Assay Ready CHO-hERG-DUO

Frozen Instant Cells

Certificate of Analysis

Lot-N°: **92-190222JP02**

Date: **04.03.2019**

BATCH SPECIFICATIONS

Lot-N°:	92-190222JP02	Cell Designation:	CHO-hERG-DUO
Batch Size:	71 Vials	Cell ID:	ID0275
Cell Count (nominal):	5 million cells / vial	Cell Origin:	provided by customer
Passage:	31		
Expansion:	HAM´s F12, 10 % FBS, 2 mM L-Glutamine		
Freezing:	HAM´s F12, 10 % USDA-FBS, 5 % DMSO		
Storage:	Below -130°C (e.g. liquid nitrogen)	Approved by:	
Recommended retesting:	every 12 months		
Approval Date:	04.03.2019	Susan Ciura (Head of Quality Control)	

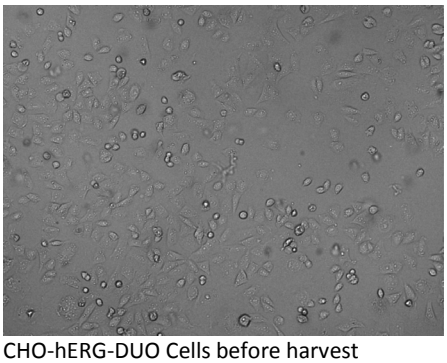
QUALITY CONTROL

Samples Tested: 0 Vials (0.0 % of production batch) – ***Values were determined during the harvest procedure.*** -

	Results	Specification Limits
Cell Count[1]	5.00E+06 (calculated)	≥ 90 % of nominal cell number
Homogeneity (deviation in cell count)	1.3 %	≤ 10 %
Viability (after thawing)	98 %	≥ 90 %
Aggregation	1.4	≤ 2.0
Debris / Cell	0.2	≤ 0.5
Proliferative Capacity	n.a.	≥ 85 %
Sterility (bacteria, yeast, fungi)[2]	no contamination detected	negative after 4 days
Sterility (mycoplasma)[3]	no mycoplasma detected	negative by PCR
Morphology	normal, no visible changes	unchanged to seed culture

[1]: as determined by CASY TT cytometer, [2]: by microscopic/visual control after four days of culture in the absence of antibiotics, [3]: as determined in the cell culture supernatant after four days of cultures by PCR,

MORPHOLOGY:



CHO-hERG-DUO Cells before harvest

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METHODS

Cell Viability Parameters: Viability parameters (viable cell count after thawing, grade of aggregation, percentage of debris) were determined from a pooled sample (SOP-2015-02). Briefly, assay ready cells were thawed in a water bath. 50 µl of each sample were pooled, diluted 1:1000 in CASY Ton buffer and measured (3 replica) in a CASY TT automatic cell counter. Vial to vial variation was determined in a plate based viability assay. Equal aliquots of each cell samples were dispensed into a 96 well-plate. A cellular dye, was added to the well to obtain fluorescent signal which is proportional to the viable cell count.

Proliferative Capacity: 2.0E+04 cells from the assay ready cell samples and from a reference of a continuously passaged culture were seed in a 96-well plate (3 replica each). After 72 hours of cultivation the proliferation of the cells was determined by addition of a metabolic cell dye (Resazurin). The proliferative capacity of the assay ready cells is calculated in percent of the exponentially growing reference. (SOP-2017-03).

Sterility Testing: Assay ready cells were seeded @ 1.0E+04 cells/cm^2 into a T25 cell culture flask in antibiotic free cell culture medium and cultivated over a course of four days. Every day, the cultures was analyzed microscopically for cell growth, cell morphology, and incidences of contamination (bacteria, yeast, or fungi). For mycoplasma testing from a three days old, sub-confluent culture 500 µl of the supernatant was taken and analyzed by PCR using a Mycoplasma detection kit (Minerva). Assay was performed according to the manufacturer protocol (SOP-2015-06).

acCELLerate is maintaining a quality management system certified according to EN ISO 9001-2015. All equipment is subject to a guided system. Regular cleaning and maintenance intervals as well as hygienic monitoring are set and complied for the devices. Suppliers are regularly evaluated, and a risk management is established. Deviations are documented, and a CAPA-system is established. Individual certificates and verification documents can be provided upon request by the quality management department.