RECOVERY Randomised Evaluation of COVID-19 Therapy	Author: RECOVERY	Date: 12-Dec-2022	Page **1** of **2**
	Approval:	Review: + 6 months	V1.2
Master Label Form Generated by:	(Sign/Date)	Checked by:	(Sign/Date)

RECOVERY Trial Pharmacy Expiry Extension Labelling Worksheet
SOTROVIMAB 500mg in 8mL Concentrate solution for infusion

Site:	
Date of over-labelling operation:	
Storage conditions whilst over-labelling:	Sotrovimab vials may be out of the fridge (2 – 8°C) for no more than 60 minutes
GSK/Vir confirmation of shelf-life expiry extension	Attach a copy to this work sheet

Product	Qty	Batch Number	Current Expiry Date	New Expiry Date	Assembled By:	Checked By:
Sotrovimab 500mg in 8mL Solution for Infusion (1 vial per carton)		UK3F				
		2T8F				

Label Production	
Master Label:	Sample Label:
	Affix the last label printed here

Method		
	Performed By:	Checked By:
1. Ensure the work area is clean and free from all materials not required in this process		
2. Calculate number of labels need A = (no. of vials x 2) +1, print the labels		
3. Remove sotrovimab vials from the fridge Record time removed: ………………		
4. Apply label to the carton and vial		
5. Replace sotrovimab vials back in the carton and into the fridge Record time replaced: ………………		
6. Calculate total time removed from fridge ………. minutes		
7. Check that this is less than 60 minutes		

Label Reconciliation

	No. of Labels	Performed By:	Checked By:
No. of labels printed (A)			
No. of sample labels attached to worksheet (B)			
No. of labels attached to vials (C)			
No. of labels attached to carton (D)			
No. of excess labels destroyed (E)			
Total number of labels accounted for A = B + C + D + E	Y / N		

Approvals:

The above product has been over-labelled with new expiry extension labels according to the instructions above. Any remaining labels have been destroyed.

Actions completed by:

_____ (Print Name) _____ (Sign) _____ (Initials) _____ (Date)

Actions Pharmacist checked by:

_____ (Print Name) _____ (Sign) _____ (Initials) _____ (Date)

Comments / Deviations

Storage of document:

Completed worksheet must be retained in the RECOVERY pharmacy site file, along with evidence of expiry date extension.