



Cellular ATMP Cryopreserved Autologous Example Receipt Checklist FINAL

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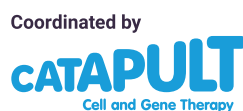
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Example checklist for receipt and storage of autologous cryopreserved cellular ATMPs

18 Nov 2020

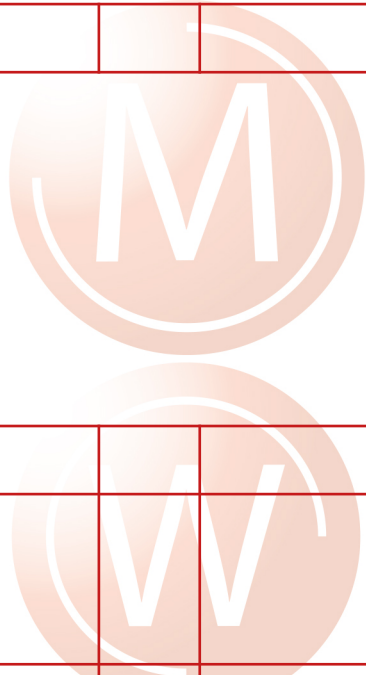
This document sets out an example generic checklist for autologous, cryopreserved, cellular Advanced Therapy Medicinal Products (ATMPs). It may require adaptation to accommodate local procedures or product-specific requirements. The checklist should be adjusted to reflect whether the ATMP is received direct from the manufacturer or via a Stem Cell Laboratory. Institutional readiness checklists produced by the Pan-UK Pharmacy ATMP Working Group for relevant cellular ATMP type should also be considered. (Available from <https://www.sps.nhs.uk/>).

Separate checklists are also available for fresh/cryopreserved allogeneic ATMPs and fresh, autologous ATMPs.

All staff handling cryopreserved ATMPs must also have demonstrated competency in handling dry ice or low temperature storage vessels as appropriate.

CRYOPRESERVED AUTOLOGOUS CELLULAR ATMP RECEIPT & STORAGE CHECKLIST

Product Name			
Sending laboratory if applicable			
Manufacturer (if different to above)			
Patient name if applicable			
Patient date of birth if applicable			
Patient hospital number if applicable			
Date & time received			
Received by (2 staff members)			
Checking step\data	Yes\No\N/A/ Data	Checker Initials	Date & time
Shipping documentation received: Shipping log Returns documents	Yes / No / N/A Yes / No / N/A		
Qualified Person (QP) Release Certificate / Certificate of Conformance/ Certificate of Analysis available (delete as applicable)	Yes / No		
Location of shipper checked on manufacturer's portal if applicable ¹ (must be expected receiving centre/location)	Yes / No / N/A		
Stem Cell Lab (SCL) ATMP Batch Processing Record is complete and signed for release if applicable ¹	Yes / No / N/A		
Temperature log received/ downloaded from manufacturer or SCL and transport/storage temperature within limits ²	Yes / No		

Any visible damage to shipper?	Yes / No			
Details and action taken				
Shipper ID matches delivery documentation	Yes / No			
Tamper-evident ties intact? Outer (Tag ID: _____) Inner (Tag ID: _____)	Yes / No			
Tamper-evident tie ID corresponds to documentation	Yes / No			
Shipper Data Temperature Logger within specification ³ (i.e. no alarms)	Yes / No			
Quantity received (no. of bags/ vials/ syringes)				
Number of bags/vials/syringes matches QP Certificate/ Certificate of Conformance/ Certificate of Analysis	Yes / No			
Product integrity visual check ⁴	Pass / Fail			
Lot/Batch number				
Donation Identification Number (DIN) or unique donation identifier correct (may be manufacturer ID)	Yes / No			
Name on product matches manufacturer portal / QP certificate / (circle applicable parts)	Yes / No			
Patient identifiers on product match manufacturer portal /QP certificate (circle applicable parts)	Yes / No			

Product dose matches Certificate of Conformance/ QP certificate/ Certificate of Analysis (circle applicable parts)	Yes / No			
Expiry date; Administration planned prior to expiry date? Yes / No			
All documentation filed as per local policy, to be retained for period appropriate to product type?	Yes / No			
Comments:				

¹ ATMPs may be received by Pharmacy/clinical area direct from the manufacturer or via the local Stem Cell Laboratory. The checklist must be amended to reflect local processes. The batch processing records apply only to ATMPs which have been received by a SCL direct from the manufacturer for storage and then subsequently delivered to Pharmacy/clinical area.

² For ATMPs received via a SCL, the temperature log for low temperature shippers may only available in retrospect once the shipper is returned to the SCL and data logger downloaded. Compliance with transit temperature parameters is assessed by the shipper data logger at the point of receipt.

³ If any temperature deviations or product defects have occurred, replace the product in the shipper and label as 'under quarantine'. For temperature deviations, liaise urgently with the SCL regarding provision of a new shipper for quarantine or on-going quarantine of product in SCL storage facilities. For defective products including cracked bags, return to SCL may be inappropriate due to risk of contamination. Contact the manufacturer immediately and refer to local Standard Operating Procedures for ATMP product deviations.

⁴ Product visual integrity check should include checking both sides of the infusion bag and the port for cracks/tears/leakage. If defects noted, refer to point 3.

PLACING CELLULAR ATMP INTO STORAGE (if applicable)

Checking step\data	Yes/No/N/A Data	Checker Initials	Date & time
Required storage temperature range (from SPC or trial protocol or manual)			
Product placed into storage, storage tank temperature verified and temperature constantly monitored?	Yes / No / N/A		
Storage tank ID/Room ID (plus entered on local database if required)	Yes / No / N/A		
Receipt documented on manufacturers platform if required	Yes / No / N/A		

Completed receipt checklist sent to Pharmacy (if applicable)	Yes / No	Initials	Date & time

FINAL CHECK	Print name	Signature	Date
Checker 1			
Checker 2			