True Testing Services
TTS LABORATUVAR HİZMETLERİ

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TTS-0006784
09-25

TEST REPORT

Report Status: **PASS**

Report No :	TTS-0006784/0/04.09.2025
Product / Licence Owner :	Royal Pharma İlaç Kozmetik Gıda San. A.Ş.
Adress :	Beylikdüzü OSB Mah. Mustafa Kurtoğlu Cad. No:31 Kat:5 Beylikdüzü/İSTANBUL
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Producer :	Royal Pharma İlaç Kozmetik Gıda San. A.Ş.
Sample Acceptance Date:	05.08.2025
Report Release Date:	04.09.2025
Report Page Number:	4
Sample Definition :	HYDRA PLUS CREAM
Charge / Serial No:	-
Production / Expiry Date:	07.2025 / -
Sample Quantity :	50 mL
Formulation Form:	PET
Sample Packaging:	Cream

	ANALYSIS NAME	METHOD DESCRIPTION	RESULT
	PATCH TEST FOR SENSITIVE SKIN 10 VOLUNTEERS	-	**NON IRRITATING**

P = PASS / **F** = FAIL / **NR** = LIMIT VALUE NOT STATED / **SC**= TEST CONTINUES / **X** = NON-TESTED SAMPLE / **NA** = NOT SUITABLE FOR THE TEST / **LS** = INSUFFICIENT SAMPLE / **NC** = NO COMMENT

Operating as an Experiment Laboratory, TTS Laboratory Services İthalat İhracat San. ve Tic. Ltd. Sti. , from TÜRKAK AB-1802-T. Accredited according to TS EN ISO / IEC 17025 standard with accreditation file number.

A Multilateral Agreement with the European Accreditation Association (EA) and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC) have been signed on the recognition of the test reports of the Turkish Accreditation Agency (TÜRKAK).
The declared expanded uncertainty of measurement is the value found by multiplying the standard uncertainty with the expansion coefficient taken as k=2 and provides 95% confidence.

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2. The test results are valid for the above example.
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5. The units of the breakpoints are the same as the units of the results.
6. Analyzes marked with '*' are within our scope, accredited by TÜRKAK according to TS EN ISO/IEC 17025.
7. Abbreviations; E: Evaluation. P: Pass F: Fail. N.I.: Not Interpretated. R.: Recovery. M.U: Measurement Uncertainty. L.M: Limit of Measurement

Seal	Sample Acceptance and Reporting Supervisor	Chemical Analyzer Laboratory Staff	Approval Laboratory Manager
TTS LABORATUVAR HİZMETLERİ	Bahar Büşra DUMAN	Ayça SARAL	Adem ÖDEKBAŞ

Date :
04.09.2025

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TEST REPORT

SAMPLE NO	PART NO	SAMPLE	EXPLANATION
A	1	HYDRA PLUS CREAM	

Part of the Test and Evaluation																				
Applied Test	**1**																			
PATCH TEST FOR SENSITIVE SKIN 10 VOLUNTEERS	**P**																			

Explanation

P : The result meets the desired values.
F : The result does not meet the desired values.
X : The relevant part is not applicable for the requested test or the test was not applied to the sample.
LS : The sample is not sufficient for testing.

PATCH TEST FOR NORMAL SKIN

Analyzes	Result	Customer Limit	Evaluation
Patch Test For Sensitive Skin 10 Volunteers	Non Irritating	The product does not cause sensitive skin irritation	**PASS**

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REPORT FROM DERMATOLOGICAL TEST

1. BASIS FOR RESEARCH IMPLEMENTATION

- Order form and test samples delivered by Principal
- Confirmation of microbiological purity / microbiological insensitivity

The Principal is responsible for compliance with the declared quality composition of the samples sent for testing.

2. PURPOSE OF RESEARCH

Product evaluation in terms of irritating and sensitizing properties.

3. LEGAL BASE OF RESEARCH

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997".
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964 - 2013).
- The Act on Cosmetic Products, October 4, 2018, Journal of Laws No. 2018 item 2227.
- Test procedure by EXTERNAL LABORATORY: PO-08 Research Implementation.
- Instruction by EXTERNAL LABORATORY: I02/PO-08 Dermatological test – patch test.
- Instruction by EXTERNAL LABORATORY: I04/PO-08 Scheme for assessing skin reactions - product classification.

4. VOLUNTEERS SELECTION

Volunteers participating in the research were selected on the basis of:

- Current European and Polish law
- Cosmetics Europe- The Personal Care Association
- Declaration of Helsinki (1964-2013)
- Test procedure by EXTERNAL LABORATORY: PO-08 Research Implementation
- Instruction by EXTERNAL LABORATORY: I01/PO-08 Volunteers qualification for the study

All volunteers selected for the study met the requirements for inclusion in the study and signed consent to voluntary participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. During the entire study, the volunteers were under the constant care of a dermatologist.

5. METHODS OF RESEARCH

The test was performed in accordance with the research procedure of EXTERNAL LABORATORY (PO-08 Research implementation) under the supervision of a dermatologist. The research model is the skin test according to Jadassohn-Bloch modified by Rudzki. The test consisted in a single application of the product to a selected area of the skin, and then observing the condition of the skin at intervals. The recording of the results and the classification of the product is made on the basis of the point classification (0-4) of the skin reaction (I04 / PO- 08). Qualification, sample application and readings take place at EXTERNAL LABORATORY in Cracow.

REPORT FROM DERMATOLOGICAL TEST

6. RESULTS

6.1. VOLUNTEERS IDENTIFICATION AND READINGS FROM THE TEST - POINT CLASSIFICATION

VOLUNTTER IDENTIFICATION NUMBER	SEX F – female M - male	AGE	RESULT	
			AFTER 48 h	
			Erythema	Edema/ Swelling
1	F	29	0	0
2	F	30	0	0
3	M	23	0	0
4	M	40	0	0
5	F	37	0	0
6	F	39	0	0
7	M	28	0	0
8	F	29	0	0
9	M	25	0	0
10	M	31	0	0

6.2. IRRITATION INDEX (x_{ir})

The average irritation index is calculated from the sum of the scores for erythema and edema. Based on the irritation index, the product is classified according to the scale.

AVERAGE IRRITATION INDEX (x_{ir})	PRODUCT CLASSIFICATION
$x_{ir} < 0,5$	non-irritating
$0,5 < x_{ir} < 2,0$	slightly irritating
$2,0 < x_{ir} < 5,0$	moderately irritating
$5,0 \leq x_{ir}$	strongly irritating

Average irritation index for tested product: $x_{ir} = 0$, where $x_{ir} = \frac{\text{sum of the scores}}{\text{volunteers number}}$

7. CONCLUSION

A dermatological study conducted on volunteers who were not allergic to any of the ingredients of the tested product confirms that the tested product is well tolerated by the skin, as it did not show any irritating or allergenic properties. The product can be classified as **NON-IRRITATING.**

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------ END OF THE REPORT ------