

Final Study Report (ECRLTX2025-0251)

Date of Report: 21NOV2025
Cosmetic Stability Study

TEST MATERIAL

Hirudin Topical Serum (2%)

INTERNAL TEST MATERIAL ID

0251-01

PURPOSE

The purpose of this study was to evaluate the stability of a formulation when subject to ambient and stress conditions, including elevated temperature and/or humidity to accelerate chemical reactions (“aging”).

STUDY DATES

This study was initiated on 23JUL2025 and completed on 07NOV2025

TEST METHOD

Individual samples were placed in a temperature-controlled chamber (40°C / <60% RH) and control conditions (Ambient) from the date of initial evaluation to their designated evaluation interval. At each evaluation interval, a test sample was evaluated for changes from initial observations of a sample and compared directly to the control for the defined duration. Evaluations were performed according to Eurofins CRL Standard Protocol MI 4.0.

TEST PARAMETERS

Evaluation Criteria	☒ Color	☒ Odor/Fragrance	☒ Texture	☒ Weight
	☒ Package Integrity	☒ pH	☒ Viscosity	
	☒ Microbiological Aerobic Plate Count		☒ Preservative Efficacy Test	
Test Duration	12 Weeks			
Control Conditions	Ambient (20-25°C)			
Test Conditions	40°C / <60% RH			
Evaluation Intervals	Initial, 3 Weeks, 6 Weeks, 9 Weeks, 12 Weeks			

Grading Scale	
NC = No Change	No observable difference between test and control samples
SM = Slightly Modified	Change can be observed when directly compared to control sample
M = Modified	Change can be observed without direct comparison to the control sample
IM = Intensely Modified	Change can be immediately identified without comparison to the control sample – product is not considered acceptable for use

RESULTS

Hirudin Topical Serum (2%)

Initial Weight Evaluations				
Initial (g)	Weight Controls			
	Ambient	40°C / <60% RH		
167	165.4	165.1		

Weight Evaluations				
Evaluation Interval	Sample	Test Sample (g)	Weight Control (g)	Calculated Change in Weight Control(g)
3 Weeks	Ambient	165.4	165.4	0
3 Weeks	40°C / <60% RH	165.3	165.1	0
6 Weeks	Ambient	165.7	165.4	0
6 Weeks	40°C / <60% RH	165.5	165.1	0
9 Weeks	Ambient	166.7	165.4	0
9 Weeks	40°C / <60% RH	164.3	165.1	0
12 Weeks	Ambient	165.2	165.4	0
12 Weeks	40°C / <60% RH	163.6	165.1	0

Initial Color Evaluations				
Primary Color	Secondary Attribute	Saturation	Brightness	Glossiness
Dark Green	Translucent	Moderately Saturated	Low to Medium Brightness	Low to Medium Glossiness

Color Evaluations				
Evaluation Interval	Sample	Change Observed	Change from Initial	Change from Control
3 Weeks	Ambient	None	NC	
3 Weeks	40°C / <60% RH	None	NC	NC
6 Weeks	Ambient	None	NC	
6 Weeks	40°C / <60% RH	None	NC	NC
9 Weeks	Ambient	None	NC	
9 Weeks	40°C / <60% RH	None	NC	NC
12 Weeks	Ambient	None	NC	
12 Weeks	40°C / <60% RH	None	NC	NC

RESULTS

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Initial Texture Evaluations				
Thickness	Creaminess	Oiliness	Grit/Grain	Form
Low Thickness	Low Creaminess	Medium Oiliness	No Grit/Grain	Liquid

Texture Evaluations				
Evaluation Interval	Sample	Change Observed	Change from Initial	Change from Control
3 Weeks	Ambient	None	NC	
3 Weeks	40°C / <60% RH	None	NC	NC
6 Weeks	Ambient	None	NC	
6 Weeks	40°C / <60% RH	None	NC	NC
9 Weeks	Ambient	None	NC	
9 Weeks	40°C / <60% RH	None	NC	NC
12 Weeks	Ambient	None	NC	
12 Weeks	40°C / <60% RH	None	NC	NC

Initial Fragrance Evaluations				
Light-Heavy	Citrus-Sweet	Natural-Medicinal	Intensity	Other:
Medium	Mildly Citric	Natural Aroma	Medium Intensity	Grassy, Tangy, Acidic Scent

Odor/Fragrance Evaluations				
Evaluation Interval	Sample	Change Observed	Change from Initial	Change from Control
3 Weeks	Ambient	None	NC	
3 Weeks	40°C / <60% RH	None	NC	NC
6 Weeks	Ambient	None	NC	
6 Weeks	40°C / <60% RH	None	NC	NC
9 Weeks	Ambient	None	NC	
9 Weeks	40°C / <60% RH	None	NC	NC
12 Weeks	Ambient	None	NC	
12 Weeks	40°C / <60% RH	None	NC	NC

RESULTS

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Initial Package Evaluations				
Material	Seal Type	Color (package / text)	Flexibility	Other:
Hard Plastic	Screw-On Cap, Pump Dispenser	Dark Amber Container with White Cap. White Label with Black Text	No Flexibility	N/A

Package Evaluations				
Evaluation Interval	Sample	Change Observed	Change from Initial	Change from Control
3 Weeks	Ambient	None	NC	
3 Weeks	40°C / <60% RH	None	NC	NC
6 Weeks	Ambient	None	NC	
6 Weeks	40°C / <60% RH	None	NC	NC
9 Weeks	Ambient	None	NC	
9 Weeks	40°C / <60% RH	None	NC	NC
12 Weeks	Ambient	None	NC	
12 Weeks	40°C / <60% RH	None	NC	NC

Initial pH Evaluation	
pH	
5.62	

pH Evaluations			
Evaluation Interval	Sample	pH	Calculated change in pH from Initial
3 Weeks	Ambient	5.61	0.01
3 Weeks	40°C / <60% RH	5.59	0.03
6 Weeks	Ambient	5.58	0.04
6 Weeks	40°C / <60% RH	5.64	-0.02
9 Weeks	Ambient	5.61	0.01
9 Weeks	40°C / <60% RH	5.54	0.08
12 Weeks	Ambient	5.61	0.01
12 Weeks	40°C / <60% RH	5.45	0.17

RESULTS

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Initial Viscosity Evaluation	
Viscosity	
72.8	

pH Evaluations			
Evaluation Interval	Sample	Viscosity	Calculated change in pH from Initial
3 Weeks	Ambient	78.3	-5.5
3 Weeks	40°C / <60% RH	79.2	-6.4
6 Weeks	Ambient	77.3	-4.5
6 Weeks	40°C / <60% RH	76.0	-3.2
9 Weeks	Ambient	72.3	0.5
9 Weeks	40°C / <60% RH	64.0	8.8
12 Weeks	Ambient	73.0	-0.2
12 Weeks	40°C / <60% RH	62.4	10.4

Initial MLT Evaluation	
TAMC CFU/mL	TYMC CFU/mL
1.20E+02	3.45E+02

Microbial Content Evaluations Total Aerobic Microbial Count (TAMC) and Total Yeasts and Molds Count (TYMC)			
Evaluation Interval	Sample	TAMC CFU/mL	TYMC CFU/mL
3 Weeks	40°C / <60% RH	123	260
6 Weeks	40°C / <60% RH	50	3.70E+02
9 Weeks	40°C / <60% RH	50	102
12 Weeks	40°C / <60% RH	5	<5

Preservative Efficacy Testing						
Sample	Challenge Test Results					
Initial		<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
	Log ₁₀ CFU/g					
	Initial Count	6.01	6.73	5.92	6.01	4.70
	Day 7	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 14	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 28	<1.71	<1.71	<1.71	<1.71	<1.70
3 Weeks		<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
	Log ₁₀ CFU/g					
	Initial Count	6.02	5.83	5.60	5.74	5.67
	Day 7	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 14	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 28	<1.71	<1.71	<1.71	<1.71	<1.70
6 Weeks		<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
	Log ₁₀ CFU/g					
	Initial Count	6.08	5.97	6.05	5.85	5.53
	Day 7	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 14	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 28	<1.70	<1.70	<1.70	<1.70	<1.70
9 Weeks		<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
	Log ₁₀ CFU/g					
	Initial Count	5.97	5.82	5.76	5.50	5.85
	Day 7	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 14	<1.71	<1.71	<1.71	<1.71	<1.70
	Day 28	<1.70	<1.70	<1.70	<1.70	<1.70
12 Weeks						