Adaption of retest date for Lentiviral Vector aCD19 hum CAR

Product: Lentiviral Vector aCD19 hum CAR

REF: 200-072-108

Category of change: Prolongation of shelf life

Current State: Lentiviral Vector aCD19 hum CAR a retest date of 24 months after production at -70°C storage temperature.

Planned change: A retest date of Lentiviral Vector aCD19 hum CAR will be set at 36 months after date of production at -70°C storage temperature.

Justification/ Evaluation: Based upon actual data provided by ongoing real time stability studies which support a prolonged retest period, the retest date 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: Mar 2022

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

17.Feb.2022

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