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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute
according to ČSN EN ISO/IEC 17025.

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Test report No. D117/2017

DETERMINATION OF BACTERICIDAL (EN 1040), FUNGICIDAL
(EN 1275), TUBERCULOCIDAL (EN 14348), SPORICIDAL (EN 14347) AND
VIRUCIDAL (EN 14476+A1) ACTIVITY OF THE PRODUCT **PASDEZ**
DETERMINATION OF ALGICIDAL (ČSN EN ISO 8692, TNV 75 7741)
ACTIVITY OF THE PRODUCT **PASDEZ**

Sample ID: D117/2017

Sample name: **PASDEZ**

Client: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Producer: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

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From pages: 19

Incoming date:
12.6.2017

Delivery date:
9.11.2017

Hodonín, 9.11.2017

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Ing. Jana Šlitrová, Head of Laboratory

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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017	Sampling date: 8.6.2017
Rep No: 152	Sample delivered: 12.6.2017
Sample name: PASDEZ	Testing date: 15.8. – 31.10.2017
Sampled: by client	Delivered amount: 2 x 500 g
Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova	
Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova	
Batch No: 01.006	Page: 2

Subject of testing:

Determination of bactericidal, fungicidal, tuberculocidal, sporicidal, virucidal and algicidal activity of the product.

Identification of the sample:

Name of the product:	PASDEZ
Batch number:	01.006
Date of manufacture:	12.5.2016
Expiry date:	12.5.2019
Manufacturer:	DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova
Incoming date:	12.6.2017
Storage conditions:	stated by the manufacturer
Active compounds and concentrations:	CAS 51580-86-0 Sodium dichlorisocyanurate, dehydrate 99%

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 1040:2005)

Period of analysis:	3.10. – 4.10.2017
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Appearance of the product:	white tablets
Test concentration:	2 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)
Product diluent:	distilled water
Contact time:	30 min
Interfering substances:	no interfering substance (distilled water)
Test organisms:	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538
Incubation conditions:	37 °C ± 1 °C, 7 days

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least 5 orders (10^5).

$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

The standard:

EN 1040:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1) December 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

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Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

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The Number of CFU in the tested product **PASDEZ**: $< 10^1$ CFU/g

1. Testing the efficacy of chemical disinfectant **PASDEZ** on *Pseudomonas aeruginosa* ATCC 15442

Tab No. 1.1 Verification of methodology

Validation of suspension (N _{V0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l							
V _{c1}		38		Φ _{N_{V0}} = 39.5	V _{c1}		30		Φ _A = 33	V _{c1}		33		Φ _B = 35	V _{c1}		26		Φ _C = 29.5
V _{c2}		41			V _{c2}		36			V _{c2}		37			V _{c2}		33		
30 ≤ Φ _{N_{V0}} ≤ 160				Φ _A ≥ 0.5 Φ _{N_{V0}}				Φ _B ≥ 0.5 Φ _{N_{V0}}				Φ _C ≥ 0.5 Φ _{N_{V0}}							
x	yes		no	x	yes		no	x	yes		no	x	yes		no				

Tab No. 1.2 Test suspension

Test suspension N $\Phi = 35.5 \times 10^7 = \lg 8.55$ $8.17 \leq \lg N \leq 8.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 7.55$ $7.17 \leq \lg N_0 \leq 7.70$
	10^{-6}	>330	>330	
	10^{-7}	34	37	
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration /contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 7.55$)
2 tabs/10 l/30	10^0	<14	<14	< 2.15	≥ 5.40

2. Testing the efficacy of chemical disinfectant **PASDEZ** on *Staphylococcus aureus* ATCC 6538

Tab No. 2.1 Verification of methodology

Validation of suspension (N _{V0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l							
V _{c1}		49		Φ _{N_{V0}} = 47	V _{c1}		55		Φ _A = 47.5	V _{c1}		39		Φ _B = 39.5	V _{c1}		52		Φ _C = 45
V _{c2}		45			V _{c2}		40			V _{c2}		40			V _{c2}		38		
30 ≤ Φ _{N_{V0}} ≤ 160					Φ _A ≥ 0.5 Φ _{N_{V0}}					Φ _B ≥ 0.5 Φ _{N_{V0}}					Φ _C ≥ 0.5 Φ _{N_{V0}}				
x	yes				x	yes				x	yes				x	yes			
	no					no					no					no			

Tab No. 2.2 Test suspension

Test suspension N $\Phi = 48.5 \times 10^7 = \lg 8.69$ $8.17 \leq \lg N \leq 8.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 7.69$ $7.17 \leq \lg N_0 \leq 7.70$
	10^{-6}	>330	>330	
	10^{-7}	56	41	
				x yes no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Staphylococcus aureus* ATCC 6538

Test concentration /contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 7.69$)
2 tabs/10 l/30	10^0	<14	<14	< 2.15	≥ 5.54

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the bacterial test suspension for validation N_{V0} = the number of cfu/ml of the bacterial test suspension for validation in the test mixture, A, B, C at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0/N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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3. Evaluation of bactericidal activity of the product **PASDEZ**

Tab No. 3.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – bactericidal activity

Bactericidal activity of the product (EN 1040:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 1040:2005	lg R
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	30	2 tabs/10 l	-	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	30	2 tabs/10 l	-	≥ 5	> 5

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the bacterial test suspension for validation N_{v0} = the number of cfu/ml of the bacterial test suspension for validation in the test mixture, A, B, C at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

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Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 1275:2005)

Period of analysis:

29.9. – 2.10.2017

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

distilled water

Test concentration:

2 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)

Contact time:

30 min

Interfering substances:

no interfering substance (distilled water)

Test organisms:

Candida albicans ATCC 10231

Aspergillus brasiliensis (*niger*) ATCC 16404

Incubation conditions:

30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Presence of a high concentration (at least 75%) of *Aspergillus brasiliensis* spiny spores in the test suspension – yes.

Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi of relevant test organisms under defined conditions by at least 4 orders (10^4).

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable vegetative yeast cells of relevant test organisms under defined conditions by at least 4 orders (10^4).

$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

The standard:

EN 1275:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1) December 2005

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Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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4. Testing the efficacy of chemical disinfectant **PASDEZ** on *Candida albicans* ATCC 10231

Tab No. 4.1 Verification of methodology

Validation of suspension (N _{V0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l			
V _{c1}	24	Φ _{N_{V0}} = 30.5		V _{c1}	28	Φ _A = 23.5		V _{c1}	20	Φ _B = 28		V _{c1}	23	Φ _C = 22	
V _{c2}	37			V _{c2}	19			V _{c2}	36			V _{c2}	21		
30 ≤ Φ _{N_{V0}} ≤ 160				Φ _A ≥ 0.5 Φ _{N_{V0}}				Φ _B ≥ 0.5 Φ _{N_{V0}}				Φ _C ≥ 0.5 Φ _{N_{V0}}			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 4.2 Test suspension

Test suspension N $\Phi = 169 \times 10^5 = \lg 7.23$ $7.17 \leq \lg N \leq 7.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 6.23$ $6.17 \leq \lg N_0 \leq 6.70$
	10^{-5}	164	173	
	10^{-6}	14	20	
				x yes no

Tab No. 4.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Candida albicans* ATCC 10231

Test concentration /contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 6.23$)
2 tabs/10 l/30	10^0	<14	<14	< 2.15	≥ 4.08

5. Testing the efficacy of chemical disinfectant **PASDEZ** on *Aspergillus brasiliensis* (niger) ATCC 16404

Tab No. 5.1 Verification of methodology

Validation of suspension (N _{v0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l							
V _{c1}		27		Φ _{N_{v0}} = 30.5	V _{c1}		25		Φ _A = 22	V _{c1}		23		Φ _B = 20.5	V _{c1}		29		Φ _C = 26
V _{c2}		34			V _{c2}		19			V _{c2}		18			V _{c2}		23		
30 ≤ Φ _{N_{v0}} ≤ 160				Φ _A ≥ 0.5 Φ _{N_{v0}}				Φ _B ≥ 0.5 Φ _{N_{v0}}				Φ _C ≥ 0.5 Φ _{N_{v0}}							
x	yes				x	yes				x	yes				x	yes			
	no					no					no					no			

Tab No. 5.2 Test suspension

Test suspension N $\Phi = 31 \times 10^6 = \lg 7.49$ $7.17 \leq \lg N \leq 7.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 6.49$ $6.17 \leq \lg N_0 \leq 6.70$
	10^{-5}	>165	>165	
	10^{-6}	34	28	
				x yes no

Tab No. 5.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Aspergillus brasiliensis* (niger) ATCC 16404

Test concentration /contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 6.49$)
2 tabs/10 l/30	10^0	<14	<14	< 2.15	≥ 4.34

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the fungal test suspension, N_0 = the number of cfu/ml of the fungal test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the fungal test suspension for validation N_{V0} = the number of cfu/ml of the fungal test suspension for validation in the test mixture A, B, C at the beginning of the contact time = 0, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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6. Evaluation of fungicidal activity of the product **PASDEZ**

Tab No. 6.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – fungicidal activity

Fungicidal activity of the product (EN 1275:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 1275:2005	lg R
<i>Candida albicans</i> ATCC 10231	20	30	2 tabs/10 l	-	≥ 4	> 4
<i>Aspergillus brasiliensis</i> (<i>niger</i>) ATCC 16404	20	30	2 tabs/10 l	-	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the fungal test suspension, N_0 = the number of cfu/ml of the fungal test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the fungal test suspension for validation N_{v0} = the number of cfu/ml of the fungal test suspension for validation in the test mixture A, B, C at the beginning of the contact time = 0, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $lg R = lg N_0 - lg N_a$

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

Page: 8

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 14348:2005)

Period of analysis:

15.8. – 5.9.2017

Test temperature:

20 °C ± 1 °C

Test method:

membrane filtration method

Filtration diluent:

rinsing liquid

Appearance of the product:

white tablets

Product diluent:

hard water

Test concentration:

2 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Mycobacterium terrae ATCC 15755

Incubation conditions:

37 °C ± 1 °C, 21 days

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least 4 orders (10^4).

Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least 4 orders (10^4).

$R = N_0 / N_a$ nebo $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

The standard:

EN 14348:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test method and requirements (phase 2, step 1) January 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

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Delivered amount: 2 x 500 g

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7. Testing the efficacy of chemical disinfectant **PASDEZ** on *Mycobacterium terrae* ATCC 15755

Tab No. 7.1 Verification of methodology, clean conditions

Validation of suspension (N _{v0})				Validation of selected experimental conditions (A)				Membrane filtration validation (B)				Method validation (C) Product conc.: 2 tabs/10 l			
V _{c1}	159	Φ _{N_{v0}} = 159.5		V _{c1}	167	Φ _A = 160		V _{c1}	147	Φ _B = 151.5		V _{c1}	162	Φ _C = 156	
V _{c2}	160			V _{c2}	153			V _{c2}	156			V _{c2}	150		
30 ≤ Φ _{N_{v0}} ≤ 160				Φ _A ≥ 0.5 Φ _{N_{v0}}				Φ _B ≥ 0.5 Φ _{N_{v0}}				Φ _C ≥ 0.5 Φ _{N_{v0}}			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 7.2 Test suspensions

Test suspension N $\Phi = 156 \times 10^7 = \lg 9.19$ $9.17 \leq \lg N \leq 9.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 8.19$ $8.17 \leq \lg N_0 \leq 8.70$
	10^{-7}	163	150	
	10^{-8}	15	16	
				x yes no

Tab No. 7.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Mycobacterium terrae* ATCC 15755

Test concentration / contact time (min)/ conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 8.19$)
2 tabs/10 l /30/clean	10^{-1}	22	52	3.57	4.62

8. Evaluation of tuberculocidal activity of the product **PASDEZ**

Tab No. 8.1 The efficacy of chemical disinfectant **PASDEZ** on test strain – tuberculocidal activity

Tuberculocidal activity of the product (EN 14348:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	$\lg R$ EN 14348:2005	$\lg R$
<i>Mycobacterium terrae</i> ATCC 15755	20	30	2 tabs/10 l	clean	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0“), N_a = the number of survivors per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0} = the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of survivors per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ nebo $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

Prepared by: Ing. Eva Kremlová, Lab Technician

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Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 14347:2005)

Period of analysis:

13.10. – 18.10.2017 (B.s.)

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

distilled water

Test concentration:

4 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)

Contact time:

30 min

Interfering substances:

no interfering substance (distilled water)

Test organisms:

Bacillus subtilis ATCC 6633

Incubation conditions:

37 °C ± 1 °C, minimum 4 and maximum 7 days

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Sporicidal activity – the capability of a product to produce a reduction in the number of bacterial spores belonging to reference strain of *Bacillus subtilis* and *Bacillus cereus* under defined conditions by at least 4 orders (10^4).

$R = N_w / N_a$ nebo $\lg R = \lg N_w - \lg N_a$ the reduction in viability

The standard:

EN 14347:2005 Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1, step 1) January 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

Page: 11

9. Testing the efficacy of chemical disinfectant **PASDEZ** on *Bacillus subtilis* ATCC 6633

Tab No. 9.1 Verification of methodology

Test suspension N1			Validation suspension Nv			Neutralizer control (B)			Method validation (C) Product conc. 4 tabs/10 l		
Dilution	V _{c1}	V _{c2}	Dilution	V _{c1}	V _{c2}	Dilution	10 ⁻⁶	10 ⁻⁶	Dilution	10 ⁻³	10 ⁻³
10 ⁻⁶	>330	>330	10 ⁻²	>330	>330	V _{c1}	54	Φ _B =	V _{c1}	38	Φ _C =
10 ⁻⁷	57	62	10 ⁻³	56	50	V _{c2}	49	51.5	V _{c2}	45	41.5
lg N1	59.5 x 10 ⁷ = lg 8.77		lg Nv	53 x 10 ³ = lg 4.72		lg B	51.5 x 10 ⁶ = lg 7.71		lg C	41.5 x 10 ³ = lg 4.62	
Norm	8.48 ≤ lg N1 ≤ 9.00		Norm	4.48 ≤ lg Nv ≤ 5.00		Norm	lg B ≥ lg Nw		Norm	4.48 ≤ lg C ≤ 5.00	
Test suspension N2			Water control Nw			ONT (original neutralization tube)			The weighted mean count – quotient Φ		
Dilution	V _{c1}	V _{c2}	Dilution	V _{c1}	V _{c2}				N	Norm	Φ
10 ⁰	>330	>330	10 ⁻⁵	>330	>330				N1	5 ≤ Φ ≤ 15	-
10 ⁻¹	55	65	10 ⁻⁶	51	47				N2	5 ≤ Φ ≤ 15	-
lg N2	60 x 10 ¹ = lg 2.78		lg Nw	49 x 10 ⁶ = lg 7.69		Percept	Visible growth		Nv	5 ≤ Φ ≤ 15	
Norm	2.48 < lg N2 < 3.00		Norm	7.48 < lg Nw < 8.00		Norm	Visible growth		Nw	5 < Φ < 15	

Tab No. 9.2 Testing the efficacy of chemical disinfectant **PASDEZ** on *Bacillus subtilis* ATCC 6633

Test concentration (%) / contact time (min)	Dilution after test procedure	V _{c1}	V _{c2}	lg N _a = lg (Φ _a x 10)	lg R (lg N _w = lg 7.69)
4 tabs/10 l/30	10 ⁻¹	40	56	3.68	4.01

10. Evaluation of sporicidal activity of the product **PASDEZ**

Tab No. 10.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – sporicidal activity

Sporicidal activity of the product (EN 14347:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 14347:2005	lg R
<i>Bacillus subtilis</i> ATCC 6633	20	30	4 tabs/10 l	distilled water	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N1 = the number of cfu/ml of the bacterial test suspension, N2 = the number of cfu/ml of the bacterial test suspension after dilution, N_v = the number of cfu/ml of the bacterial test suspension for validation, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_w = the number of cfu/ml of the bacterial test suspension in water control, B and C = the number of survivors per ml in control tests (B – neutralizer control, C – method validation), R = N_w / N_a nebo lg R = lg N_w – lg N_a the reduction in viability

Prepared by: Mgr. Mirka Horáková, Ph.D., Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

Page: 12

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00
(EN 14476:2013 +A1:2015)

Period of analysis:

19.9. – 26.9.2016

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product:

white tablets

Product diluent:

distilled water

Test concentration:

2 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)**

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K47740803613, expiry date: 31.3.2018

Test virus:

Adenovirus type 5, strain Adenoid 75, ATCC VR-5 (5th passage)

Cell lines:

HeLa cells

Incubation:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the cell culture
3. Preparation of the test virus suspension
4. Test of the viral infectivity
5. Virus titration with the interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for the virucidal activity of the product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders.

**The test was performed by using MicroSpinTM S 400 HR.

The standard:

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

Page: 13

11. Testing the efficacy of chemical disinfectant **PASDEZ** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5**

Tab No. 11.1 Table of results of product **PASDEZ** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Product	Concentration**	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
PASDEZ	2 tabs/10 l	clean	≤ 2.50	4.50	-
Formaldehyde	0.7 % (w/v)	PBS	≤ 1.50	6.33	5.00
			Virus titration, time = 0		
Virus control	-	PBS	9.50	9.50	9.33
Virus control	-	clean	9.50	9.50	-

Tab No. 11.2 Testing the efficacy of chemical disinfectant **PASDEZ** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Test concentration**	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
2 tabs/10 l	9.50	clean	30 min	4.50	5.00

12. Evaluation of virucidal activity of the product **PASDEZ**

Tab No. 12.1 The efficacy of chemical disinfectant **PASDEZ** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A1:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+A1:2015	Δlog ₁₀ TCID ₅₀
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5**	20	30	2 tabs/10 l	clean	≥ 4	> 4

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

**The test was performed by using MicroSpin™ S 400 HR.

Prepared by: Bc. Iva Čížová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

Page: 14

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 14347:2005)

Period of analysis:

26.10. – 31.10.2017 (B.c.)

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

distilled water

Test concentration:

4 tablets/10 l ($m_{\text{tab}} = 2.817 \text{ g}$)

Contact time:

30 min

Interfering substances:

no interfering substance (distilled water)

Test organisms:

Bacillus cereus ATCC 12826

Incubation conditions:

37 °C ± 1 °C, minimum 4 and maximum 7 days

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Sporicidal activity – the capability of a product to produce a reduction in the number of bacterial spores belonging to reference strain of *Bacillus subtilis* and *Bacillus cereus* under defined conditions by at least 4 orders (10^4).

$R = N_w / N_a$ nebo $\lg R = \lg N_w - \lg N_a$ the reduction in viability

The standard:

EN 14347:2005 Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1, step 1) January 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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13. Testing the efficacy of chemical disinfectant **PASDEZ** on *Bacillus cereus* ATCC 12826

Tab No. 13.1 Verification of methodology

Test suspension N1			Validation suspension Nv			Neutralizer control (B)			Method validation (C) Product conc. 4 tabs/10 l		
Dilution	V _{c1}	V _{c2}	Dilution	V _{c1}	V _{c2}	Dilution	10 ⁻⁶	10 ⁻⁶	Dilution	10 ⁻³	10 ⁻³
10 ⁻⁶	>330	>330	10 ⁻²	>330	>330	V _{c1}	67	Φ _B = 75	V _{c1}	24	Φ _C = 37
10 ⁻⁷	54	40	10 ⁻³	77	48	V _{c2}	83		V _{c2}	50	
lg N1	47 x 10 ⁷ = lg 8.67		lg Nv	62.5 x 10 ³ = lg 4.80		lg B	46 x 10 ⁶ = lg 7.88		lg C	37 x 10 ³ = lg 4.57	
Norm	8.48 ≤ lg N1 ≤ 9.00		Norm	4.48 ≤ lg Nv ≤ 5.00		Norm	lg B ≥ lg Nw		Norm	4.48 ≤ lg C ≤ 5.00	
Test suspension N2			Water control Nw			ONT (original neutralization tube)			The weighted mean count – quotient Φ		
Dilution	V _{c1}	V _{c2}	Dilution	V _{c1}	V _{c2}				N	Norm	Φ
10 ⁰	>330	>330	10 ⁻⁵	>330	>330				N1	5 ≤ Φ ≤ 15	-
10 ⁻¹	49	56	10 ⁻⁶	55	62				N2	5 ≤ Φ ≤ 15	-
lg N2	52.5 x 10 ¹ = lg 2.72		lg Nw	58.5 x 10 ⁶ = lg 7.77		Percept	Visible growth		Nv	5 ≤ Φ ≤ 15	
Norm	2.48 ≤ lg N2 ≤ 3.00		Norm	7.48 ≤ lg Nw ≤ 8.00		Norm	Visible growth		Nw	5 ≤ Φ ≤ 15	

Tab No. 13.2 Testing the efficacy of chemical disinfectant **PASDEZ** on *Bacillus cereus* ATCC 12826

Test concentration/ contact time (min)	Dilution after test procedure	V _{c1}	V _{c2}	lg N _a = lg (Φ _a x 10)	lg R (lg N _w = lg 7.77)
4 tabs/10 l/30	10 ⁻²	105	114	5.04	2.73

14. Evaluation of sporicidal activity of the product **PASDEZ**

Tab No. 14.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – sporicidal activity

Sporicidal activity of the product (EN 14347:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 14347:2005	lg R
<i>Bacillus cereus</i> ATCC 12826	20	30	4 tabs/10 l	distilled water	≥ 4	< 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N1 = the number of cfu/ml of the bacterial test suspension, N2 = the number of cfu/ml of the bacterial test suspension after dilution, N_v = the number of cfu/ml of the bacterial test suspension for validation, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_w = the number of cfu/ml of the bacterial test suspension in water control, B and C = the number of survivors per ml in control tests (B – neutralizer control, C – method validation), R = N_w / N_a nebo lg R = lg N_w – lg N_a the reduction in viability

Prepared by: Mgr. Mirka Horáková, Ph.D., Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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Experimental conditions:

Freshwater algae growth inhibition test

SOP-M-19-00 (ČSN EN ISO 8692:2012, TNV 75 7741:1995)

Period of analysis:

23.10. – 28.10.2016

Test temperature:

30 °C ± 2 °C

Test method:

micromethod of algal growth inhibition test

Spectrophotometer:

Reader SpectraMAX PLUS 384

Wavelength:

670 nm

Product diluent:

distilled water

Appearance of the product:

white tablets

Test concentration:

4 tabs/1 m³

Contact time:

5 days

Test organisms:

Parachlorella kessleri FOTT et NOVÁKOVÁ LARG/1

Test procedure:

1. Preparation of algal test suspension
2. Counting of test suspension
3. Quantitative algal test

Note:

Algicidal activity (%) = $((A_0 - A_v)/A_0) \cdot 100$

A₀ – absorbtion of algal test suspension, A_v – absorbtion of the solution of the product and algal test suspension

The product is efficient when algicidal activity > 50%

The standard:

ČSN EN ISO 8692 Water quality - Freshwater algal growth inhibition test with unicellular green algae. August 2012

TNV 75 7741 Micromethod of algal growth inhibition test, 1995

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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15. Evaluation of the algicidal activity of chemical disinfectant **PASDEZ**

Tab No. 15 Testing the efficacy of chemical disinfectant **PASDEZ** on *Parachlorella kessleri* FOTT et NOVÁKOVÁ LARG/1

Contact time (days)	Algicidal activity % for concentration
	4 tabs/1 m ³
1	47.7
2	74.4
3	87.5
4	95.8
5	96.5

The product is efficient when algicidal activity > 50%

Prepared by: Mgr. Alena Rýdlová, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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Interpretation:

Results of tests are in Tabs.

The tested product **PASDEZ**, batch No. 01.006, in the concentration 2 tablets/10 l, diluted in distilled water, in the contact time 30 min at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** the number of alive microbes *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 by at least 5 (lg) orders (EN 1040:2005).

The tested product **PASDEZ**, batch No. 01.006, in the concentration 2 tablets/10 l, diluted in distilled water, in the contact time 30 min at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** the number of alive microbes *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis (niger)* ATCC 16404 by at least 4 (lg) orders (EN 1275:2005).

The tested product **PASDEZ**, batch No. 01.006, in the concentration 2 tablets/10 l, diluted in hard water, and in the contact time 30 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the membrane filtration method **decreased** the number of alive microbes *Mycobacterium terrae* ATCC 15755 by at least 4 (lg) orders (EN 14348:2005).

The tested product **PASDEZ**, batch No. 01.006, in the concentration 4 tablets/10 l, diluted in distilled water, in the contact time 30 min at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** the number of alive microbes *Bacillus subtilis* ATCC 6633 by at least 4 (lg) orders (EN 14347:2005).

According to the EN 14476:2013 +A1:2015 the tested product **PASDEZ**, batch No. 01.006, in the concentration 2 tablets/10 l**, diluted in hard water, and in the contact time 30 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 particles under defined conditions by 4 (lg) orders.

**The test was performed by using MicroSpin™ S 400 HR.

The tested product **PASDEZ**, batch No. 01.006, in the concentration 4 tablets/10 l, diluted in distilled water, in the contact time 30 min at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **did not decrease** the number of alive microbes *Bacillus cereus* ATCC 12826 by at least 4 (lg) orders (EN 14347:2005).

According to ČSN EN ISO 8692:2012 and TNV 75 7741:1995 the tested product **PASDEZ**, batch No. 01.006, in the concentration 4 tabs/1 m³, diluted in distilled water, by the micromethod of algal growth inhibition test at temperature $30\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ **proved** to decrease the number of alive cells *Parachlorella kessleri* FOTT et NOVÁKOVÁ LARG/1 by 50% since the second day.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D117/2017

Rep No: 152

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Client DEZFARMTEH SRL, Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Batch No: 01.006

Sampling date: 8.6.2017

Sample delivered: 12.6.2017

Testing date: 15.8. – 31.10.2017

Delivered amount: 2 x 500 g

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Conclusion:

The product **PASDEZ** is capable of reducing the number of viable bacterial and mycobacterial cells, vegetative yeast cells and mould spores of the relevant organisms under defined conditions to the declared values, and consequently, may be called bactericidal, tuberculocidal and fungicidal.

The product **PASDEZ** is capable of reducing the number of bacterial spores of *Bacillus subtilis* under defined conditions to the declared values, and consequently, may be called sporicidal on *Bacillus subtilis*.

The product **PASDEZ** is not capable of reducing the number of bacterial spores of *Bacillus cereus* under defined conditions to the declared values, and consequently, cannot be called sporicidal on *Bacillus cereus*.

The product **PASDEZ** is capable of reducing the number of infectious *Adenovirus* particles under defined conditions to the declared values, and consequently, may be called virucidal on *Adenovirus*.

The product **PASDEZ** is capable of reducing the number of viable algae cells of the relevant organisms under defined conditions to the declared values, and consequently, may be called algicidal.

9.11.2017, Hodonín

.....
Ing. Barbora Stoklásková, Leader of Study

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute
according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S286-1/2019

DETERMINATION OF BACTERICIDAL (EN 13727:2012+A2:2015) AND FUNGICIDAL (EN 13624:2013, EN 13697:2015+A1:2019) ACTIVITY OF THE PRODUCT **PASDEZ**

Sample ID: S286/2019

Sample name: **PASDEZ**

Client: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Producer: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Sampling point: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

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From pages: 13

Incoming date:
11.9.2019

Delivery date:
20.11.2019

Hodonín, 20.11.2019



Ing. Jana Šlitrová, Head of Laboratory

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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S286/2019
Rep No: 133
Sample name: **PASDEZ**
Sampled: by client
Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova
Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019
Sample delivered: 11.9.2019
Testing date: 15.10. – 21.10.2019
Delivered amount: 2 x 500 g
Batch No: 6
Page: 2

Subject of testing:

Determination of bactericidal and fungicidal activity of the product.

Identification of the sample:

Name of the product:	PASDEZ
Batch number:	6
Date of manufacture:	20.08.2019
Expiry date:	20.08.2022
Manufacturer:	DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova
Incoming date:	11.9.2019
Storage conditions:	stated by the manufacturer
Active ingredients:	CAS 51580-86-0 Sodium dichloro izocyanurate >99%

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

	SOP-M-19-00 (EN 13727:2012+A2:2015)
Period of analysis:	15.10. – 16.10.2019
Test temperature:	23 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Appearance of the product:	white tablets
Product diluent:	hard water
Test concentration:	2 tabs/10 l (colourless liquid)
Contact time:	5 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541
Incubation conditions:	37 °C ± 1 °C, 24 hours

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least a 5 lg reduction (10^5).

$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

The standard:

EN 13727:2012+A2:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1) October 2015

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

Page: 3

The Number of CFU in the tested product: $<10^1$ CFU/g

1. Testing the efficacy of chemical disinfectant **PASDEZ** on *Pseudomonas aeruginosa* ATCC 15442

Tab No. 1.1 Verification of methodology, clean conditions

Tab No. 1.1 Verification of methodology, and conditions																							
Validation of suspension (N _{V0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l											
V _{e1}		69		Φ _{N_{V0}} = 76		V _{e1}		74		Φ _A = 69.5		V _{e1}		76		Φ _B = 69.5		V _{e1}		78		Φ _C = 74	
V _{e2}		83				V _{e2}		65				V _{e2}		63				V _{e2}		70			
30 ≤ Φ _{N_{V0}} ≤ 160				Φ _A ≥ 0.5 Φ _{N_{V0}}				Φ _B ≥ 0.5 Φ _{N_{V0}}				Φ _C ≥ 0.5 Φ _{N_{V0}}											
x		yes				no		x		Yes				no		x		yes				no	
Validation of suspension (N _{V_B})				V _{e1}		81		V _{e2}		73		Φ _{N_{V_B}}		77		30 < Φ _{N_{V_B} (N_{V_B}/1000) ≤ 160}							
				x		yes										x		yes				no	

Tab No. 1.2 Test suspension

Test suspension N		N	V _{el}	V _{el}	Test suspension N ₀ (time = 0)	
Φ = 286 x 10 ⁶ = lg 8.46 8.17 ≤ lg N ≤ 8.70		10 ⁻⁶	312	263	lg N ₀ = lg N/10 = lg 7.46	
		10 ⁻⁷	25	29	7.17 ≤ lg N ₀ ≤ 7.70	
					x	yes
						no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 7.46$)
2 tabs/10 l / 5 / clean	10^0	<14	<14	< 2.15	≥ 5.31

2. Testing the efficacy of chemical disinfectant **PASDEZ** on *Staphylococcus aureus* ATCC 6538

Tab No. 2.1 Verification of methodology, clean conditions

Tab No. 2.1 Verification of methodology, clean conditions																									
Validation of suspension (N_{V0})				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc.: 2 tabs/10 l													
V_{c1}		53		$\Phi_{N_{V0}} = 69$		V_{c1}		67		$\Phi_A = 68.5$		V_{c1}		79		$\Phi_B = 65$		V_{c1}		79		$\Phi_C = 67$			
V_{c2}		85				V_{c2}		70				V_{c2}		51				V_{c2}		55					
$30 \leq \Phi_{N_{V0}} \leq 160$				$\Phi_A \geq 0.5 \Phi_{N_{V0}}$				$\Phi_B \geq 0.5 \Phi_{N_{V0}}$				$\Phi_C \geq 0.5 \Phi_{N_{V0}}$													
x		yes		no		x		Yes		no		x		yes		no		x		yes		no			
Validation of suspension (N_{VB})																									
V_{c1}				77		V_{c2}		67		Φ_{NVB}				72		$30 < \Phi_{NVB} (N_{VB}/1000) \leq 160$									
																x		yes		no					

Tab No. 2.2 Test suspension

Test suspension N		N	V _{el}	V _{el}	Test suspension N ₀ (time = 0)	
Φ = 285 x 10 ⁶ = lg 8.45		10 ⁻⁶	251	319	lg N ₀ = lg N/10 = lg 7.45	
8.17 ≤ lg N ≤ 8.70		10 ⁻⁷	30	27	7.17 ≤ lg N ₀ ≤ 7.70	
					x	yes
						no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Staphylococcus aureus* ATCC 6538

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 7.45$)
2 tabs/10 l / 5 / clean	10^0	<14	<14	< 2.15	≥ 5.30

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of viable bacterial cells per ml in the test mixture, A, B, C = the number of viable bacterial cells per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

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3. Testing the efficacy of chemical disinfectant **PASDEZ** on *Enterococcus hirae* ATCC 10541

Tab No. 3.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc.: 2 tabs/10 l					
V_{c1}	43	$\Phi_{N_{V0}} = 46.5$	V_{c1}	46	$\Phi_A = 43.5$	V_{c1}	43	$\Phi_B = 45$	V_{c1}	36	$\Phi_C = 42$
V_{c2}	50		V_{c2}	41		V_{c2}	47		V_{c2}	48	
$30 \leq \Phi_{N_{V0}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{V0}}$			$\Phi_B \geq 0.5 \Phi_{N_{V0}}$			$\Phi_C \geq 0.5 \Phi_{N_{V0}}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})		V_{c1}	47	V_{c2}	47	Φ_{NVB}	47	$30 \leq \Phi_{NVB} (N_{VB}/1000) \leq 160$			
								x	yes		no

Tab No. 3.2 Test suspension

Test suspension N		N	V _{el}	V _{el}	Test suspension N ₀ (time = 0) lg N ₀ = lg N/10 = lg 7.66 7.17 ≤ lg N ₀ ≤ 7.70			
Φ = 45.5 x 10 ⁷ = lg 8.66		10 ⁻⁶	> 330	> 330				
8.17 ≤ lg N ≤ 8.70		10 ⁻⁷	48	43				
					x	yes		no

Tab No. 3.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Enterococcus hirae* ATCC 10541

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 7.66$)
2 tabs/10 l / 5 / clean	10^0	<14	<14	< 2.15	≥ 5.51

4. Evaluation of bactericidal activity of the product **PASDEZ**

Tab No. 4.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – bactericidal activity

Bactericidal activity of the product (EN 13727:2012+A2:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	$\lg R$ EN 13727:2012 +A2:2015	$\lg R$
<i>Pseudomonas aeruginosa</i> ATCC 15442	23	5	2 tabs/10 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	23	5	2 tabs/10 l	clean	≥ 5	> 5
<i>Enterococcus hirae</i> ATCC 10541	23	5	2 tabs/10 l	clean	≥ 5	> 5

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of viable bacterial cells per ml in the test mixture, A, B, C = the number of viable bacterial cells per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

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Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 13624:2013)

Period of analysis:

18.10. – 21.10.2019

Test temperature:

23 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

hard water

Test concentration:

2 tabs/10 l (colourless liquid)

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Candida albicans ATCC 10231

Aspergillus brasiliensis (*niger*) ATCC 16404

Incubation conditions:

30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Presence of a high concentration (at least 75%) of *Aspergillus brasiliensis* spiny spores in the test suspension – yes.

Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi belonging to reference strains under defined conditions by at least a 4 lg reduction (10^4).

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of relevant test organisms under defined conditions by at least a 4 lg reduction (10^4).

$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

The standard:

EN 13624:2013 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1) September 2013

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

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5. Testing the efficacy of chemical disinfectant **PASDEZ** on *Candida albicans* ATCC 10231

Tab No. 5.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc. 2 tabs/10 l					
V_{c1}	71	$\Phi_{N_{V0}} = 85$	V_{c1}	83	$\Phi_A = 79.5$	V_{c1}	94	$\Phi_B = 79.5$	V_{c1}	76	$\Phi_C = 72.5$
V_{c2}	99		V_{c2}	76		V_{c2}	65		V_{c2}	69	
$30 \leq \Phi_{N_{V0}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{V0}}$			$\Phi_B \geq 0.5 \Phi_{N_{V0}}$			$\Phi_C \geq 0.5 \Phi_{N_{V0}}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})											
V_{c1}		88	V_{c2}		81	Φ_{NVB}		84.5	$30 \leq \Phi_{NVB} (N_{VB}/1000) \leq 160$		
x		yes							no		

Tab No. 5.2 Test suspension

Test suspension N $\Phi = 183 \times 10^5 = \lg 7.26$ $7.17 \leq \lg N \leq 7.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 6.26$ $6.17 \leq \lg N_0 \leq 6.70$
	10^{-5}	174	194	
	10^{-6}	20	15	
				x yes no

Tab No. 5.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Candida albicans* ATCC 10231

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 6.26$)
2 tabs/10 l / 30 / clean	10^0	<14	<14	< 2.15	≥ 4.11

6. Testing the efficacy of chemical disinfectant **PASDEZ** on *Aspergillus brasiliensis* (niger) ATCC 16404

Tab No. 6.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})		Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Method validation (C) Product conc. 2 tabs/10 l			
V_{c1}	59	$\Phi_{N_{V0}} = 61.5$	V_{c1}	60	$\Phi_A = 51.5$	V_{c1}	64	$\Phi_B = 50.5$	V_{c1}	47	$\Phi_C = 51$		
V_{c2}	64		V_{c2}	43		V_{c2}	37		V_{c2}	55			
$30 \leq \Phi_{N_{V0}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{V0}}$			$\Phi_B \geq 0.5 \Phi_{N_{V0}}$			$\Phi_C \geq 0.5 \Phi_{N_{V0}}$				
x	yes		no	x	yes		no	x	yes		no		
Validation of suspension (N_{VB})													
V_{c1}	54	V_{c2}	67	Φ_{NVB}	60.5	$30 \leq \Phi_{NVB} (N_{VB}/1000) \leq 160$							
										x	yes		no

Tab No. 6.2 Test suspension

Test suspension N $\Phi = 49 \times 10^6 = \lg 7.69$ $7.17 \leq \lg N \leq 7.70$	N	V_{c1}	V_{c2}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 6.69$ $6.17 \leq \lg N_0 \leq 6.70$
	10^{-5}	> 165	> 165	
	10^{-6}	55	43	
				x yes no

Tab No. 6.3 Testing the efficacy of chemical disinfectant **PASDEZ** on *Aspergillus brasiliensis* (niger) ATCC 16404

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a =$ $\lg (\Phi_a \times 10)$	$\lg R$ ($\lg N_0 = \lg 6.69$)
2 tabs/10 l / 30 / clean	10^0	<14	<14	< 2.15	≥ 4.54

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0/N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

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7. Evaluation of fungicidal activity of the product **PASDEZ**

Tab No. 7.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – fungicidal activity

Fungicidal activity of the product (EN 13624:2013)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 13624:2013	lg R
<i>Candida albicans</i> ATCC 10231	23	30	2 tabs/10 l	clean	≥ 4	> 4
<i>Aspergillus brasiliensis</i> (niger) ATCC 16404	23	30	2 tabs/10 l	clean	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the test suspension for validation, N_{v0} (A,C), N_{vB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $lg R = lg N_0 - lg N_a$

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

Page: 8

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-22-12 (EN 13697:2015+A1:2019)

Period of analysis:

18.10. – 21.10.2019

Test temperature:

23 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

hard water

Test concentration:

2 tabs/10 l (colourless liquid)

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Candida albicans

ATCC 10231

Aspergillus brasiliensis (niger)

ATCC 16404

Incubation conditions:

30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative carrier test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Presence of a high concentration (at least 75%) of *Aspergillus brasiliensis* spiny spores in the test suspension – yes.

Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi of relevant organisms on carriers under defined conditions by at least 3 orders (10^3).

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable fungi belonging to reference strain *Candida albicans* on carriers under defined conditions by at least a 3 lg reduction (10^3).

The drying time: 30 – 35 min.

The standard:

EN 13697:2015+A1:2019 Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2) April 2015 + August 2019

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

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8. Testing the efficacy of chemical disinfectant **PASDEZ** on carriers – fungicidal activity

Tab No. 8.1 Verification of methodology, clean conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 2 tabs/10 l) Neutralization test	NC Neutralization control
<i>Candida albicans</i> ATCC 10231	10 ⁻⁵ : >330, >330 10 ⁻⁶ : 55, 39 N: 6.07	10 ⁻³ : 152, 163 10 ⁻⁴ : 16, 17 NT: 6.20	10 ⁻³ : 167, 172 10 ⁻⁴ : 17, 17 NC: 6.23
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	10 ⁻⁵ : >165, >165 10 ⁻⁶ : 47, 41 N: 6.04	10 ⁻² : >165, >165 10 ⁻³ : 82, 70 NT: 5.88	10 ⁻² : >165, >165 10 ⁻³ : 90, 69 NC: 5.90
Limit	5.57 ≤ lg N ≤ 6.10	NT ≥ 0.5 x Nc	NC ≥ 0.5 x Nc

$$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$$

where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

$$NC \text{ or } NT = \log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

Tab No. 8.2 Testing the efficacy of chemical disinfectant **PASDEZ** on test strain, clean conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations / contact time (min)
		2 tabs/10 l / 30
<i>Candida albicans</i> ATCC 10231	10 ⁻³ : 184, 191 10 ⁻⁴ : 20, 18 Nc: 6.27 Nts: >100	10 ⁰ : <14, <14 Nd: < 2.15 Nts: 0 R: ≥ 4.12
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	10 ⁻² : >165, >165 10 ⁻³ : 72, 100 Nc: 5.93 Nts: >100	10 ⁰ : <14, <14 Nd: < 2.15 Nts: 0 R: ≥ 3.78
Limit	lg Nc ≥ lg 5.27	Nts: <100 CFU/ml for active concentration

$$Nc \text{ or } Nd = \log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

$$\text{Reduction } R = Nc - Nd$$

9. Evaluation of fungicidal activity of the product **PASDEZ** on carriers

Tab No. 9.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – fungicidal activity on carriers

Fungicidal activity of the product on carriers (EN 13697:2015+A1:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	R EN 13697:2015+A1:2019	R
<i>Candida albicans</i> ATCC 10231	23	30	2 tabs/10 l	clean	≥ 3	> 3
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	23	30	2 tabs/10 l	clean	≥ 3	> 3

$$\text{Reduction } R = Nc - Nd$$

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 15.10. – 21.10.2019

Delivered amount: 2 x 500 g

Batch No: 6

Page: 10

Interpretation:

Results of tests are in Tabs.

According to EN 13727:2012+A2:2015 the tested product **PASDEZ**, batch No. 6, in the concentration 2 tabs/10 l, diluted in hard water, and in the contact time 5 min under clean conditions at temperature $23\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

According to EN 13624:2013 the tested product **PASDEZ**, batch No. 6, in the concentration 2 tabs/10 l, diluted in hard water, and in the contact time 30 min under clean conditions at temperature $23\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** the number of viable yeast cells of *Candida albicans* ATCC 10231 and the number of mould spores of *Aspergillus brasiliensis* (*niger*) ATCC 16404 by at least a 4 lg reduction.

According to EN 13697:2015+A1:2019 the tested product **PASDEZ**, batch No. 6, in the concentration 2 tabs/10 l, diluted in hard water, and in the contact time 30 min under clean conditions at temperature $23\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of viable yeast cells of *Candida albicans* ATCC 10231 and the number of mould spores of *Aspergillus brasiliensis* (*niger*) ATCC 16404 by at least a 3 lg reduction.

Conclusion:

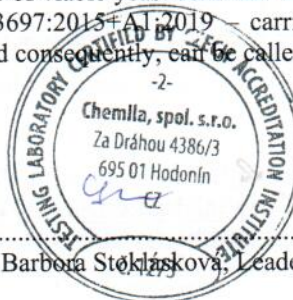
The product **PASDEZ** is capable of reducing the number of viable bacterial cells of the relevant organisms under defined conditions (EN 13727:2012+A2:20 – 2 tabs/10 l, 5 min, clean, $23\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called bactericidal.

The product **PASDEZ** is capable of reducing the number of viable vegetative yeast cells and mould spores of the relevant organisms under defined conditions (EN 13624:2013 – 2 tabs/10 l, 30 min, clean, $23\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called fungicidal.

The product **PASDEZ** is capable of reducing the number of viable yeast cells and the number of mould spores of the relevant organism under defined conditions (EN 13697:2015+A1:2019 – carriers – stainless steel discs, 2 tabs/10 l, 30 min, clean, $23\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called fungicidal.

20.11.2019, Hodonín

Ing. Barbora Stoklasková, Leader of Study





Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute
according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S286-3/2019
DRAFT
DETERMINATION OF BACTERICIDAL (EN 13697:2015+A1:2019)
ACTIVITY OF THE PRODUCT PASDEZ

Sample ID: S286/2019

Sample name: **PASDEZ**

Client: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Producer: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Sampling point: DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Page: 1

From pages: 5

Incoming date:
11.9.2019

Delivery date:
12.12.2019

Hodonín, 12.12.2019

.....
Ing. Jana Šlitrová, Head of Laboratory

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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 10.12. – 11.12.2019

Delivered amount: 2 x 500 g

Batch No: 6

Page: 2

Subject of testing:

Determination of bactericidal activity of the product.

Identification of the sample:

Name of the product:

PASDEZ

Batch number:

6

Date of manufacture:

20.08.2019

Expiry date:

20.08.2022

Manufacturer:

DEZFARMTEH S.R.L., Mihai Eminescu 30 ap. 3, Chisinau, Republica Moldova

Incoming date:

11.9.2019

Storage conditions:

stated by the manufacturer

Active ingredients:

CAS 51580-86-0 Sodium dichloro izocyanurate >99%

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-22-12 (EN 13697:2015+A1:2019)

Period of analysis:

10.12. – 11.12.2019

Test temperature:

23 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tablets

Product diluent:

hard water

Test concentration:

2 tabs/10 l (colourless liquid)

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Escherichia coli

ATCC 10536

Pseudomonas aeruginosa

ATCC 15442

Staphylococcus aureus

ATCC 6538

Enterococcus hirae

ATCC 10541

Incubation conditions:

37 °C ± 1 °C, 24 hours

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative carrier test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms on carriers under defined conditions by at least a 4 lg reduction (10^4).

The drying time: 35 – 50 min

The standard:

EN 13697:2015+A1:2019 Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2) April 2015 + August 2019

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

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Page: 3

The Number of CFU in the tested product: $<10^1$ CFU/g

1. Testing the efficacy of chemical disinfectant **PASDEZ** on carriers – bactericidal activity, clean conditions

Tab No. 1.1 Verification of methodology, clean conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 2 tabs/10 l) Neutralization test	NC Neutralization control
<i>Escherichia coli</i> ATCC 10536	10^{-6} : 149, 196 10^{-7} : 15, 29 N: 6.65	10^{-3} : >330, >330 10^{-4} : 37, 45 NT: 6.61	10^{-3} : >330, >330 10^{-4} : 41, 43 NC: 6.62
<i>Staphylococcus aureus</i> ATCC 6538	10^{-6} : 173, 167 10^{-7} : 18, 17 N: 6.63	10^{-3} : >330, >330 10^{-4} : 33, 39 NT: 6.56	10^{-3} : >330, >330 10^{-4} : 46, 33 NC: 6.60
<i>Enterococcus hirae</i> ATCC 10541	10^{-6} : 158, 163 10^{-7} : 43, 40 N: 7.01	10^{-3} : >330, >330 10^{-4} : 86, 122 NT: 7.02	10^{-3} : >330, >330 10^{-4} : 136, 81 NC: 7.04
Limit	$6.57 \leq \lg N \leq 7.10$	NT - Nc $\leq \pm 0.3 \lg$	NC - Nc $\leq \pm 0.3 \lg$
Validation test			
		NT (Product conc.: 2 tabs/10 l) Neutralization test	NC Neutralization control
<i>Pseudomonas aeruginosa</i> ATCC 15442	10^{-7} : 195, 161 10^{-8} : 17, 19 N: 7.65	10^{-3} : >330, >330 10^{-4} : 42, 40 NT: 6.61	10^{-3} : >330, >330 10^{-4} : 40, 45 NC: 6.63
Limit	$7.57 \leq \lg N \leq 8.10$	NT - Nc $\leq \pm 0.3 \lg$	NC - Nc $\leq \pm 0.3 \lg$

$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$ where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

NC or NT = $\log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Tab No. 1.2 Testing the efficacy of chemical disinfectant **PASDEZ** on test strain, clean conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations / contact time (min)
		2 tabs/10 l / 30
<i>Escherichia coli</i> ATCC 10536	10^{-3} : >330, >330 10^{-4} : 43, 45 Nc: 6.64 Nts: >100	10^0 : <14, <14 Nd : < 2.15 Nts: 0 R : ≥ 4.49
<i>Pseudomonas aeruginosa</i> ATCC 15442	10^{-3} : >330, >330 10^{-4} : 42, 47 Nc: 6.65 Nts: >100	10^0 : <14, <14 Nd : < 2.15 Nts: 0 R : ≥ 4.50
<i>Staphylococcus aureus</i> ATCC 6538	10^{-3} : >330, >330 10^{-4} : 48, 31 Nc: 6.60 Nts: >100	10^0 : <14, <14 Nd : < 2.15 Nts: 0 R : ≥ 4.45
<i>Enterococcus hirae</i> ATCC 10541	10^{-3} : >330, >330 10^{-4} : 122, 101 Nc: 7.05 Nts: >100	10^0 : <14, <14 Nd : < 2.15 Nts: 0 R : ≥ 4.90
Limit	Nts: <100 CFU/ml for active concentration	

Nc or Nd = $\log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Reduction R = Nc – Nd

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

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Batch No: 6

Page: 4

2. Evaluation of bactericidal activity of the product **PASDEZ** on carriers

Tab No. 2.1 The efficacy of chemical disinfectant **PASDEZ** on test strains – bactericidal activity on carriers

Bactericidal and fungicidal activity of the product on carriers (EN 13697:2015+A1:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	R EN 13697:2015+A1:2019	R
<i>Escherichia coli</i> ATCC 10536	23	30	2 tabs/10 l	clean	≥ 4	> 4
<i>Pseudomonas aeruginosa</i> ATCC 15442	23	30	2 tabs/10 l	clean	≥ 4	> 4
<i>Staphylococcus aureus</i> ATCC 6538	23	30	2 tabs/10 l	clean	≥ 4	> 4
<i>Enterococcus hirae</i> ATCC 10541	23	30	2 tabs/10 l	clean	≥ 4	> 4

Reduction R= Nc – Nd

Prepared by: Ing. Barbora Stoklášková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S286/2019

Rep No: 133

Sample name: **PASDEZ**

Sampled: by client

Sampling point: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Client: DEZFARMTEH S.R.L., Chisinau, Republica Moldova

Sampling date: 6.9.2019

Sample delivered: 11.9.2019

Testing date: 10.12. – 11.12.2019

Delivered amount: 2 x 500 g

Batch No: 6

Page: 5

Interpretation:

Results of tests are in Tabs.

According to EN 13697:2015+A1:2019 the tested product **PASDEZ**, batch No. 6, in the concentration 2 tabs/10 l, diluted in hard water, and in the contact time 30 min under clean conditions at temperature $23\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 4 lg reduction.

Conclusion:

The product **PASDEZ** is capable of reducing the number of viable bacterial cells of the relevant organisms under defined conditions (EN 13697:2015+A1:2019 – carriers – stainless steel discs, 2 tabs/10 l, 30 min, clean, $23\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called bactericidal on carriers.

12.12.2019, Hodonín

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Ing. Eva Kremlová, Leader of Study