

CERTIFICATE OF QUALIFICATION

PRODUCT	celCradle-500 Bottle
PRODUCT NO.	1400001
LOT NO. / SERIAL NO.	Lot No.: 105030001 Serial No.: BC5-08514 ~ BC5-08593
DESCRIPTION	Disposable Device for Cell Culture
MANUFACTURE DATE	2016/08
EXPIRATION DATE	2018/07

Thank you for purchasing Esco Vaccixcell products. Our products pass the following inspection items:

QC item	Criteria	Result	Pass/Fail	Regulation
<i>Integrity Test</i>	No leakage	No leakage	Pass	N/A ^a
<i>Gamma Irradiation</i>	1. γ -ray indicator turn red 2. γ -ray dosage certificate	1. red 2. 18.2 kGy	Pass	N/A
<i>Durable Test</i>	No breakage	No breakage	Pass	N/A ^b
<i>LAL Test</i>	< 0.25 EU/ml	< 0.25 EU/ml	Pass	USP36-NF31 <85> ^c
<i>Biological Reactivity Test</i>	Grade 0	Grade 0	Pass	USP36-NF31 <87> ^d
<i>Bioburden Test</i>	≤ 10 CFU per bottle	0 CFU/bt	Pass	USP36-NF31 <61> ^e
<i>Average Amount of Carriers</i>	798 pcs \leq 1 bottle \leq 908 pcs	829 \pm 7 pcs/bt	Pass	N/A ^a

Note :

a Pressure and Leakage Test @ 0.07 Kg/cm², 100% inspection. Internal standards.

b 200,000 Compression-Expansion cycle Test.

c <85>BACTERIAL ENDOTOXINS TESTS, Gel Clot Method

d <87>BIOLOGICAL REACTIVITY TESTS *in Vitro*, L-929 Cell Culture Test (Serum-Containing Medium)

e <61>MICROBIAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS

I HEREBY CERTIFY THAT THIS ANALYSIS IS TRUE AND ACCURATE, AND EVERY PART AND MATERIAL WILL NOT BE ALTERED WITHOUT PRIOR WRITTEN NOTIFICATION OF IMPENDING MODIFICATIONS OF PRODUCT.



16 August 2016

SIGNATURE OF QA ENGINEER

DATE