



Place in Site Master File #10

Receipt of trial medication

When you receive packages with trial medication (IMP and placebo) for the SUP-ICU Trial you will receive an "IMP Transmittal Sheet" to fill out (see below).

IMP TRANSMITTAL SHEET		Nomeco CTSM			
Trial No.:		Centre No.:			
Country:		Nomeco A/S			
		Contact person: CTSM team			
		Phone: +45 3614 2066			
		Email: ctsm@nomeco.dk			
		Fax: +45 3614 1245			
Transmittal from: (enter code)....		Transmittal to: (enter code)....			
Transmittal Codes:		Materials Codes:			
A	Nomeco	1	New trial medication		
B	Investigator site	2	Codebreak cards /treatment allocation cards		
C	Other (define)	3	Returned trial medication (from trial subjects)		
D		4	Unused, undispensed trial medication		
E		5	Other (define)		
Documentation attached to the shipment					
<input type="checkbox"/> Copy of order					
<input type="checkbox"/> CoA's / Batch Release Certificates					
<input type="checkbox"/> Instruction: How to read temperature logger					
<input type="checkbox"/> Copy of import license					
<input type="checkbox"/> Material Safety Data Sheet (MSDS)					
<input type="checkbox"/> Commercial invoice					
<input type="checkbox"/> Value statement and packaging list					
<input type="checkbox"/> End use letter					
<input type="checkbox"/> Other:					
<input type="checkbox"/> Other:					
Details					
Material codes	Medication ID no./ Subject no./ Rand. code	Strength (e.g. mg)	Quantity and units (e.g. 12 boxes / 50 tablets each)	Expiry date of medication	Other relevant information
Pulled from stock by (signature/date):.....				Recipient Name:	
Verified and released by (signature/date):.....				Recipient Title:	
Method of dispatch.....				Signature:	
Date of dispatch:				Date:	
				Nomeco-No.:	
				Average: Min.: Max.:	
				Date/Signature:	
<p>Upon receipt of drugs/materials this form must be filled in, signed and e-mailed/faxed to Nomeco, Att. CTSM: ctsm@nomeco.dk / + 45 3614 1245.</p> <p>Document no.: VCTSM.05.04.02. Version 1.0</p>					

Please, follow the instructions that comes with the "IMP Transmittal Sheet" entitled "Guidance – How to fill out IMP transmittal Sheet upon receipt of IMP" (see page 2 of 2).



Guidance - How to fill out *IMP Transmittal Sheet* upon receipt of IMP

- 1) *IMP Transmittal Sheet* is following a shipment of IMP from Nomeco, CTSM.
- 2) Please, check information given at the *IMP Transmittal Sheet*.
- 3) Complete the document by filling out the box in the lower right corner. Please note that a signature confirms that the right quantity of IMP with the correct ID numbers is receipt and also that the shipment is receipt in good condition. Please add temperature monitor readings – average, minimum and maximum to the document and sign off.
- 4) The completed *IMP Transmittal sheet* together with PDF file from the temptale 4 logger device are returned to Nomeco, CTSM by fax or email (+45 3614 1245 or ctsm@nomeco.dk).
- 5) Do not use IMP until Nomeco, CTSM has confirmed by email that IMP is ready for use.

Please, call CRIC at +45 35 45 71 67 if you need help to fill out the sheet upon receipt of medication.