

Challenge Test

R2301139372

PRESERVATION EFFICACY TEST
CERTIFICATE OF ANALYSIS No R2301139372 / 20.01.2023

Attn: Mrs.

Client:

Tel: +30 210 2513930 Fax: +30 210 2513250

Sample description: Cosmetic

Client labeling: BL-1312, Product: ID3078- F-0080 PREMIUM HAIR & BODY WASH BASE + 10% ADDITIVES,
LOT: T13/BL10390, Customer:108, Prod.Date:-, pH:5,60 Code:TEST13, Preservative System: SODIUM BENZOATE
0,3675%, BENZYL ALCOHOL 0,86925%, Preservative Booster: ETHYLHEXYLGLYCERIN 0,10925%

Skylab-Med reference: 2211-1228/05

Sample packaging / weight: Plastic sterile container, 1x160ml

Sampling: Client **Transport:** Skylab-Med

Received on: 25/11/2022 **Condition upon receipt:** Normal

Duration of analyses: 25/11-29/12/2022

RESULTS

The Challenge Test was performed according to the experimental protocol of European Pharmacopoeia.

The examined micro-organisms are:

Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus niger, Escherichia coli.

The product is assessed as having sufficient marginal antimicrobial protection according to Criteria A

Please find attached:

- 1) Table with the concentrations of the microorganisms versus test time.
- 2) Diagrams showing the % presence of each examined microorganism with time. In the same diagrams we show the typical profile that the microorganism should have according to European Pharmacopoeia.

SIGNATURE



Dr. Nicoletta Yannovits
Analytical Dept. Manager

Challenge Test

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Company name:108

Product description: ID3078

Sampler:

Starting date of analyses: 25/11/2022

Test material remarks: code: Test 13, lot: T13/BL10390, ph: 5.60

Preservatives used: SODIUM BENZOATE 0,3675%, BENZYL ALCOHOL 0,86925%,

Preservative Booster: ETHYLHEXYLGLYCERIN 0,10925%

RESULTS

The Challenge Test was performed according to the experimental protocol of European Pharmacopoeia.

The examined micro-organisms are:

Pseudomonas aeruginosa, *Staphylococcus aureus*, *Candida albicans*, *Aspergillus niger*, *Escherichia coli*.

The product is assessed as having sufficient marginal antimicrobial protection according to Criteria A

Please find attached:

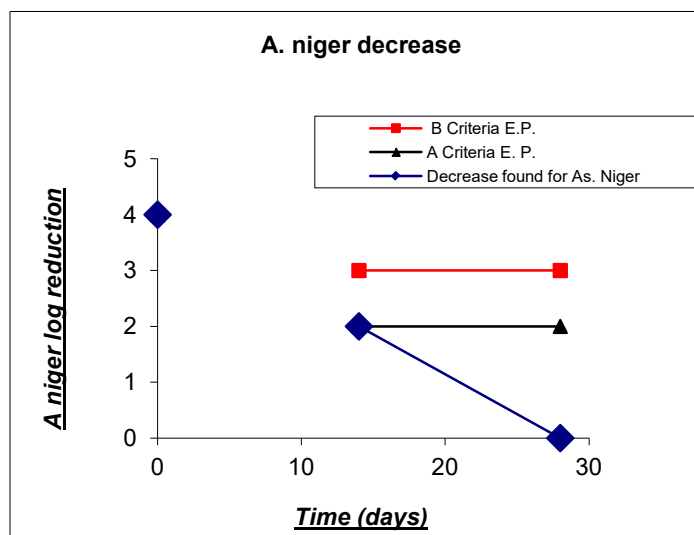
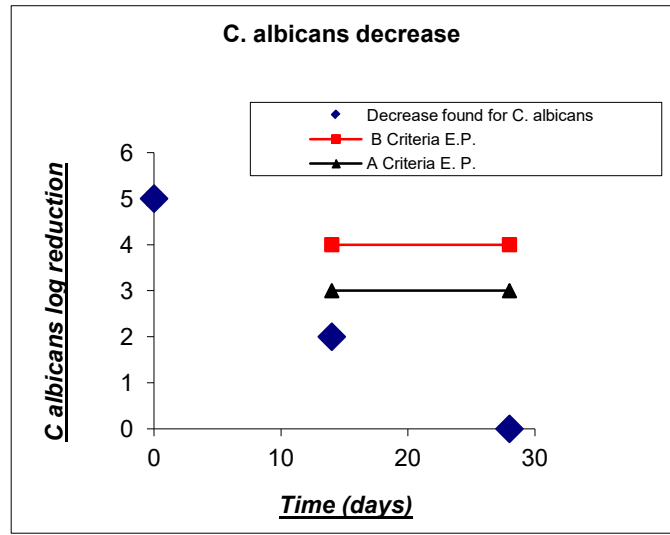
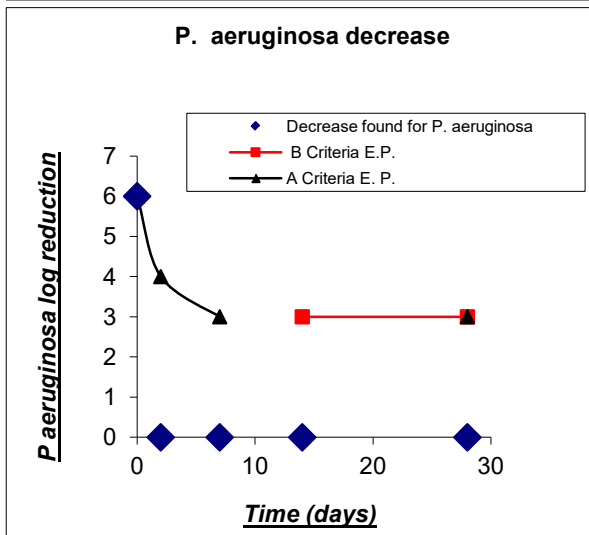
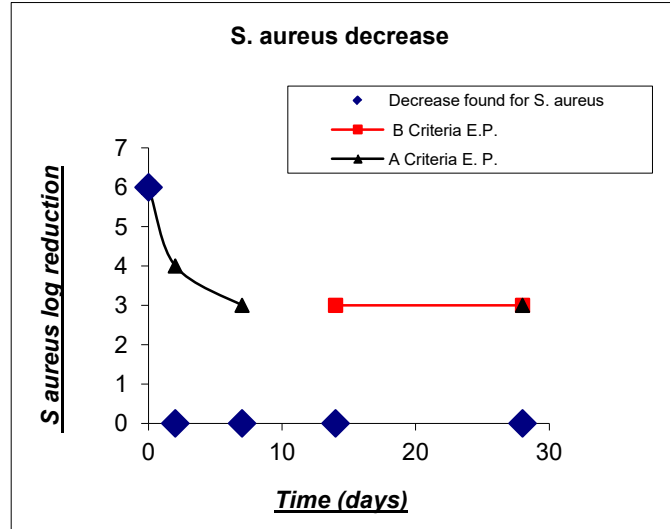
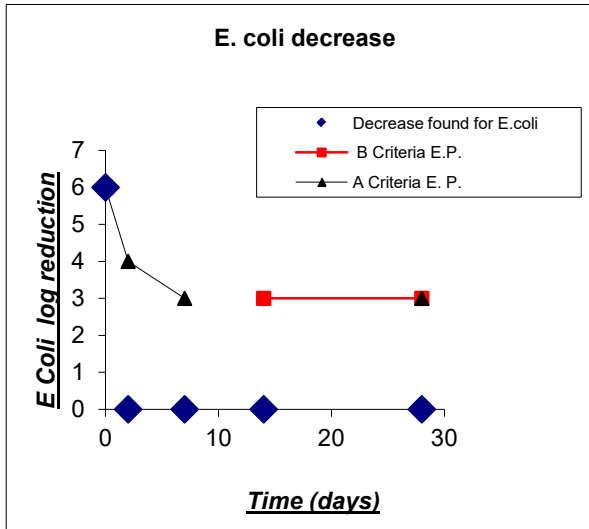
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- 2) Diagrams showing the % presence of each examined microorganism with time. In the same diagrams we show the typical profile that the microorganism should have according to European Pharmacopoeia.

SAMPLE 2211-1228/05

Days		Concentration per ml			
		2	7	14	28
<i>Escherichia coli</i>	$5,5 \times 10^6$	<10	<10	-	<10
<i>Pseudomonas aeruginosa</i>	$1,1 \times 10^6$	<10	<10	-	<10
<i>Staphylococcus aureus</i>	$3,2 \times 10^6$	<10	<10	-	<10
<i>Candida albicans</i>	$1,4 \times 10^5$	-	-	$8,6 \times 10^2$	<10
<i>Aspergillus niger</i>	$3,3 \times 10^4$	-	-	$2,5 \times 10^2$	<10

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**PRESERVATION EFFICACY TEST
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EFFICASY OF ANTIMICROBIAL PRESERVATION

DAY		m/o Gram-	m/o Gram-	m/o Gram+	m/o yeast	m/o mould
		E.coli	P.aeruginosa	S.aureus	C.albicans	A.brasiliensis
0	cfu/g	5,5 *10 ⁶	1,1 *10 ⁶	3,2 0 ⁶	1,4 *10 ⁵	3,3 *10 ⁴
	log	6,7	6,0	6,5	5,1	4,5
2	cfu/g	<10	<10	<10		
	log	<1	<1	<1		
	log reduction	> 5,7	> 5,0	> 5,5		
7	cfu/g	<10	<10	<10		
	log	<1	<1	<1		
	log reduction	> 5,7	> 5,0	> 5,5		
14	cfu/g	<10	<10	<10	<10	<10
	log	<1	<1	<1	<1	<1
	log reduction	> 5,7	> 5,0	> 5,5	> 4,1	> 3,5
28	cfu/g	<10	<10	<10	<10	<10
	log	<1	<1	<1	<1	<1
	log reduction	> 5,7	> 5,0	> 5,5	> 4,1	> 3,5