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| **Product Information** |
| Dinoprostone 50 micrograms in 50mL Glucose 5%  Syringe for intravenous infusion |

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| Stability ref | QCNW study ref S/A/2007/2 | Concentration | 1microgram /mL | Expiry | 7 days |
| Storage | 2-8°C (fridge) | | Final Container | 50mL Polypropylene syringe | |
| Additional Information | * Volume of Dinoprostone concentrate added to bag is specific to the average overage of a 500ml **Baxter Viaflo** bag (Average fill volume = ~530ml). Overage in other brands of bag may vary, therefore volume of DInoprostone may require adjusting if a different bag is used. * When adding Dinoprostone to the bag, the needle must be primed and added as a single push (**do not** draw back from the bag to flush the needle). * This worksheet is intended for single patient use only. | | | | |

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| **Patient details (SOP XXX)** | | | |
| Name |  | Unit number |  |
| Date of Birth |  | Weight |  |
| Consultant |  | Ward |  |
| Clinical check by |  | Aseptic verification by |  |

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| **Dispensing Details (SOP XXX)** | | | |
| Date dose(s) required |  | Quantity required |  |
| Date of Dispensing |  | Batch Number |  |
| Time of Dispensing |  | Expiry Date |  |
| Date worksheet prepared |  | Worksheet Prepared By |  |
| Date worksheet checked |  | Worksheet Checked By |  |

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| **Label Printing (SOP XXX)** | | | | | | | | |
| Master Product Label (Code: **XXX**) | | | | | Sample Label | | | |
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| No. of Labels Printed |  | Printed By |  | No. Attached to Worksheet | |  | No. Issued for Use |  |
| Labels Checked By |  | Supervisor authorisation to proceed to assembly | | | |  |

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| **Starting Materials (SOP XXX)** | | | | | | |
| Assemble all starting materials listed below and enter the batch numbers and expiry dates for each item. Sign for assembling each item. Each item must then be subject to an independent documented second check. | | | | | | |
| Product | Qty | Manufacturer | Batch Number | Expiry | Assembled By | Checked By |
| Dinoprostone 1mg/mL (0.75mL) Ampoule | 1 | Pfizer |  |  |  |  |
| Glucose 5% 500mL **Viaflo** Infusion Bag | 1 | **Baxter** |  |  |  |  |
| 50ml Polypropylene syringe |  |  |  |  |  |  |
| Syringe end cap |  |  |  |  |  |  |
| 1ml Syringe | 1 |  |  |  |  |  |
| Needle 19g |  |  |  |  |  |  |
| 5 Micron filter needle | 1 |  |  |  |  |  |
| Non-vented resealing dispensing pin | 1 |  |  |  |  |  |

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| **Transfer Sanitisation (SOP XXX)** | | | |
| Transfer materials into the clean room in accordance with the appropriate local SOP. | | | |
| Stage 1 Transfer Performed By |  | Stage 2 Transfer Performed By |  |

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| **Production Method (SOP XXX )** | | | | | | |
| Operator 1 |  | Operator 2 (if applicable) |  | Cabinet Used |  | **Supervisor Check** |
| 1.Swab top/neck of the ampoule, the additive port of the bag and the administration port of the bag with sterile 70% alcohol wipes. | | | | | |  |
| 2. Using a 1ml syringe and 19g needle, draw up the full contents of the Dinoprostone 1 mg/mL concentrate ampoule. Resheath the needle with a hands free aid. | | | | | |  |
| 3. Remove the 19g needle, and attach a new 5 micron filter needle to the syringe. | | | | | |  |
| 4. Adjust the volume contained in the syringe to **0.53 mL,** ensuring the filter needle is fully primed. Obtain an in process check  *NB: The excess solution may be expelled into the used ampoule to prevent spillage.* | | | | | |  |
| 5. Using the same primed filter needle add the **0.53mL** of dinoprostone concentrate to the Glucose 5% 500ml **(Baxter Vialo)** bag via the additive port. | | | | | |  |
| 6. Mix the bag thoroughly by inverting 10 times. | | | | | |  |
| 7. Insert a non-vented resealing dispensing pin into the Glucose 5% 500ml bag via the administration port | | | | | |  |
| 8. Attach a 50ml syringe to the non-vented resealing dispensing pin in the Glucose 5% 500ml bag and withdraw 50ml. | | | | | |  |
| 9. Remove syringe from the non-vented resealing dispensing pin and attach a new 19g needle. | | | | | |  |
| 10. Expel any excess air from syringe, remove needle and attach end cap. Visually inspect syringe for particles, leaks, fluid in thread and liquid bridge across flanges. | | | | | |  |
| 11. Repeat steps 8 to 10 a further ……….. times to produce a total of ………….syringes | | | | | |  |
| **Supervisor Check** - Good aseptic technique and clean room practices were observed. Preparation took place in strict accordance with the defined production method above. | | | | | |  |
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| **Product Inspection, Labelling and Packing (SOP XXX)** | | | | |
| Check each syringe for leaks and visible particles. Label each syringe and overwrap according to local procedure. Document label & product reconciliation in table below. | | | | |
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| Product Reconciliation | | Label Reconciliation | |
| No. Expected |  | No. Issued |  |
| No. Dispensed |  | No. Attached to products |  |
| No. Failed |  | No. Spoiled |  |
| No. Passed |  | No. Excess |  |
| Product Reconciliation Completed By |  | No Destroyed |  |
|  | | Destroyed by |  |
| Label Reconciliation Completed By |  |

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| **Product Approval & Release (SOP XXX)** | | | | |
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| Patient details on the worksheet and labels match the details on the prescription | | | |  |
| Product, dose, diluent, volume on the worksheet and labels match the details on the prescription | | | |  |
| The fill volume of each syringe is 50mL | | | |  |
| The quantity prepared is appropriate and the expiry is sufficient to cover the infusion time from the scheduled start time of the infusion | | | |  |
| Deviations are documented and authorised, as appropriate | | | |  |
| Starting materials, batch number and expiry dates are documented on the worksheet and reconciled | | | |  |
| Expiry of all starting materials is after the expiry of the final product | | | |  |
| All product and label reconciliations tally and are recorded | | | |  |
| All worksheet checks and production checks are present | | | |  |
| All critical components and final products are present and are correct for the dose and quantity prepared | | | |  |
| All products appear as expected and are free from damage. Check each syringe for leaks and visible particles. | | | |  |
| Labels adhere to the final product | | | |  |
| Labelled overwrap present | | | |  |
| Release | | | | |
| I accept responsibility for ensuring that this product has been compounded in accordance with GMP. The product complies with all release criteria and can be issued and transported to the point of intended use. | | | | |
| Signature: |  | Date: |  | |

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| **Comments** |
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