).
* The punctured vaccine vial is physiochemically stable for 12 hours. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible and within 6 hours.
  1. Dispose of outer cartons by defacing using permanent black marker pens, and placing in the general waste stream. Note: the packaging can be flattened easily. For mass vaccination centres packaging must be stored in a secure container(s) and shredded on-site.

1. **Document history**

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| --- | --- | --- | --- |
| **Date** | **Version** | **Section** | **Details** |
| 04/10/23 | 1.0 | All | This is the first version published. |

1. **References**
   1. [Comirnaty Omicron XBB.1.5 (3 micrograms/dose) concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) raxtozinameran SPC](https://www.medicines.org.uk/emc/product/15044/smpc)
2. **Supporting Documents**

SOP HCV 6:Use of cool boxes to transport COVID-19 vaccines to end user locations.

**Appendix 1** – Room temperature expiry label (to be created locally). Only required if removing multiple vials from a refrigerator, see step 4.1

**Comirnaty 3 (THREE) Concentrate COVID-19 Vaccine**

Concentrate Room Temperature Bag Expiry Label

**Removed from refrigerator**:

DD/MM/YY at HH:MM

**Discard after:**

DD/MM/YY at HH:MM

Batch No:

Signed: \_\_\_\_\_\_\_\_

Checked: \_\_\_\_\_\_\_