Change Notification
CC-21-0280

Prolongation of shelf life of MACS® GMP T Cell TransAct™ – Large Scale

Product: MACS GMP T Cell TransAct – Large Scale
REF: 170-076-177

Category of change: Prolongation of shelf life

Current State: The MACS GMP T Cell TransAct – Large Scale has a shelf life of five months at 2 – 8 °C storage temperature.

Planned change: The shelf life of the MACS GMP T Cell TransAct – Large Scale will be extended to 10 months at 2 – 8 °C storage temperature.

Justification/Evaluation: Based upon actual data provided by ongoing real time stability studies which support a prolonged shelf life, the shelf life can be adapted accordingly.

There is no change of raw material or manufacturing process. Therefore no impact on the performance, quality and safety of the affected product could be identified.

Estimated Implementation: Q3/2021

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG

10.Aug.2021