

ANALYSIS REPORT

<p>Customer Name: KUATRA PHARMA</p> <p>Customer Address: KUATRA PHARMA SANİYE SİBEL COŞKUN RAGIP TÜZÜN MAH. LEVENT SOK. NO:106/4 YENİMAHALLE ANKARA</p> <p>Product Name/ Definition: KUATRA NIPPLE CARE</p> <p>Product Condition/ Total Package: Original Package – 6 Piece (15 ml.)</p> <p>Batch/ Lot Number: KPC10001</p> <p>Production and Expiration Date: 09/2021</p> <p>Manufacturer Name: DYS KOZMETİK KİMYAEVİ MD. LTD. ŞTİ.</p> <p>Receipt Date: 27.11.2019</p> <p>Storage Condition: Room Temperature</p>	<p>Analysis Start Date: 18.12.2019</p> <p>Analysis End Date: 20.01.2020</p> <p>Conditions of Analysis Environment (°C/ Humidity): max. 25°C / max. 75</p>
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LAB ID: 19031963

Product Full Name/ Definition: KUATRA NIPPLE CARE - Original Package – 6 Piece (15 ml.)

DESCRIPTION OF ANALYSIS: (Challenge Test- ISO 11930)

The content of a cosmetic sample is prepared as a standard (prepared from the corresponding microorganism strain) include the formulation of inoculation. Analysis carried out during the 28-day test is determined by the number of viable microorganisms. Calculated each time and the log reduction values for each strain and evaluation criteria of A or B is compared to the required minimum values.

ANALYSIS	ATCC	INOCULATION	DAY 7	DAY 14	DAY 28
<i>Pseudomonas aeruginosa</i>	9027	2,2x10 ⁶	<10	<10	<10
<i>Staphylococcus aureus</i>	6538	21,4x10 ⁸	<10	<10	<10
<i>Escherichia coli</i>	8739	9,5x10 ⁸	<10	<10	<10
<i>Candida albicans</i>	10231	4,2x10 ⁵	<10	<10	<10
<i>Aspergillus brasiliensis</i>	16404	5,1x10 ⁶	4,0x10 ²	2,0x10 ²	<10

Birim: kob/gr

TEST MICROORGANISMS				
<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
ATCC 9027	ATCC 6538	ATCC 8739	ATCC 10231	ATCC 16404

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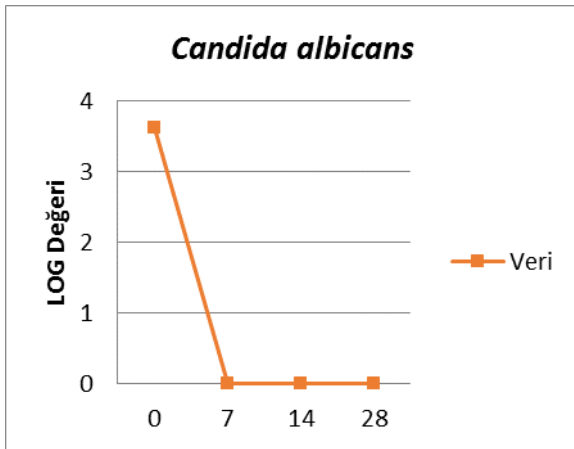
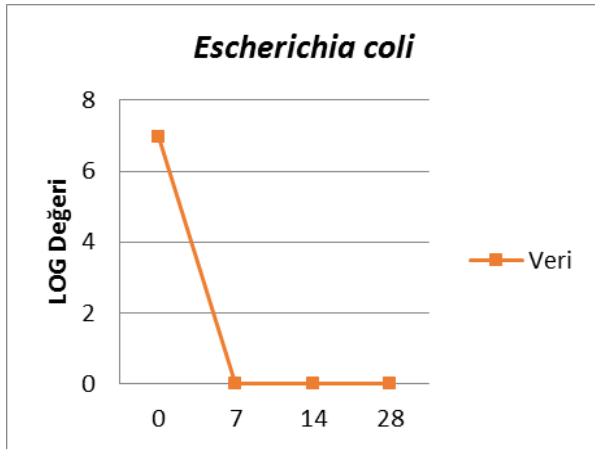
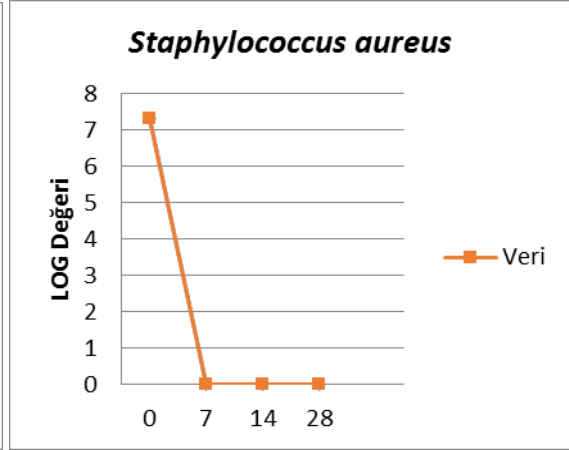
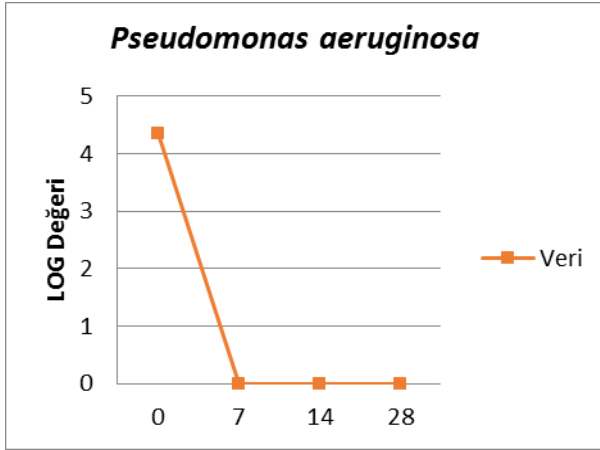
ISO 11930 CRITERIA A AND B ACCEPTANCE POINT

Criteria A				Criteria B			
Time	Day 7	Day 14	Day 28	Time	Day 7	Day 14	Day 28
Bacteria	≥3	≥3+Artış Yok	≥3+Artış Yok	Bacteria	-	≥3	≥3+Artış Yok
Mould	-	≥0	≥1	Mould	-	≥0	≥0+Artış Yok
Yeast	≥1	≥1+Artış Yok	≥1+Artış Yok	Yeast	-	≥1	≥1+Artış Yok

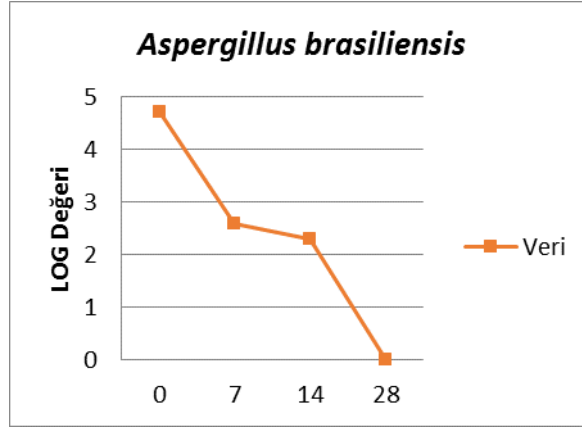
Criteria A and B Logarithmic Decrease Chart

Time	Day 7	Day 14	Day 28
<i>Pseudomonas aeruginosa</i>	NI	NI	NI
<i>Staphylococcus aureus</i>	NI	NI	NI
<i>Escherichia coli</i>	NI	NI	NI
<i>Candida albicans</i>	NI	NI	NI
<i>Aspergillus brasiliensis</i>	2,1 log	2,4 log	NI

NI: No Increase



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EXPLANATION: The product was suitable of **Criteria-A**

Check The Microbiological Quality Of The Product		Neutralizing the Validation
Bacteries (cfu/gr.)	1/10	DE Broth
Yeast and Moulds (cfu/gr.)	1/10	DE Broth

Materials and Certified Products

Strains	Storage Conditions	Mediums	(CFU/ml)	Incubation temperature
<i>Pseudomonas aeruginosa</i> ATCC 9027	- 18°C ± 5°C	Tryptic Soy Agar	10 ⁷ - 10 ⁸	30°C- 35°C
<i>Staphylococcus aureus</i> ATCC 6538	- 18°C ± 5°C	Tryptic Soy Agar	10 ⁷ - 10 ⁸	30°C- 35°C
<i>Escherichia coli</i> ATCC 8739	- 18°C ± 5°C	Tryptic Soy Agar	10 ⁷ - 10 ⁸	30°C- 35°C
<i>Candida albicans</i> ATCC 10231	- 18°C ± 5°C	Sabouraud Dextrose	10 ⁶ - 10 ⁷	20°C- 25°C
<i>Aspergillus brasiliensis</i> ATCC 16404	- 18°C ± 5°C	Potato Extract Agar	10 ⁶ - 10 ⁷	20°C- 25°C

Neutralizing:

DE Broth

Glucose 10g/L - Lecithin 7g/L - Sodium Thiosulphate 6g/L - Tween 80 5g/L - Tryptone 5g/L - Sodium Bisulphite 2,5g/L - Sodium Thioglycollate 1g/L - Bromocresol purple 0,02g/L - Yeast Extract 2,5g/L

Storage Conditions of Sample:

22.5°C ± 2.5°C – oda sıcaklığında, güneş ışığına maruz bırakmadan

DESCRIPTION OF ANALYSIS: Product to be tested is transferred in appropriate amounts in sterile containers for each microorganism. Transfer made this inoculation is done in accordance with the density value of each strain into containers. Neutralizer until the appropriate dilution of units is calculated as 1/10 and 1/100 are defined. The sample dilutions made in accordance with the calculated amount of density in the time required for each test microorganism, logarithmic evaluation is done.

ANALYSIS REPORT

ANALYST

Ceyda ÖZTÜRK
EXPERT
SIGNATURE

APPROVED BY

Pervin EJDER
LABORATORY MANAGER
SIGNATURE

CONFIRMABLE,
21.01.2020
STAMP

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- * This analysis report can not be copied or reproduced partially or entirely without the laboratories written authorization.
- * This analysis report has been prepared with seal and signature and is not valid without seal and signature.
- * The analysis performed at the subcontractor are indicated with the symbol (**).
- * The retest for this sample can be performed, in case the customer request is approved and the necessary amount of sample is present.

Report End

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