

BIENOX

Clostridium Botulinum Toxin Type A



BIENOX, THE APEX OF BEAUTY

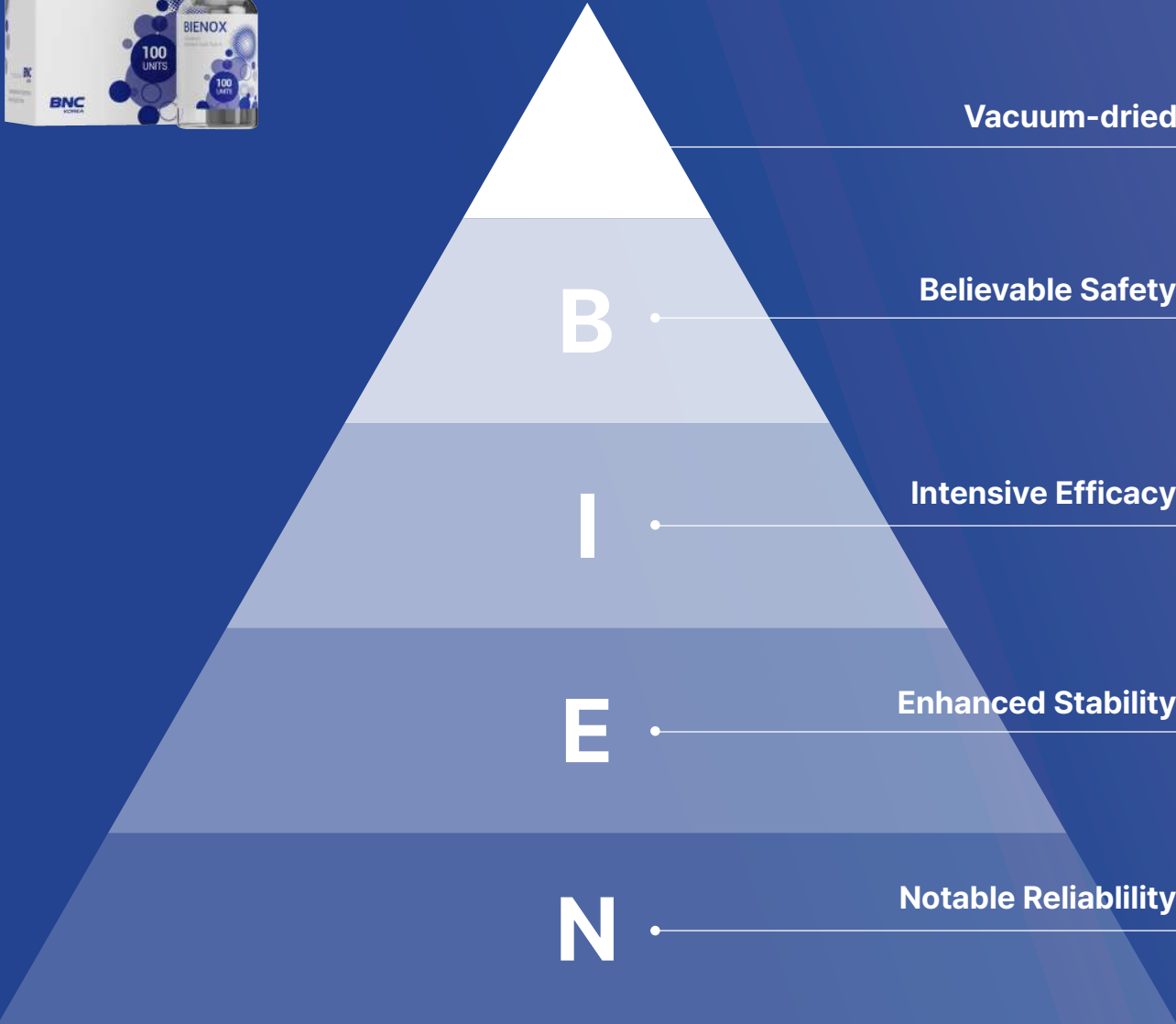


[Well, good] [Botulinum toxin]

BIEN + OX

BIEN, derived from a Latin word “bene”, means “well” or “good”.
Our destination is to be an expert in beauty as a “good” skin solution to everyone.

BIENOX, THE APEX OF BEAUTY



BIENOX is vacuum-dried botulinum toxin type A product.

There are two methods used for the production of botulinum toxin products :
vacuum drying and freeze drying.

Vacuum Drying	A method used to remove moisture or solvents from a substance under reduced pressure
Freeze Drying (Lyophilization)	A dehydration process by freezing the material and then reducing the surrounding pressure to allow the frozen solvents to sublime directly from solid to vapor, bypassing the liquid phase.

Unlike lots of other botulinum toxin products,
BIENOX is manufactured with vacuum-drying process,
ensuring the highest standards of quality and potency.

	BIENOX	Freeze Drying
Potency Loss	Low	High
Processing Time	Short	Long
Production Efficiency	High	Low
Purity	Very high	High
Damage During Process	Minimized	-
Inactive Protein	Minimized	-
Cake (Appearance)	Hardly visible, firm and uniform	Visible, easily cracked and not uniform

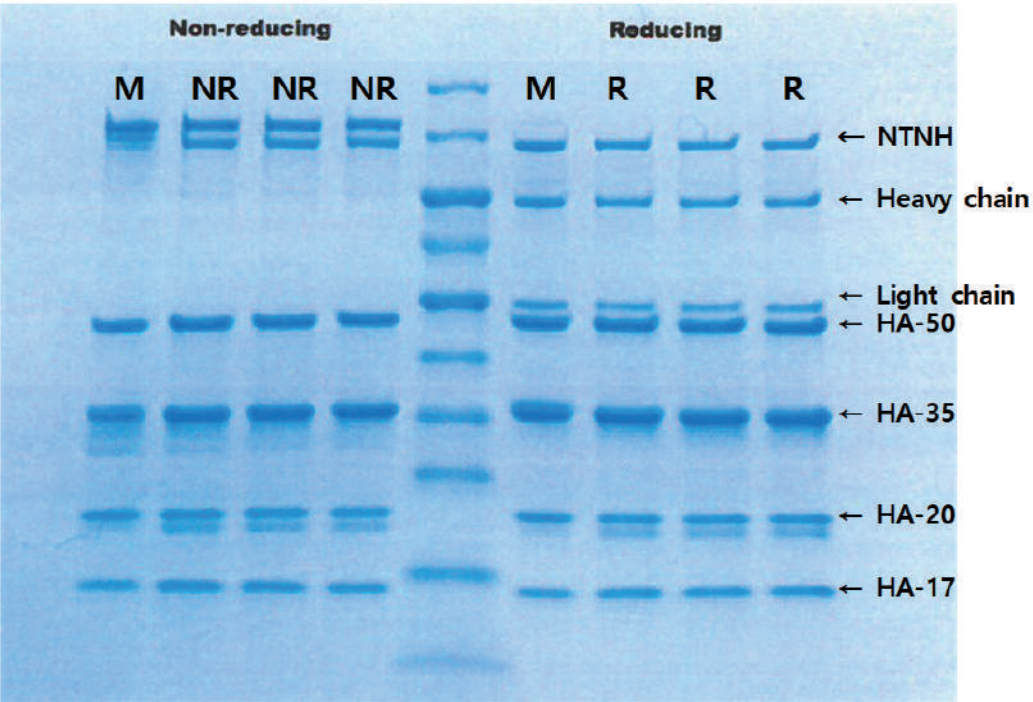
Ref.
Bhambhani, A., Stanbro, J., Roth, D. et al. Evaluation of Microwave Vacuum Drying as an Alternative to Freeze-Drying of Biologics and Vaccines: the Power of Simple Modeling to Identify a Mechanism for Faster Drying Times Achieved with Microwave. AAPS PharmSciTech 22, 52 (2021)

Parikh, Dilip M. "Vacuum drying: basics and application." Chemical Engineering 122.4 (2015): 48-54.

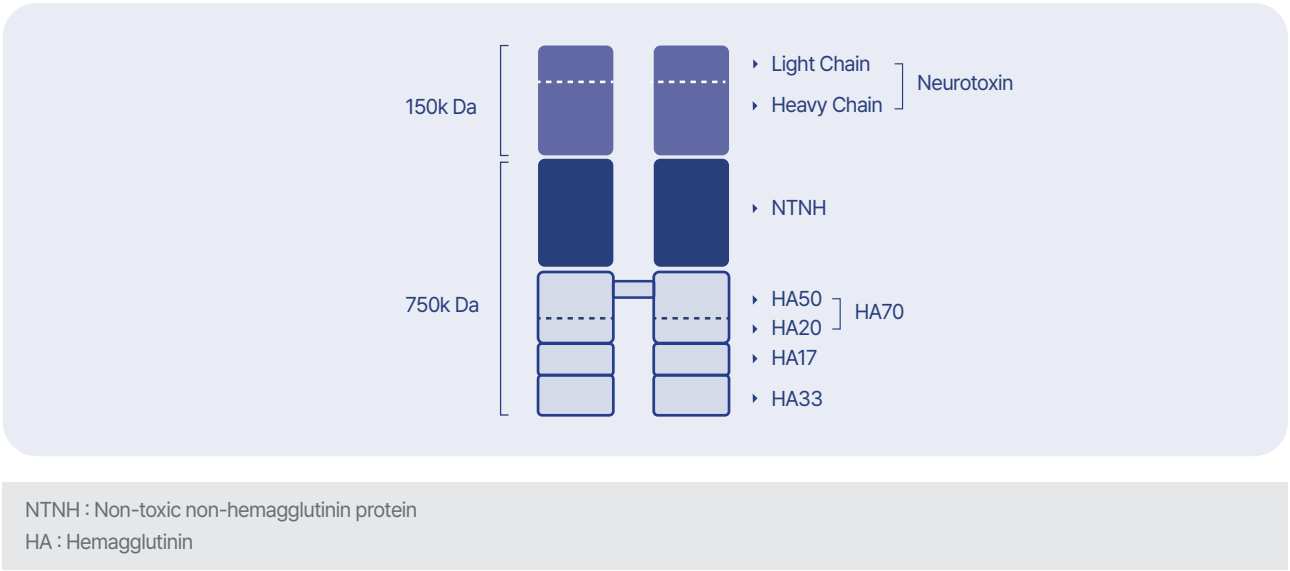
The structure of Botulinum Toxin Type A of BIENOX was confirmed by SDS-PAGE.

Molecular weight of protein subunits constituting botulinum toxin type A complex was confirmed through SDS-PAGE. As a result, same molecular weight as the data expected from BIENOX was verified. BIENOX upholds the commitment to safety and reliability through rigorous analysis.

SDS-PAGE Results for BIENOX



900kDa Botulinum Toxin Type A Complex (19S)



BIENOX is safe with low risks of adverse events.

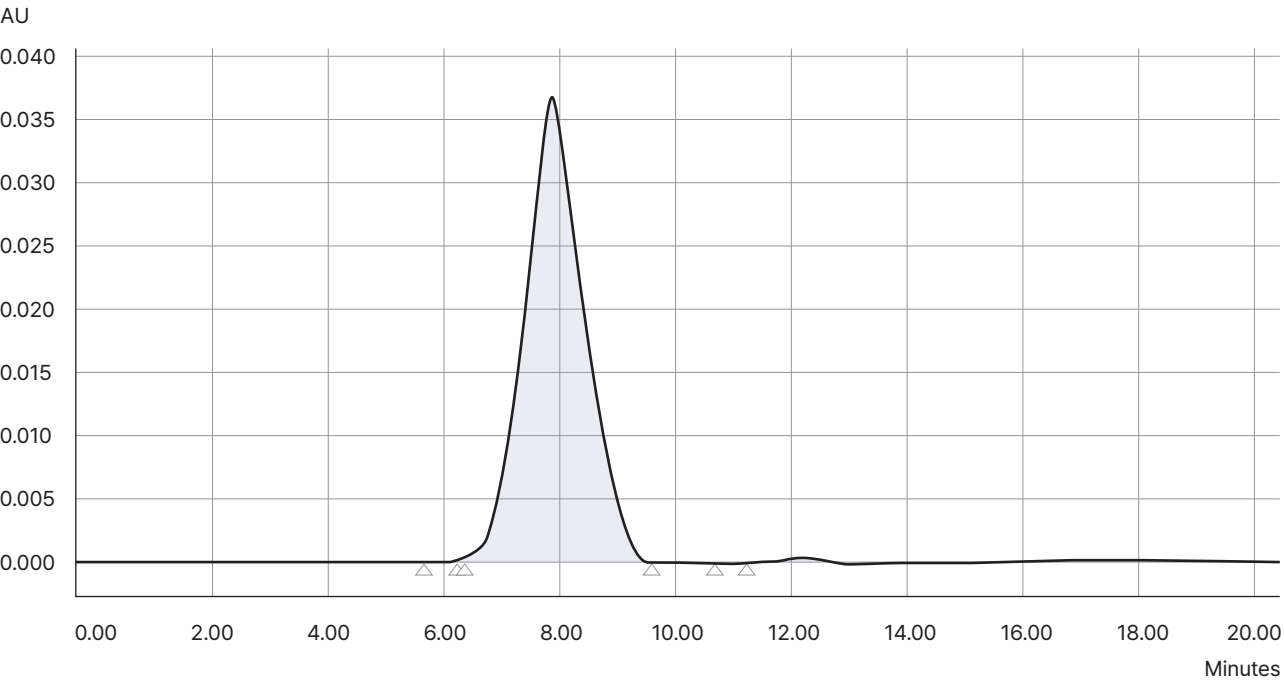
Safety is the top priority of BIENOX, which is the reason why BIENOX contains a lower concentration of neurotoxin compared to others under identical conditions. By minimizing the neurotoxin content per vial, we mitigate the risk of adverse events while delivering effective and reliable results.

Amount of Neurotoxin in Various Products

Product	Amount of Neurotoxin (ng/vial)	Ref. Frevort J. Content of botulinum neurotoxin in Botox®/Vistabel®, Dysport®/Azzalure®, and Xeomin®/Bocouture®. Drugs R D. 2010;10(2):67-73 Frevort J, Ahn KY, Park MY, Sunga O. Comparison of botulinum neurotoxin type A formulations in Asia. Clin Cosmet Investig Dermatol. 2018 Jul 5;11:327-331.
BIENOX	3.59	
Product A	4.38	
Product B	3.90	
Product C	4.52	

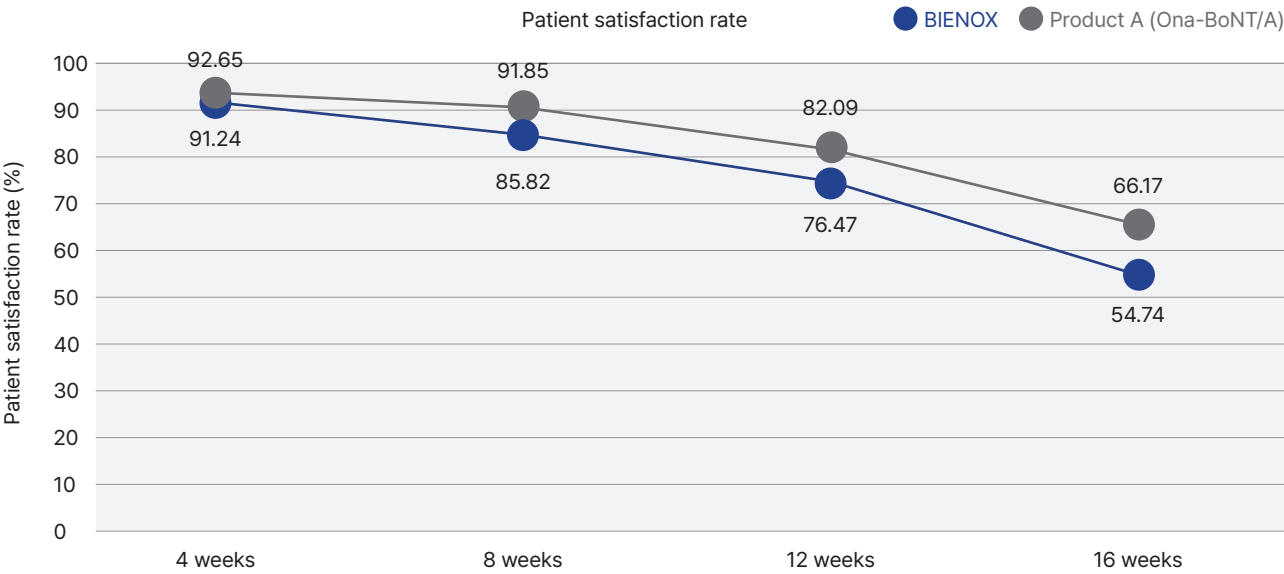
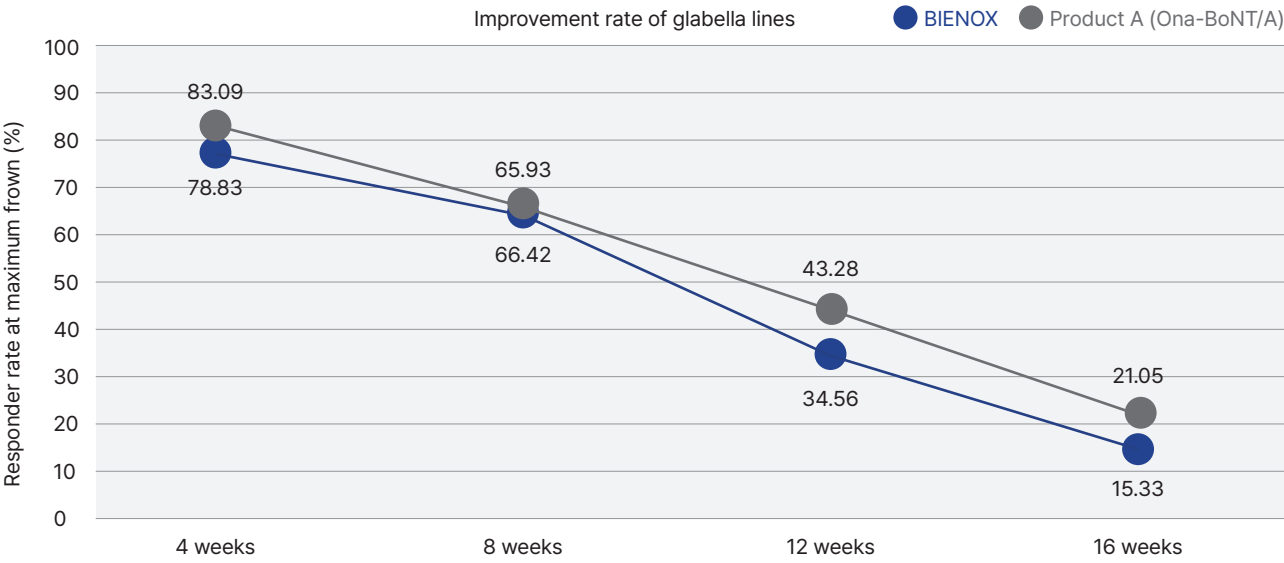
Authentic safety begins with purity. By using our purification process, BIENOX boasts an average purity of 99.59% according to SEC-HPLC analysis, surpassing regulatory criteria of 95%.

Purity Test of BIENOX (SEC-HPLC)



BIENOX's efficacy in glabellar lines improvement was validated in a comprehensive clinical trial.

The results underscore the efficacy of BIENOX in the treatment of moderate to severe glabellar lines. With 278 participants with moderate to severe glabellar lines, both BIENOX and Product A treatments yielded similar improvement rates in glabellar lines and patient satisfaction levels at 4, 8, 12, and 16 weeks post-injection. The difference in improvement rate between two groups was not statistically significant which proved that BIENOX is not inferior compared to the control group.



Study Methodology : Multicenter, double-blinded, randomized, parallel-group, active-controlled, phase III clinical study
Study Design : 278 cases with moderate to severe glabellar lines were randomized to BIENOX group (139 cases) and product A group (137 cases) with intramuscular injection of total 20U in 5 sites of glabella lines and evaluated 4, 8, 12, 16 weeks after the injection

BIENOX is meticulously controlled to ensure stability and efficacy.

During the 36-month of long-term stability test, BIENOX showed no changes in its physical and chemical properties, meeting all standards set for safety and effectiveness. Potency results also remained consistent throughout the testing period, affirming BIENOX's reliability.

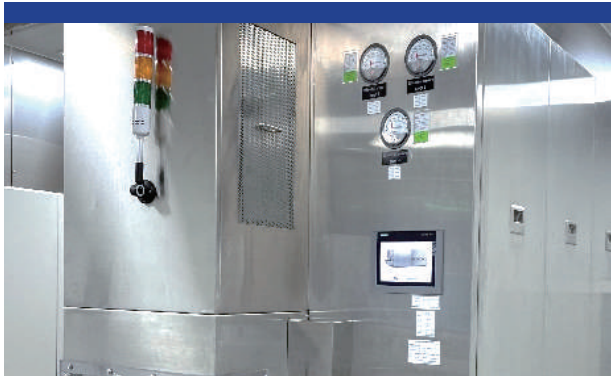
Product	BIENOX Inj. (Clostridium Botulinum Toxin Type A)			
Method	Storage Condition	Test Period	Test Details	Results
Vacuum Dried (Lot No.: E2010, E2011, E2012)	2 ~ 8 °C	36 months	1. Physicochemical characteristics 2. Potency	Passed

Maintaining stability and high potency is important to provide predictable outcomes and minimizing the risk of under or over-treatment. Rigorously controlled during manufacturing process, BIENOX guarantees optimal efficacy and safety, empowering both patients and users.

	Potency test criteria	Results
Korean Pharmacopoeia	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	N/A
European Pharmacopoeia	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	N/A
BIENOX	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	All KP, EP criteria met

BIENOX :
Efforts to be an expert in beauty

On the forefront of aesthetic innovation, BIENOX is manufactured with precision and expertise by BNC KOREA. Achieving excellence as a manufacturer of botulinum toxin product is no easy feat, yet BNC KOREA has risen to the challenge with dedication and commitment. With GMP certification for manufacturing site and KFDA approval for BIENOX (expected in 2024), BNC KOREA showcases its unwavering pursuit of quality and safety. As an expert in beauty, BNC KOREA continues to lead the industry with BIENOX, empowering individuals worldwide to look and feel their best with confidence.



BNC KOREA Products

Cross-linked HA + PN dermal filler

JUVEGEL®

Cross-linked HA dermal filler

 **VOLIFIL**

Cross-linked HA dermal filler

 **FLORE** Lidocaine

Skinboosters

   **HyaRepair**

Clostridium botulinum toxin type A

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Product	BIENOX Injection
Classification	Prescription Medicine
Active Ingredient	Clostridium Botulinum Toxin Type A
Contents (1 vial)	Clostridium Botulinum Toxin Type A – 100 unit Human Serum Albumin – 0.5mg Sodium Chloride – 0.9mg
Appearance	A white or pale yellow dried product in a colorless, transparent vial that, when dissolved in physiological saline, is a clear and transparent solution
Indication	Temporary improvement of moderate to severe glabella wrinkles due to activities of the corrugator and/or procerus muscles in adults between the ages of 10 and 65
Mechanism	A temporary reduction in muscle activity for medical and aesthetic use
Storage Condition	Store at sealed containers, refrigeration (2~8°C)
Shelf Life	24 months from manufacturing date