



EVS-EN 17126:2018
INTERFLO OÜ
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Quantitative suspension test for the evaluation of sporicidal activity in the medical area (phase 2, step 1)

TEST REPORT no 806

1. General information and material

Client:

MEDISEPT SP. ZOO
Reg. 946001016, Ludwika Spiessa 2, 20 270 Lublin
2023/08/29; 2023/09/12

Date of orders:

2. Identification of sample

Name of the product:

VIRUTON PULVER

Batch number:

LOT 230622 6

Manufacturer:

MEDISEPT SP. ZOO

Date of delivery:

2023/08/24

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 percarbonate – 44 %; TAED – 26 %

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3. Test conditions

Test period:	2023/09/05 – 2023/10/02
Date of tests:	2023/09/05; 2023/09/27
Product test concentrations:	1,0 %; 4,0 %
Exposure time:	10 min
Test temperature:	19,5 ± 0,5°C
Temperature of incubation	36,5 ± 0,5°C
Organic load:	3,0 g/l bovine albumin and 3,0 ml/l sheep erythrocytes for high-level soiling
Neutralizer:	Polysorbate 80, 30 g/l, Sodium thiosulphate, 5 g/l, Lecithin, 3 g/l
Test organisms:	Bacillus cereus ATCC 12826, Bacillus subtilis ATCC 6633, Clostridium difficile ATCC 9689

4. Methods

Test method and its validation: dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 17126:2018, the product VIRUTON PULVER (LOT 230622 6) with concentration 4,0 % under dirty conditions at 10 min possesses sporicidal activity in suspension test at 20 °C for referenced strains Bacillus cereus ATCC 12826 and Bacillus subtilis ATCC 6633. The product VIRUTON PULVER (LOT 230622 6) with concentration 1,0 % under dirty conditions at 10 min. and 60 min. possesses sporicidal activity in suspension test at 20 °C for reference strain Clostridium difficile ATCC 9689. The product VIRUTON PULVER (LOT 230622 6) demonstrates at least a 4 lg reduction for referenced strains Bacillus cereus ATCC 12826, Bacillus subtilis ATCC 6633 and Clostridium difficile ATCC 9689.

The conclusion is true only for the studied sample of the product VIRUTON PULVER (LOT 230622 6).

Total 6 pages

Annex on 4 pages

Maardu, 2023/10/02

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Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _{vo} Dilution range -1			Validation suspension N _{vb} Dilution range -3			Experimental conditions control A			Neutralizer control B Dilution range -2			Method validation C Concentration 4,0 %		
	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}
Bacillus subtilis ATCC 6633	50	63	57	71	80	76	65	60	63	82	74	78	53	57	55
Bacillus cereus ATCC 12826	40	51	46	38	42	40	37	40	39	43	35	39	40	44	42
Clostridium difficile ATCC 9689	62	55	59	80	92	86	57	64	61	70	63	67	50	54	52

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Annex 2

TEST SUSPENSIONS

Test organisms	Dilution range	Vc1	Vc2	N, No
Bacillus subtilis ATCC 6633	-5	161	149	N = 156,36 x 10 ⁵ = lg 7,19 No 6,19 6,17 ≤ lg No ≤ 6,70
	-6	18	14	
Bacillus cereus ATCC 12826	-5	>300	>300	N = 4,6 x 10 ⁷ = lg 7,66 No 6,66 6,17 ≤ lg No ≤ 6,70
	-6	40	52	
Clostridium difficile ATCC 9689	-5	149	157	N = 153,6 x 10 ⁵ = lg 7,19 No 6,19 6,17 ≤ lg No ≤ 6,70
	-6	15	17	

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Annex 3

TESTS

Test organisms	Dilution range	Vc1	Vc2	Na x 10	Ig Na	Ig R	Concentrations	Conditions	Contact time
Bacillus subtilis ATCC 6633	1	0	0	<140	<2,15	>4,04	4,0%	Dirty	10 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
Bacillus cereus ATCC 12826	1	0	0	<140	<2,15	>4,51	4,0 %	Dirty	10 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
Clostridium difficile ATCC 9689	1	0	0	<140	<2,15	>4,04	1,0 %	Dirty	10 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
	1	0	0	<140	<2,15	>4,04	1,0 %	Dirty	60 min
	-1	0	0						
	-2	0	0						
	-3	0	0						

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Annex 4

$$N = c / (n_1 + 0,1 n_2) \times 10^{-z}$$

$$N_0 = N / 10$$

$$N_a = c \times 10 / n$$

$$R = \lg N_0 - \lg N_a$$

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

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