



Quality control card / Scheda Controllo Qualità

PRODOTTO
PRODUCT **B193360 Piastre/Plates Columbia CNA Modificato + 5% S. mont. (Sheep blood)**

SCADENZA / EXP. DATE **21/05/17** LOTTO/LOT **2817301407**

Test di sterilità Sterility control	Data di produzione martedì 07/03/17 Test di sterilità a 22°C (± 2°C) x 3 gg / Sterility control at 22°C (± 2°C) for 3 days.	Test di sterilità a 37°C (± 2°C) x 3 gg / Sterility control at 37°C (± 2°C) for 3 days: Assenza di crescita microbica / No microbial growth																																
Test di shock termico / Shock termic test	Assenza di crescita microbica / No microbial growth Conservazione nella confezione minima di vendita per 6 gg a 23 ± 2°C / Storage (in minimum selling packaging) for 6 days at 23 ± 2°C; Nessuna variazione significativa dell'aspetto e della performance / No significant variation in appearance and performance	Assenza di crescita microbica / No microbial growth Conservazione nella confezione d'imballo per 3 gg a 40 ± 2°C / Storage in shipping packaging for 3 days at 40 ± 2°C; Nessuna variazione significativa dell'aspetto e della performance / No significant variation in appearance and performance																																
Procedure secondo indicazioni/As per directives: European Pharmacopoeia (EP) United States USP CLSI M22-A3 UNI EN ISO 11133	<table border="1"> <thead> <tr> <th data-bbox="624 898 639 1317">Caratteristiche fisiche / Physical characteristics</th> <th data-bbox="624 463 639 875">Attese / Expected</th> <th data-bbox="624 898 639 1317">Osservate / Observed</th> </tr> </thead> <tbody> <tr> <td data-bbox="639 898 655 1317">Trasparenza / Transparency</td> <td data-bbox="639 463 655 875">Opalino / Opalescent</td> <td data-bbox="639 898 655 1317">Opalino / Opalescent</td> </tr> <tr> <td data-bbox="655 898 671 1317">Colore / Colour</td> <td data-bbox="655 463 671 875">rosso vivo / red</td> <td data-bbox="655 898 671 1317">rosso vivo / red</td> </tr> <tr> <td data-bbox="671 898 687 1317">pH (20-25°C)</td> <td data-bbox="671 463 687 875">7,3 ± 0,2</td> <td data-bbox="671 898 687 1317">7,27</td> </tr> </tbody> </table>		Caratteristiche fisiche / Physical characteristics	Attese / Expected	Osservate / Observed	Trasparenza / Transparency	Opalino / Opalescent	Opalino / Opalescent	Colore / Colour	rosso vivo / red	rosso vivo / red	pH (20-25°C)	7,3 ± 0,2	7,27																				
Caratteristiche fisiche / Physical characteristics	Attese / Expected	Osservate / Observed																																
Trasparenza / Transparency	Opalino / Opalescent	Opalino / Opalescent																																
Colore / Colour	rosso vivo / red	rosso vivo / red																																
pH (20-25°C)	7,3 ± 0,2	7,27																																
Microorganismi testati / Tested	<table border="1"> <thead> <tr> <th data-bbox="799 898 815 1317">Metodo di semina e incubazione / Inoculation method and incubation</th> <th data-bbox="799 463 815 875">Risultati attesi Expected results</th> <th data-bbox="799 898 815 1317">Risultati osservati Observed results</th> <th data-bbox="799 463 815 875">PR or SF</th> </tr> </thead> <tbody> <tr> <td data-bbox="815 898 831 1317">Sospensione d'inoculo/ Inoculum level</td> <td></td> <td></td> <td></td> </tr> <tr> <td data-bbox="831 898 847 1317"><i>Streptococcus pyogenes</i>* 10-102UFC</td> <td data-bbox="831 463 847 875">Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="831 898 847 1317">Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="831 463 847 875">0,93</td> </tr> <tr> <td data-bbox="847 898 863 1317"><i>Streptococcus pneumoniae</i>* 10-102UFC</td> <td data-bbox="847 463 863 875">Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="847 898 863 1317">Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="847 463 863 875">0,94</td> </tr> <tr> <td data-bbox="863 898 879 1317"><i>Streptococcus agalactiae</i>* 10-102UFC</td> <td data-bbox="863 463 879 875">Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="863 898 879 1317">Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="863 463 879 875">0,99</td> </tr> <tr> <td data-bbox="879 898 895 1317"><i>Staphylococcus aureus</i>* 10-102UFC</td> <td data-bbox="879 463 895 875">Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="879 898 895 1317">Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="879 463 895 875">0,91</td> </tr> <tr> <td data-bbox="895 898 911 1317"><i>Enterococcus faecalis</i>* 10-102UFC</td> <td data-bbox="895 463 911 875">Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="895 898 911 1317">Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7</td> <td data-bbox="895 463 911 875">0,85</td> </tr> <tr> <td data-bbox="911 898 927 1317"><i>Escherichia coli</i>* 104-106UFC</td> <td data-bbox="911 463 927 875">Inibizione totale / Total inhibition</td> <td data-bbox="911 898 927 1317">Inibizione totale / Total inhibition</td> <td data-bbox="911 463 927 875">-</td> </tr> </tbody> </table>		Metodo di semina e incubazione / Inoculation method and incubation	Risultati attesi Expected results	Risultati osservati Observed results	PR or SF	Sospensione d'inoculo/ Inoculum level				<i>Streptococcus pyogenes</i> * 10-102UFC	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	0,93	<i>Streptococcus pneumoniae</i> * 10-102UFC	Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7	Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7	0,94	<i>Streptococcus agalactiae</i> * 10-102UFC	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	0,99	<i>Staphylococcus aureus</i> * 10-102UFC	Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7	Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7	0,91	<i>Enterococcus faecalis</i> * 10-102UFC	Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7	Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7	0,85	<i>Escherichia coli</i> * 104-106UFC	Inibizione totale / Total inhibition	Inibizione totale / Total inhibition	-
Metodo di semina e incubazione / Inoculation method and incubation	Risultati attesi Expected results	Risultati osservati Observed results	PR or SF																															
Sospensione d'inoculo/ Inoculum level																																		
<i>Streptococcus pyogenes</i> * 10-102UFC	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	0,93																															
<i>Streptococcus pneumoniae</i> * 10-102UFC	Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7	Crescita, α emolisi / Growth, α hemolysis PR (Productivity Ratio) >0,7	0,94																															
<i>Streptococcus agalactiae</i> * 10-102UFC	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	Crescita, β emolisi / Growth, β hemolysis PR (Productivity Ratio) >0,7	0,99																															
<i>Staphylococcus aureus</i> * 10-102UFC	Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7	Crescita ± emolisi / Growth ± hemolysis PR (Productivity Ratio) >0,7	0,91																															
<i>Enterococcus faecalis</i> * 10-102UFC	Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7	Crescita senza emolisi / Growth w/o hemolysis PR (Productivity Ratio) >0,7	0,85																															
<i>Escherichia coli</i> * 104-106UFC	Inibizione totale / Total inhibition	Inibizione totale / Total inhibition	-																															

* Semina in superficie (Miles-Misra modificato) ed incubazione in CO2 10% a 37 °C per 24 ore / * Surface plating (Miles-Misra modified) and CO2 10% incubation at 37°C for 24 hours.

Test n. 17639

Data controllo 10/03/17
Control date

Il responsabile del controllo / Quality control responsible

Dott. DANIELE Edoardo

Questo documento è stato emesso elettronicamente / This document has been delivered electronically
MEUS SRL Via Leonardo da Vinci n. 24/b - 35028 PIOVE DI SACCO (PD) - e-mail: meus@tecnomeus.it