Report for Bioburden test

[Before & After Sterilization]

Approval	Title	Name	Date	Sign
Writing	Researcher	Lexi Kim	2026.03.30	
Review				
Approval	QMS	Boeung Kim	2026.03.30	

Revision History

Revision No.	Revision	Details	Note
00	**Date**	enactment	
	2026.03.30		

Contents

1. Purpose

1.1. The purpose is to measure the bioburden changes of the product group formule series (HANSA CELLUXE SKIN BOOSTER before and after the sterilization process manufactured by ZOE BIO Co., Ltd.

2. Scope

2.1. This corresponds to the product group formule series (HANSA CELLUXE SKIN BOOSTER manufactured by our company.

2.2. The formule series (HANSA CELLUXE SKIN BOOSTER) products apply the sterilization process.

2.3. Product information is as follows.

Brand Name	Model Name	Application	Product Type	Purpose
formule series	HANSA CELLUXE	Cosmetic	Basic Skincare	Skin Conditioning
	P+			
	HP+			
	HiLo+			
	PHiLo+			

3. Test

3.1. Bioburden Test

3.1.1. Mix 1 syringe (2.5 mL) of sample and 47.5 mL of sterilized saline phosphate solution in a glass test tube.

3.1.2. Take 1 mL from 3.1.1, inoculate it on the tryptic soy agar, and spread it to ensure sufficient penetration.

3.1.3. Incubate at 30 ~ 35 ℃ for 2 ~5 days.

3.1.4. Dilute 20 ea/Lot of samples in the same test as above and incubate.

3.2. Sterility Test

3.2.1. It was commissioned to an authorized external testing agency (KTR, KTL, etc.) and tested according to the 12th revised sterility test method of the Korean Pharmacopoeia.

3.3. Sampling

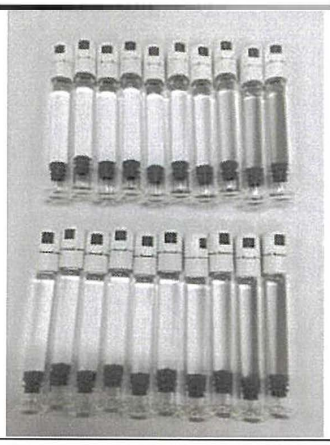
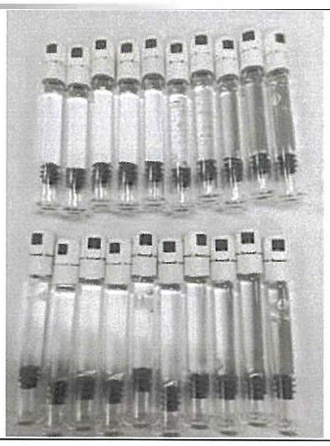
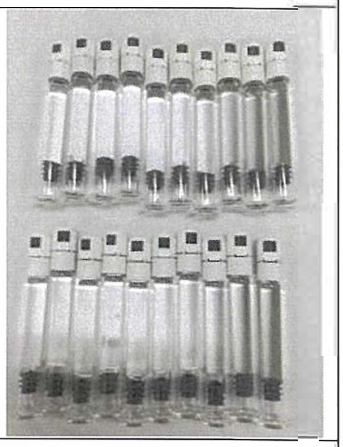
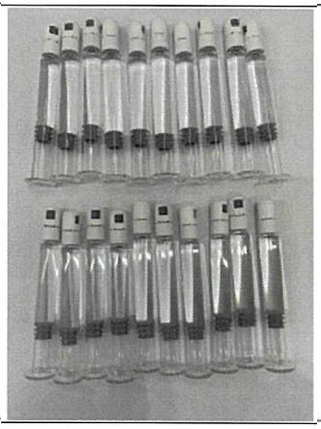
3.3.1. Number of samples

: 20

3.3.2. Collection method

: Random collection

3.3.3. Sample information

1) **Product Name**	HANSA CELLUXE SKIN BOOSTER	formule P+	formule HP+
Sample Picture			
Product Name	formule HiLo+	formule PHiLo+	
Sample Picture			**N/A**

[Table 1]

3.4. Incubation condition

3.4.1. Bioburden Test

1) Tryptic Soy Agar (TSA)
2) Incubate at 30 ~ 35 ℃ for 2 ~5 days.

3.4.2. Sterility Test

1) Fluid Thioglycolate
2) Incubate at 30 ~ 35 ℃ for 3 day.
3) Tryptic Soy
4) Incubate at 20 ~ 25 ℃ for 3 ~ 4 days.

4. Equipment

4.1. Bioburden Test

4.1.1. Clean Bench
4.1.2. Autoclave
4.1.3. Incubator
4.1.4. Vortex Mixer
4.1.5. Pipette Aid
4.1.6. Stirrer
4.1.7. pH meter
4.1.8. Weighing dish
4.1.9. Disposal Pipette 10 mL/1 mL
4.1.10. Petri Dish 87 X 15 mm
4.1.11. Forceps
4.1.12. Spreader
4.1.13. Disposable Test Tube 18 X 180 mm
4.1.14. Sili-Stopper
4.1.15. Wire Rack
4.1.16. Alcohol Lamp
4.1.17. Beaker
4.1.18. Surgical Sterilized Glove

4.2. Sterility Test

4.2.1. It was commissioned to an authorized external testing agency (KTR, KTL, etc.) and tested according to the 12th revised sterility test method of the Korean Pharmacopoeia.

5. Criteria standard

5.1. Bioburden Test

5.1.1. Determine the final bioburden by multiplying the identified bioburden by Correction Factor*1.
5.1.2. *1Correction Factor
It narrows the difference between the actual bioburden and the bioburden seen through the section.

5.2. Sterility Test

5.2.1. When no bacterial growth is observed in the test result, it is judged as acceptable, and when bacterial growth is observed, it is judged as unacceptable.

6. Results

6.1. Bioburden Test

6.1.1. The bioburden results of the sterilized products manufactured by ZOE BIO Co., Ltd. are as shown in Table 2 below, and the average bioburden is "**2.68 X 10^2 CFU/syringe**".

CFU/ea (Corretion Factor = 1.2)										
No.	"formule" series									
	HANSA CELLUXE		P+		HP+		HiLo+		PHiLo+	
	Results	Bioburden	Results	Bioburden	Results	Bioburden	Results	Bioburden	Results	Bioburden
1	3	3.6	4	4.8	1	1.2	5	6	2	2.4
2	5	6	6	7.2	5	6	5	6	2	2.4
3	4	4.8	8	9.6	6	7.2	4	4.8	4	4.8
4	6	7.2	7	8.4	4	4.8	3	3.6	1	1.2
5	8	9.6	4	4.8	3	3.6	6	7.2	5	6
6	7	8.4	5	6	5	6	8	9.6	7	8.4
7	2	2.4	1	1.2	8	9.6	5	6	8	9.6
8	8	9.6	2	2.4	7	8.4	2	2.4	3	3.6
9	6	7.2	9	10.8	1	1.2	1	1.2	5	6
10	10	12	8	9.6	5	6	8	9.6	1	1.2
11	3	3.6	6	7.2	3	3.6	1	1.2	2	2.4
12	5	6	5	6	6	7.2	2	2.4	3	3.6
13	8	9.6	3	3.6	5	6	0	0	5	6
14	7	8.4	4	4.8	4	4.8	1	1.2	4	4.8
15	9	10.8	8	9.6	6	7.2	4	4.8	0	0
16	4	4.8	2	2.4	8	9.6	8	9.6	1	1.2
17	4	4.8	1	1.2	8	9.6	2	2.4	0	0
18	5	6	5	6	2	2.4	0	0	5	6
19	4	4.8	8	9.6	4	4.8	1	1.2	1	1.2
20	6	7.2	7	8.4	5	6	6	7.2	2	2.4
AVG	***5.7***	***6.84***	***5.15***	***6.18***	***4.8***	***5.76***	***3.6***	***4.32***	***3.05***	***3.66***

*Bioburden Results = [Results] X [Correction Factor (1.2)]

Bioburden						
Brand name	**formule**					
Model name	HANSA CELLUXE	**P+**	**HP+**	**HiLo+**	**PHiLo+**	**AVG**
CFU/syringe	3.42 X 10^2	3.09 X 10^2	2.88 X 10^2	2.16 X 10^2	1.83 X 10^2	2.68 X 10^2

*CFU/syringe = [Bioburden Results] x [Dilution factor (1 syr. 2.5 mL + Saline phosphate solution 47.5 mL)]

6.2. Sterility Test

6.2.1. As a result of conducting a sterility test on the test material suggested by the client under the conditions of this test, **no bacterial growth was observed in either the liquid thioglycolate medium or tryptic soy medium**.

6.2.2. Therefore, the test material conformed to the sterility test method test standard of the 12th revision of the Korean Pharmacopoeia. In addition, since the suitability of the medium used in this test was confirmed, it can be said that the validity of this test is proven.

Product Name	Culture media	Confirm	Acceptance
HANSA CELLUXE SKIN BOOSTER	Fluid Thioglycolate	N.G.	Pass
	Trypticase Soy	N.G.	Pass
formule P+	Fluid Thioglycolate	N.G.	Pass
	Trypticase Soy	N.G.	Pass
formule HP+	Fluid Thioglycolate	N.G.	Pass
	Trypticase Soy	N.G.	Pass
formule HiLo+	Fluid Thioglycolate	N.G.	Pass
	Trypticase Soy	N.G.	Pass
formule PHiLo+	Fluid Thioglycolate	N.G.	Pass
	Trypticase Soy	N.G.	Pass

*G.: Growth / N.G.: No Growth

7. Conclusion

7.1. The average bioburden of the pre-sterilization samples of the formule series (HANSA CELLUXE SKIN BOOSTER) product line manufactured by ZOE BIO Co., Ltd. was found to be 2.68 X 102 CFU/syringe, but no bacterial growth was observed after sterilization.

8. Reference

8.1. BS EN ISO11737-1: Sterilization of medical devices

8.2. Guidelines for Sterilization Validation

8.3. Estimation of the population of microorganisms on product

8.4. Korean Pharmacopoeia, 12th Edition, Sterility Test Method

8.5. The UNITED STATES PHARMACOPOEIA 39, <71> STERILITY TEST

9. Attachment

9.1. N/A

Stability Assessment Report

for formule series

Approval	Title	Name	Date	Sign
Writing	Researcher	Levi Kim	2026.03.25	
Review				
Approval	QMS	Boung Kim	2026.03.25	

Revision History

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00	2026.03.25	enactment	

Contents

1. Purpose

1.1. It can be used as a basis for determining the storage conditions and expiration date of products manufactured by ZOE BIO Co., Ltd., and to check the decomposition process and decomposition products of cosmetics under harsh conditions.

2. Scope

2.1. This corresponds to the product group formule series (HANSA CELLUXE SKIN BOOSTER) manufactured by our company.

2.2. In general, the stability was confirmed by the heat acclimation treatment method in order to examine the vulnerability of individual cosmetics and the quality changes that may occur unexpectedly during the expected transportation, storage, display, and use processes under harsh conditions.

2.3. Product information is as follows.

Brand Name	Model Name	Application	Product Type	Purpose
formule	HANSA CELLUXE P+	Cosmetic	Basic Skincare	Skin Conditioning
	HP+			
	HiLo+			
	PHiLo+			

3. Test

3.1. Accelerated Stability Test

3.1.1. Performed under accelerated conditions for 12 hours at each temperature.

3.1.2. The temperature cycle is as follows.

[RT*1 → 4 ℃ → -20 ℃ → 4 ℃ → 42 ℃ → RT , *1RT: 25 ℃]

3.1.3. The above cycle is performed 3 times in total as 1 cycle.

3.1.4. The properties, pH, discoloration and odor of the formulation are observed to evaluate whether they are suitable for the standard range.

4. Equipment

4.1. Accelerated Stability Test

4.1.1. Incubator

4.1.2. Refrigerator

4.1.3. pH meter

4.1.4. Balance

4.1.5. Weighing dish

5. Results

5.1. Accelerated Stability Test

5.1.1. The accelerated stability results of the products manufactured by ZOE BIO Co., Ltd. are as shown in Table 1 below.

Accelerated Stability							
Brand name			formule				
Model name			HANSA CELLUXE	P plus	HP plus	HiLo plus	PHiLo plus
Time	Test	Criteria standard					
1st	Properties	Colorless & transparent, viscous liquid	Pass	Pass	Pass	Pass	Pass
	pH	6 ~ 8	Pass	Pass	Pass	Pass	Pass
	Discoloration	No discoloration	Pass	Pass	Pass	Pass	Pass
	Odor	No change	Pass	Pass	Pass	Pass	Pass
2nd	Properties	Colorless & transparent, viscous liquid	Pass	Pass	Pass	Pass	Pass
	pH	6 ~ 8	Pass	Pass	Pass	Pass	Pass
	Discoloration	No discoloration	Pass	Pass	Pass	Pass	Pass
	Odor	No change	Pass	Pass	Pass	Pass	Pass
3rd	Properties	Colorless & transparent, viscous liquid	Pass	Pass	Pass	Pass	Pass
	pH	6 ~ 8	Pass	Pass	Pass	Pass	Pass
	Discoloration	No discoloration	Pass	Pass	Pass	Pass	Pass
	Odor	No change	Pass	Pass	Pass	Pass	Pass

[Table 1]

6. Conclusion

6.1. The stability of the formule series HANSA CELLUXE SKIN BOOSTER) product line produced by Zoe Bio Co., Ltd. has been verified under harsh conditions ranging from a minimum of -20 ℃ to a maximum of 42 ℃, and the physical properties and characteristics of all products did not change. In other words, although the storage temperature of 2 to 25℃ is recommended, the stability of the products has been proven even when the standard is deviated.

7. Reference

7.1. PCPC/US, Guideline for Industry: The Stability Testing of Cosmetic Products, 2011

7.2. ANVISA/BR, Cosmetic Products Stability Guide, 2005

7.3. CTFA & Colipa, Guidelines on Stability Testing of Cosmetic Products, 2004

7.4. ISO, ISO/ TR 18811, Cosmetics - Guidelines on the stability testing of cosmetics products, 2018