Adaption of specification of Lentiviral Vector aCD20-CD19 Tandem CAR

Product: Lentiviral Vector aCD20-CD19 Tandem CAR

REF: 200-072-103

Category of change: Adaption of specification

Current State: Currently, a specification for the functional titer (CFrag qPCR) is set and the "physical titer (p24 ELISA)" is measured for information only. The specification is not mentioned on the Certificate of Analysis (CoA) of the Lentiviral Vector aCD20-CD19 Tandem CAR.

Planned change: The specification for "physical titer (p24 protein) is set to ≥106 ng/mL and the new parameter “functional titer/physical titer ratio” with the specification ≥366 TU/ng is introduced. The CoA will be replaced by a Product Quality Certificate (PQC, please refer to CN_CC-20-0233 Introduction of Product Quality Certificate). Thereby, the specification will be revised and state the functional titer.

Justification/Evaluation: The change considers current process understanding for broader assessment of vector quality and improves evaluation of process reliability. Additional information regarding functional titer on the PQC will increase customer satisfaction.

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: Q1/2022

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

Manager QA Audit/Customer/Supplier
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