Prolongation of shelf life of MACS® GMP PBS/MgCl₂ Buffer and MACS GMP Tytonase

Product | REF |
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MACS GMP PBS/MgCl₂ Buffer | 170-076-155 |
MACS GMP Tytonase | 170-076-210 |

**Category of change:** Adaption of Shelf life

**Current State:** The MACS GMP PBS/MgCl₂ Buffer has a shelf life of 35 months after sterilization when stored at room temperature. The MACS GMP Tytonase has a shelf life of 3 months when stored at 2 - 8°C.

**Planned change:** The shelf life of MACS GMP PBS/MgCl₂ Buffer will be extended to 5 years after sterilization when stored at room temperature. The shelf life of MACS GMP Tytonase Running Buffer will be extended to 6 months when stored at 2 - 8°C.

**Justification/ Evaluation:** Based upon actual data provided by ongoing real time stability studies which support a prolonged shelf life, the shelf life of the MACS GMP PBS/MgCl₂ Buffer and MACS GMP Tytonase 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** 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
Miltenyi Biotec B.V. & Co.KG

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