

Title: QA Certificate



QA CERTIFICATE

**SITE OF MANUFACTURING:** Janssen Pharmaceuticals  
1000 U.S. Route 202 South, Raritan, NJ, USA 08869

**PRODUCT NAME:** CARVYKTI (ciltacabtagene autoleucel)  
Dispersion or Suspension, for Intravenous Infusion only

**STATEMENT OF ACTIVE SUBSTANCE:** Autologous human T cells genetically modified ex vivo using a lentiviral vector encoding an anti-BCMA chimeric antigen receptor (CAR).

PATIENT INFORMATION			
Patient Name			
Patient DOB			
SEC / DIN			
Order ID			
Patient weight (Kg)	Kg		
BATCH INFORMATION			
Batch/Lot Number	COI Bag ID	Total Volume (mL) per Bag	Product Dose per Bag
		mL	
Expiration Date			
Package Size and Type	One sterile bag for Infusion and one metal cassette containing one individually packed Infusion bag.		
Product NDC			
PCC Number			
MARKETING AUTHORIZATION HOLDER			
Name and Address			
Marketing Authorization Number			
Country			
SPECIAL STORAGE CONDITION			
Store and transport frozen ( $\leq -120^{\circ}\text{C}$ ). Keep infusion bag in the metal cassette until ready for thaw and administration. Once thawed do not shake, refrigerate or re-freeze			
SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE			
This medicine contains genetically modified cells. Unused medicine or waste material must be disposed of in compliance with the local guidelines on handling of waste of human-derived material.			
OTHER SPECIAL WARNING(S), IF NECESSARY			
SAVE THIS DOCUMENT AND PREPARE TO HAVE IT AVAILABLE AT THE TIME OF INFUSION For autologous use only. Do Not Irradiate. Do Not Use a Leukodepletion Filter. Read the package leaflet before use.			
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above-mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.			Check applicable box <input type="checkbox"/> Release without Exception <input type="checkbox"/> Release with Exception
Completed By/Date:		Authorized by QA Batch Release Designee/Date:	

\*\*\*END OF DOCUMENT\*\*\*

HIGHLY RESTRICTED: CONTAINS PERSONAL MEDICAL INFORMATION