Certificate of Analysis

Human Mesenchymal Stem Cells With GFP
Cryopreservation Date: 2015-12-22
Passage Number: 5

Catalog No. HUXMA-01101
Lot Number: 151222I31

Viability
Cells are assayed for viability post-thaw using vital staining assay with trypan blue.
Specification: Cells should exhibit ≥ 80% viability.

Sterility
Bacterial and Fungal Contamination: Samples are inoculated and cultured in blood agar plate, thioglycolate broth, tryptocase soy broth and sabouraud dextrose agar.
Specification: No growth must be observed.

Mycoplasma: Samples are tested for mycoplasma contamination using a PCR-based assay and direct culture.
Specification: Results must be negative.

Endotoxin: Samples are tested for endotoxin contamination with LAL test.
Specification: Results must show ≤ 10EU/ml.

Exogenous Virus： Samples using ELISA assay to detect HIV, HBV, HCV and Syphilis.
Specification: Results must be negative.

Purity
Cells are assayed for purity using flow cytometric analysis of cell surface antigen expression after cryopreservation. Cells are immunofluorescently stained with fluorochrome−conjugated antibodies specific to cell surface antigens CD29 CD105, CD44, CD45, CD11b and CD34.
Specification: Cells must show ≥ 70% positivity for expression of cell surface antigens CD29, CD44 and CD105. Cells must show ≤ 5% positivity for expression of cell surface antigens CD34, CD11b and CD45.

Proliferation Ability
Cells are characterized by their ability to proliferate in culture with an attached well-spread morphology for ≥ 5 passages, and ≤ 5% cells exhibit spontaneous differentiation in each passage.

GFP Expression
Expression of constitutive GFP is assayed by visual inspection of GFP fluorescence signal.

Specification: The results must indicate ≥80% of cells are visually inspected for GFP fluorescence signal during extensive subcultivation.

Differentiation Ability

Cells are assayed after cryopreservation for their ability of tri-lineage differentiation. Cells must be able to differentiate to osteocytes, adipocytes and chondrocytes when cultured in the appropriate differentiation media.

Results:

All specifications have been met.

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Dec 16, 2016