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Issue No.: 1

Test report No. S257+S262-2/2019

DETERMINATION OF TUBERCULOCIDAL (EN 14348:2005,  
EN 14563:2008) ACTIVITY OF THE PRODUCT  
**DETRO PAA 1500**

Sample ID: S257+S262/2019

Sample name: **DETRO PAA 1500**

Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Producer: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Incoming date:  
30.7.2019

Delivery date:  
19.12.2019

Hodonín, 19.12.2019

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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: S257+S262/2019	Sampling date: 26.7.2019
Rep No: 128	Sample delivered: 30.7.2019
Sample name: <b>DETRO PAA 1500 + DETRO PAA 1500 activator</b>	Testing date: 19.11. – 11.12.2019
Sampled: by client	Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detrol Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY	Batch No: 7762019001, 5432019001
Client: Detrol Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY	Page: 2

Subject of testing:

Determination of tuberculocidal activity of the product.

Identification of the sample:

Sample ID:	S257/2019
Name of the product:	<b>DETRO PAA 1500</b>
Batch number:	7762019001
Date of manufacture:	11.07.2019
Expiry date:	11.07.2021
Manufacturer:	Detrol Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Incoming date:	30.7.2019
Storage conditions:	stated by the manufacturer
Active ingredients:	
Hydrogen Peroxide %3 w/w (CAS 7722-84-1), Complexing agent, pH buffer	
Activated Solution : %0,15 (1500 ppm) Peracetic Acid (CAS 201-186-8)	
Tested Solution: 1500 ppm x %60 = 900 ppm	

Sample ID:	S262/2019
Name of the product:	<b>DETRO PAA 1500 activator</b>
Batch number:	5432019001
Date of manufacture:	11.07.2019
Expiry date:	11.07.2021
Manufacturer:	Detrol Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Incoming date:	30.7.2019
Storage conditions:	stated by the manufacturer
Active ingredients:	
N-Acetyl Caprolactam <%40 w/w , Isopropanol and solvents.	

Product preparation: Peracetic acid generated by mixing base and activator. **DETRO PAA 1500 activator** is poured into **DETRO PAA 1500** base drum. Shake for 5 mins and wait for 30 mins: prepare 60% solution from the **DETRO PAA 1500** generated and 30 mins waited solution. For ex: 1 liter test solution 600 g active **DETRO PAA 1500** solution + 400 g distilled water (the tests are performed with this solution – RTU product – 100%(97%)).

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

Sample ID: S257+S262/2019

Rep No: 128

Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator**

Sampled: by client

Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Sampling date: 26.7.2019

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Delivered amount: 10 x 500 ml, 10 x 50 ml

Batch No: 7762019001, 5432019001

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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:

19.11. – 11.12.2019

Test temperature:

20 °C ± 1 °C

Test method:

membrane filtration method

Filtration diluent:

rinsing liquid

Appearance of the product:

colorless liquid

Test concentration:

100% (concentrated)\*

Contact time:

5 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 a 4 lg reduction ( $10^4$ ).

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 a 4 lg reduction ( $10^4$ ).

\* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

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: S257+S262/2019

Rep No: 128

Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator**

Sampled: by client

Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

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The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Mycobacterium terrae* ATCC 15755

Tab No. 1.1 Verification of methodology, clean conditions

Validation of suspension (N <sub>vo</sub> )				Validation of selected experimental conditions (A)				Membrane filtration control (B)				Method validation (C) Product conc.: 100%*							
V <sub>c1</sub>		32		Φ <sub>N<sub>vo</sub></sub> = 30.5	V <sub>c1</sub>		20		Φ <sub>A</sub> = 28	V <sub>c1</sub>		29		Φ <sub>B</sub> = 25.5	V <sub>c1</sub>		29		Φ <sub>C</sub> = 30
V <sub>c2</sub>		29			V <sub>c2</sub>		36			V <sub>c2</sub>		22			V <sub>c2</sub>		31		
30 ≤ Φ <sub>N<sub>vo</sub></sub> ≤ 160					Φ <sub>A</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>					Φ <sub>B</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>					Φ <sub>C</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>				
x	yes				x	yes				x	yes				x	yes			
	no					no					no					no			

Tab No. 1.2 Test suspensions

Test suspension N $\Phi = 32 \times 10^8 = \lg 9.51$ $9.17 \leq \lg N \leq 9.70$	N	$V_{c1}$	$V_{c1}$	Test suspension $N_0$ (time = 0)* $\lg N_0 = \lg N/100 = \lg 7.51$ $7.17 \leq \lg N_0 \leq 7.70$
	$10^{-7}$	>165	>165	
	$10^{-8}$	32	32	
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Mycobacterium terrae* ATCC 15755

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	$V_{c1}$	$V_{c2}$	$\lg N_a =$ $\lg (\Phi_a \times 10)$	<b><math>\lg R</math></b> ( $\lg N_0 = \lg 7.51$ )
100* / 5 / clean	$10^{-1}$	<14	<14	<3.15	<b><math>\geq 4.36</math></b>

2. Evaluation of tuberculocidal activity of the product **DETRO PAA 1500**

Tab No. 2.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strain – tuberculocidal activity

Mycobactericidal and 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	<b><math>\lg R</math></b>
<i>Mycobacterium terrae</i> ATCC 15755	20	5	100	clean	$\geq 4$	<b>&gt; 4</b>

Note:  $V_c$  = value is the number of cfu per ml,  $\Phi$  = 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 viable cells 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 viable cells per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation),  $R = N_0 / N_a$  or  $\lg R = \lg N_0 - \lg N_a$  the reduction in viability

\* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Ing. Eva Kremlová, Lab Technician

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

Sample ID: S257+S262/2019

Rep No: 128

Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator**

Sampled: by client

Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Sampling date: 26.7.2019

Sample delivered: 30.7.2019

Testing date: 19.11. – 11.12.2019

Delivered amount: 10 x 500 ml, 10 x 50 ml

Batch No: 7762019001, 5432019001

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Experimental conditions:

Period of analysis:

Test temperature:

Test method:

Neutralization medium:

Appearance of the product:

Test concentration:

Contact time:

Interfering substances:

Test organisms:

Incubation conditions:

**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-22-12 (EN 14563:2008)**

19.11. – 11.12.2019

20 °C ± 1 °C

dilution neutralization method

Dey-Engley Neutralizing Broth M 1062

colorless liquid

100% (concentrated)

5 min

0.3 g/l BSA (clean conditions)

*Mycobacterium terrae* ATCC 15755

37 °C ± 1 °C, 21 days

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative carrier 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 a 4 lg reduction ( $10^4$ ).

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 a 4 lg reduction ( $10^4$ ). The drying time: 30-35 min

The standard:

EN 14563:2008 Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2) November 2008

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S257+S262/2019

Rep No: 128

Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator**

Sampled: by client

Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

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Delivered amount: 10 x 500 ml, 10 x 50 ml

Batch No: 7762019001, 5432019001

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3. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Mycobacterium terrae* ATCC 15755

Tab No. 5.1 Verification of methodology, clean conditions

Validation of suspension (N <sub>vo</sub> )				Validation of selected experimental conditions (A)				Neutralizer toxicity control (B)				Dilution neutralization control (C), product conc.: 100%			
V <sub>c1</sub>	32	Φ <sub>N<sub>vo</sub></sub> = 30		V <sub>c1</sub>	20	Φ <sub>A</sub> = 26.5		V <sub>c1</sub>	29	Φ <sub>B</sub> = 26		V <sub>c1</sub>	24	Φ <sub>C</sub> = 26	
V <sub>c2</sub>	28			V <sub>c2</sub>	33			V <sub>c2</sub>	23			V <sub>c2</sub>	28		
30 ≤ Φ <sub>N<sub>vo</sub></sub> ≤ 160				Φ <sub>A</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>				Φ <sub>B</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>				Φ <sub>C</sub> ≥ 0.5 Φ <sub>N<sub>vo</sub></sub>			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 3.2 Test suspension

Test suspension (N)	N	$V_{c1}$	$V_{c2}$	$\Phi = 35 \times 10^8 = \lg 9.54$ $9.17 \leq \lg N \leq 9.70$		
	$10^{-7}$	> 330	> 330			
	$10^{-8}$	32	38			
				x	yes	no

Tab No. 3.2.1 The control test suspension, clean conditions

Test suspension ( $N_w$ )	$N_w$	$V_{c1}$	$V_{c2}$	$\Phi \times 10 = 370 \times 10^4 = \lg 6.57$ $\lg N_w = \lg 6.57$ $6.15 \leq \lg N_w \leq (\lg N - 1.3) 8.24$		
	$10^{-4}$	38	36			
				x	yes	no

Tab No. 3.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Mycobacterium terrae* ATCC 15755 on carriers, clean conditions

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	$V_{c1}$	$V_{c2}$	$\lg N_a = \lg (\Phi_a \times 10)$	<b><math>\lg R</math></b> ( $\lg N_w = \lg 6.57$ )
100 / 5 / clean	$10^0$	<14	<14	< 2.15	<b><math>\geq 4.42</math></b>

4. Evaluation of tuberculocidal activity of the product **DETRO PAA 1500**

Tab No. 4.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strain – tuberculocidal activity on carriers

Mycobactericidal and tuberculocidal activity of the product (EN 14563:2008)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	$\lg R$ EN 14563:2008	<b><math>\lg R</math></b>
<i>Mycobacterium terrae</i> ATCC 15755	20	5	100	clean	$\geq 4$	<b>&gt; 4</b>

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

Prepared by: Ing. Eva Kremlová, Lab Technician

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

Sample ID: S257+S262/2019

Rep No: 128

Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator**

Sampled: by client

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Sampling date: 26.7.2019

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Testing date: 19.11. – 11.12.2019

Delivered amount: 10 x 500 ml, 10 x 50 ml

Batch No: 7762019001, 5432019001

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Interpretation:

Results of tests are in Tabs.

The tested product **DETRO PAA 1500 + DETRO PAA 1500 activator**, batch No. 7762019001, 5432019001, in the concentration **60%\* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 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 viable bacterial cells of *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction (EN 14348:2005).

\* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

The tested product **DETRO PAA 1500 + DETRO PAA 1500 activator**, batch No. 7762019001, 5432019001, in the concentration **60% solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature  $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$  by the dilution neutralization method **decreased** on carriers the number of viable bacterial cells of *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction (EN 14563:2008).

Conclusion:

The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable mycobacterial cells of *Mycobacterium terrae* ATCC 15755 under defined conditions (EN 14348:2005 – real concentration 58.2% solution of activated **Detro PAA 1500**, 5 min, clean conditions,  $20\text{ }^{\circ}\text{C}$ ) to the declared values, and consequently, can be called tuberculocidal.

The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable mycobacterial cells of *Mycobacterium terrae* ATCC 15755 on carriers under defined conditions (EN 14563:2008 – real concentration 60% solution of activated **Detro PAA 1500**, 5 min, clean conditions,  $20\text{ }^{\circ}\text{C}$ ) to the declared values, and consequently, can be called tuberculocidal on carriers.

19.12.2019, Hodonín

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Ing. Barbora Stoklásková, Leader of Study