

Sterilization process validation report

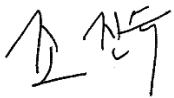
ZOE BIO Inc., located at #617 (Partial), #618 (Partial), 26 Beotkkot-ro 24-gil, Geumcheon-gu, Seoul, 08517, Republic of Korea, hereby declare that **HANSA CELLUXE SKIN BOOSTER has been subjected to validated sterilization, bioburden testing, and comprehensive quality control procedures in full compliance with international standards.** The procedures were conducted in accordance with the 12th revised Sterility Test Method of the Korean Pharmacopoeia, BS EN ISO11737-1, and USP <71> Sterility Test. A bioburden test conducted prior to sterilization showed an average count of 2.68×10^2 CFU/syringe. Following sterilization, sterility tests using Fluid Thioglycolate and Trypticase Soy media were performed by certified external laboratories (e.g., KTR, KTL). All tested samples showed **no bacterial growth, confirming the effectiveness of the sterilization process.** The product successfully met the established sterility acceptance criteria.

Additionally, **HANSA CELLUXE SKIN BOOSTER confirms full compliance with** product specifications, including:

1. **Microbiological Test:** The product is intended for single use and is sterile, with no route of microbial entry prior to its first and only use. Therefore, a study on preservative efficacy over time is not required.
2. **Toxicity Test for Ingredients:** Toxicity information is provided by raw material suppliers. Characteristics, hazards, and safety data are verified through the Safety Data Sheet (SDS) for each ingredient.
3. **Challenge Test:** No preservative challenge test was conducted, as the product qualifies as a low-microbiological-risk item
4. **Biosafety Test:** The manufacturer conducted a Stability Assessment (Report No. SA-R-01), verifying that physicochemical parameters remained stable over time under storage conditions from -20°C to 42°C. Analyses performed across three cycles demonstrated no significant changes, confirming the product's long-term stability.

Conclusion

*All test results confirm that **HANSA CELLUXE SKIN BOOSTER meets the highest standards of microbiological safety, sterility, formulation stability, and toxicological compliance.** Based on these findings, we declare that the product is safe, sterile, effective, and fully compliant with applicable cosmetic and safety regulations.*



Jinsuk Cho / QMR/ ZOE BIO Inc.

ZOE BIO Inc. Issue date: 2026.03.30



ZOE BIO Inc.

CEO YOUNG SHIN LEE