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| **Product Information** |
| Sotrovimab 500mg in 50mL Sodium Chloride 0.9% Infusion Bag  (Total volume = 58mL) For Intravenous Infusion |

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| Stability ref | SPC | Concentration range | 500mg in 58mL | Expiry | 24 hours |
| Storage | 2-8°C (fridge) | | Final Container | 50mL Infusion Bag | |
| Additional Information | Do not shake or freeze the vials. | | | | |

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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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| **Batch Specific Details (SOP XXX)** | | | |
| Date dose(s) required |  | Quantity required | 1 |
| 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 |
| Sotrovimab 500mg (62.5mg/mL) Concentrate for Solution for Infusion vial | 1 | GSK |  |  |  |  |
| Sodium Chloride 0.9% 50mL Infusion Bag | 1 |  |  |  |  |  |
| Polypropylene Syringe 10mL | 1 |  |  |  |  |  |
| 19g Needle | 2 |  |  |  |  |  |
| Additive port cap | 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 bung of 1 x Sotrovimab 500mg (62.5mg/mL) Concentrate for Solution for Infusion vial with sterile 70% alcohol wipe prior to use. | | | | | |  |
| 2. Gently swirl the vial several times before use without creating air bubbles. **Do not shake or vigorously agitate the vial.** | | | | | |  |
| 3. Using a 10mL syringe and a 19g needle draw up **1** x **8mL** of Sotrovimab (62.5mg/mL) from the vial. Resheath needle with a hands free aid and replace with a new 19g needle. | | | | | |  |
| 4. Obtain an in process check on accuracy of volume drawn up **1 x 8mL** Sotrovimab (62.5mg/mL) | | | | | |  |
| 5. Swab the additive port of the Sodium Chloride 0.9% 50mL Infusion Bag with sterile 70% alcohol wipe prior to use. | | | | | |  |
| 6. Add **1 x 8mL** Sotrovimab (62.5mg/mL) to the Sodium Chloride 0.9% 50mL Infusion Bag, via the 19g needle. Record in process check of addition. | | | | | |  |
| 7. Gently rock the infusion bag back and forth 3 to 5 times. **Do not invert the infusion bag. Avoid forming air bubbles.** **Do not shake** **the bag**. Record in process check of mixing. | | | | | |  |
| 8. Attach additive port cap and visually inspect Infusion bag for particles and leaks. | | | | | |  |
| **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 infusion bag for leaks and visible particles. Label each product according to local procedure. Label each Infusion bag and overwrap. Document label & product reconciliation in table below. | | | | | |
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| No. Attached to products |  | No. Attached overwrap |  | Labelled by |  |
| No. Spoiled/ excess |  | No. Destroyed |  | Destroyed by |  |
| Number of Products Prepared |  |  | | | |

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| **Product Approval & Release (SOP XXX)** | | | | |
|  | | | | Yes / No |
| 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 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 with tamper evident closure | | | |  |
| 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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