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ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L236

EVS-EN 17126:2018
INTERFLO OÜ
LABORATORY
Supluse pst. 5-3, 11911, Tallinn,
Estonia
Tel.+372 58098890
e-mail: norbak@norbak.ee

Quantitative suspension test for the evaluation of sporicidal activity in the medical area (phase 2, step 1)

TEST REPORT no 709

1. General information and material

Client:	MEDISEPT SP. ZOO NIP: 9460010016
Date of order:	2022/02/25

2. Identification of sample

Name of the product:	VIRUTON PULVER
Batch number:	sample
Manufacturer:	MEDISEPT SP. ZOO
Date of delivery:	2022/02/21
Storage conditions:	room temperature and darkness
Apperance of the product:	white powder with blue granules

Recommended diluent:	water 30 °C, testing 15 min after dilution
Active substance and concentration:	Sodium percabonate – 44 %; TAED – 26 %

3. Test conditions

Test period:	2022/03/01 – 2022/03/04
Date of test:	2022/03/01
Product test concentrations:	1,0 %; 2,0 %
Exposure time:	10 min
Test temperature:	19,5 ± 0,5ºC
Temperature of incubation	36,5 ± 0,5ºC
Organic load:	3,0 g/l bovine albumin and 3,0 ml/l sheep erythrocytes for high-level soiling 0,3 g/l bovine albumin for low-level soiling
Neutralizer:	Polysorbate 80, 30 g/l, Sodium thiosulphate, 5 g/l, Lecithin, 3 g/l
Test organisms:	Clostridium difficile (R027) DSM 27147

4. Methods

Test method and its validation:	dilution neutralisation

5. Results see annex

6. Conclusion

In accordance with EN 17126:2018, product VIRUTON PULVER (sample) with concentration 1,0 % under clean conditions and with concentration 2,0 % under dirty conditions at 10 min possesses sporicidal activity in suspension test at 20 ºC for reference strain Clostridium difficile (R027) DSM 27147.

The product VIRUTON PULVER (sample) demonstrates at least a 4 lg reduction for reference strain Clostridium difficile (R027) DSM 27147.

The conclusion is true only for the studied sample of the product VIRUTON PULVER (sample).

Total 6 pages
Annex on 4 pages
Tallinn, 2022/03/04

Microbiologist
Ljudmila Shljapnikova
Ph.D.
Head of the Laboratory

EESTI VABARIIK
OÜ INTERFLO
Reg.kood 11586747

Annex 1

VALIDATION AND CONTROLS

Test organism	**Validation suspension Nvo** Dilution range -1			**Validation suspension Nvb** Dilution range -3			**Experimental conditions control A**			**Neutralizer control B** Dilution range -2			**Method validation C** Concentration 2,0 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
Clostridium difficile (R027) DSM 27147	70	64	77	35	39	37	61	66	64	33	37	35	60	62	61

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Annex 2

TEST SUSPENSION

Test organism	**Dilution range**	**Vc1**	**Vc2**	**N, No**
Clostridium difficile (R027) DSM 27147	-5 -6	172 19	153 13	N = 1,62 x 10^{7} = lg 7,21 **No 6,21** 6,17≤lg No≤6,70

Annex 3

TEST 1

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentrations	Conditions	Contact time
Clostridium difficile (R027) DSM 27147	1	0	0	<140	<2,15	**>4,06**	1,0 %	Clean	10 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
	1	0	0	<140	<2,15	**>4,06**	2,0 %	Dirty	10 min
	-1	0	0						
	-2	0	0						
	-3	0	0						

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Annex 4

$N = c / (n1 + 0{,}1\ n2) \times 10^{-z}$

$No = N / 10$

$Na = c \times 10 / n$

$R = \lg No - \lg Na$

N – is the number of colonies for 1 ml test suspension
Vc1, Vc2 - is the is number of colonies for 1 ml sample
n – is the number of Vc-values taken into account
z – is the dilution factor corresponding to the lower dilution
R – reduction