Adaption of retest date for Lentiviral Vector aBCMA CAR

Product: Lentiviral Vector aBCMA CAR

REF: 200-072-113

Category of change: Prolongation of shelf life

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

Planned change: The retest date of Lentiviral Vector aBCMA CAR will be set to 36 months after date of production and 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: Feb 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.


QA Audit/Customer/Supplier Management
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