JETEMA
THE TOXIN

Botulinum Toxin Type A

JETEMA THE TOXIN™

JETEMA THE TOXIN™ is manufactured with the original strain from European Company and is a high purity product with low immunogenicity risk that complies with cGMP standards for safe & fast wrinkle improvement.

Low Immunogenicity

Original Strain from Europe

High Purity & Biological activity

Original Strain from European Company

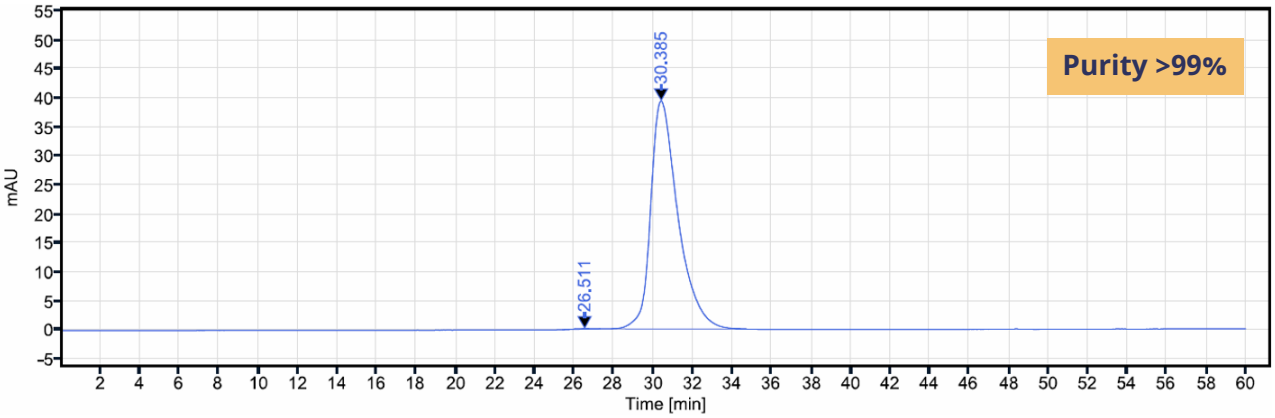
The strain of JETEMA THE TOXIN™ is listed on GenBank® with complete genomic sequence data.

*GenBank: National Institutes of Health genetic sequence database
*NCBI: National Center for Biotechnology Information

Product Name	JETEMA THE TOXIN™
Units	100 Units / vial
Active Ingredient	*Clostridium Botulinum* toxin type A
NCBI Registration No.	CP046450
Drying	Patented vacuum drying process
Storage	Refrigerate at 2 – 8 ℃
Packaging	1 vial / box
Expiry Period	36 months
Indications	For the temporary improvement of glabellar lines
Dilution	Dilute to 100 Units per 2.5ml with sterile, preservative-free 0.9% normal saline
Dosage	A total of 20 Units (0.5ml) is injected by injecting 0.1ml into 5 areas of each of the two corrugator muscles and one of the procerus muscle

High Purity and High Biological Activity

Faster and more consistent effect can be expected due to high purity (> 99%) and high biological activity compared to existing products.



Name	RT [min]	Type	Area	Area%	Width [min]	Height
RRT0.87	26.511	MM m	7.22	0.19	0.83	0.10
BotulinumA	30.385	BB	3781.07	99.81	7.11	39.32
		Sum	3788.29			

Ref. In-house data

JETEMA THE TOXIN™ Safety

JETEMA THE TOXIN™ excludes animal-derived ingredients in the entire process to prevent TSE (Transmissible spongiform encephalopathy) infection. JETEMA THE TOXIN™ even excludes plant-derived ingredients that can induce allergies such as wheat, nuts, and soybeans.

JETEMA THE TOXIN™ has maximized the safety by excluding all ingredients that can cause adverse events.

Low Immunogenicity Risk

The amount of neurotoxin (dose of the antigen) determines the antibody formation. Other products contain more denatured inactive neurotoxin, which means the dose of the antigen is higher, which may be responsible for the formation of neutralizing antibodies leading to therapeutic failure. It is crucial to prevent the formation of antibodies in the first place by using JETEMA THE TOXIN™ with low immunogenicity risk.

Comparison of toxin content (ng/vial)

JETEMA THE TOXIN™ Amount of toxin	2.82 ng / vial
Specific Potency	4.0 x 10^7 units / mg

B Product	4.90
D Product	3.90
L Product	5.06
M Product	3.45
N Product	4.52
R Product	3.47

JETEMA THE TOXIN™ has minimized the potential immunogenicity risk by reducing neurotoxin protein content to 2.82 ng per 100 U vial while maintaining the potency.

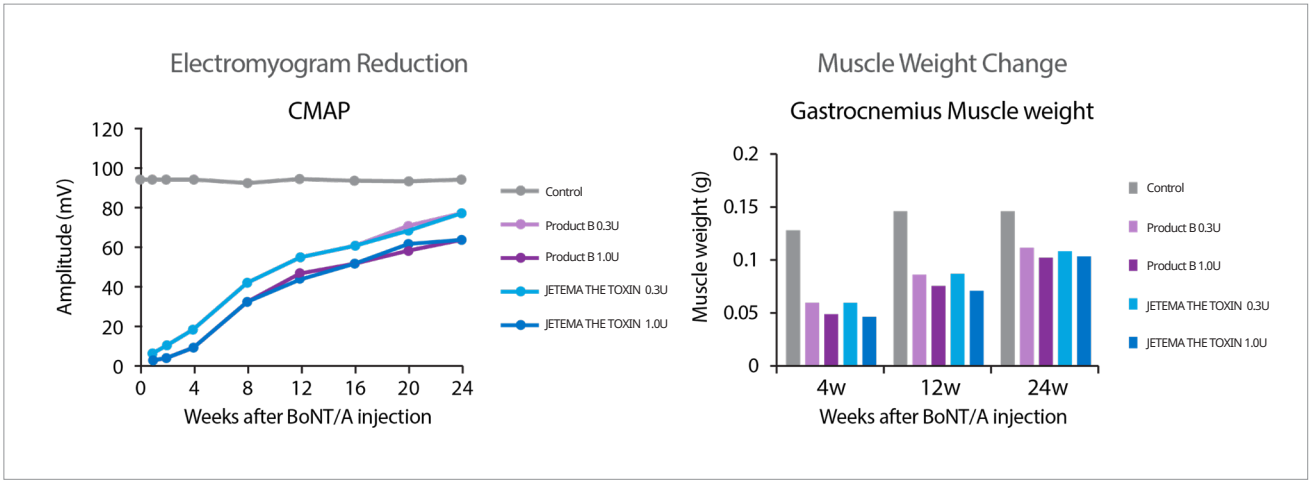
Na, Jungtae, et al. "Long-term efficacy and safety of a new botulinum toxin type A preparation in mouse gastrocnemius muscle." Toxicon 187 (2020): 163-170.

Frevert, Jürgen. "Content of botulinum neurotoxin in botox®/vistabel®, dysport®/azzalure®, and xeomin®/bocouture®." Drugs in R & D 10.2 (2010): 67-73.

Frevert, Jürgen, et al. "Comparison of botulinum neurotoxin type A formulations in Asia." Clinical, cosmetic and investigational dermatology 11 (2018): 327.

Pre-clinical Study for Efficacy and Safety

JETEMA THE TOXIN™ demonstrated non-inferiority in efficacy to that of competing product B.
Safety test (toxicity, pharmacology, reproductive/developmental toxicity) was completed.



Ref.
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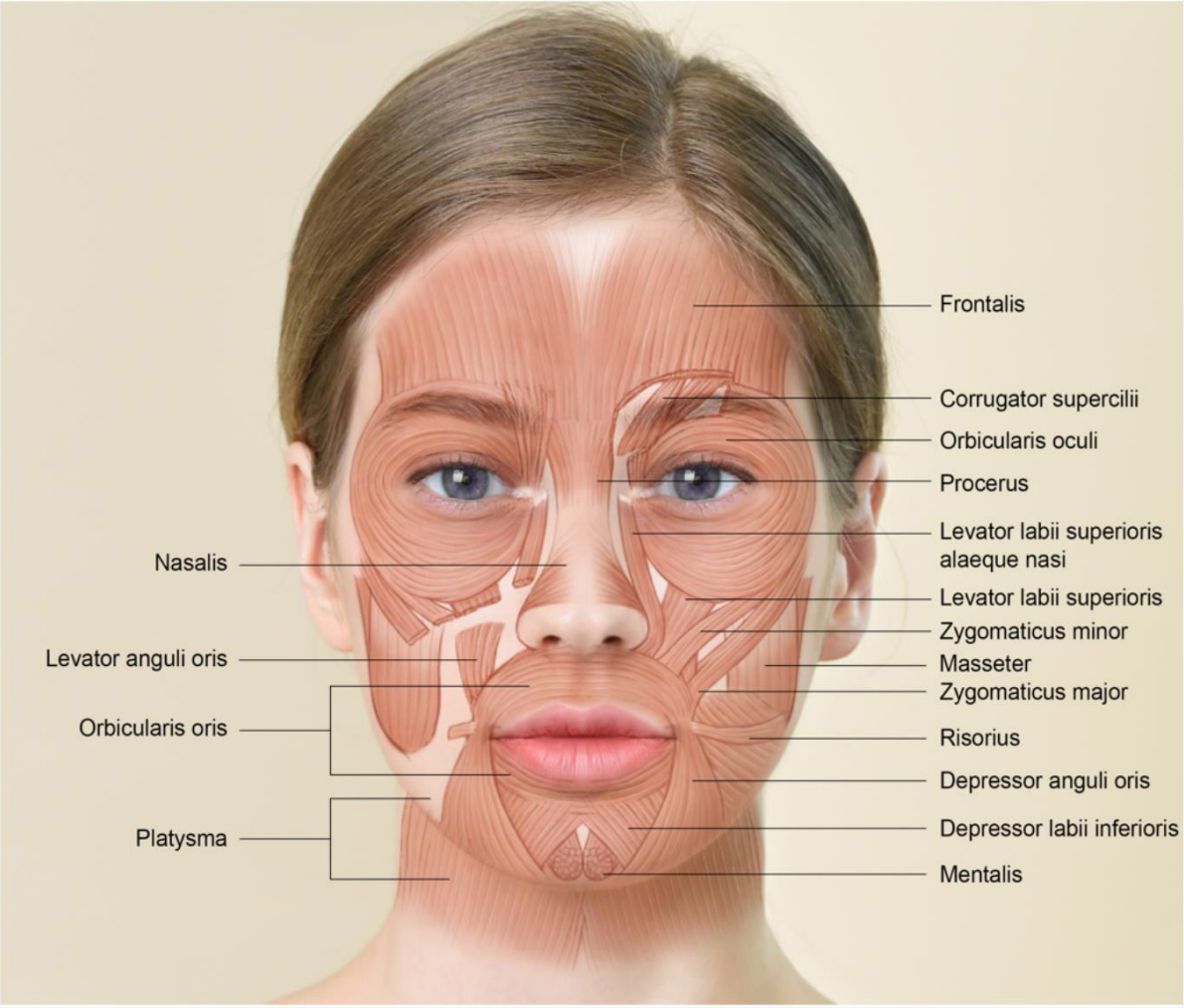
Clinical Trial Phase I – Safety Evaluation

JETEMA THE TOXIN™ demonstrated similar safety to the competing Product B.
JETEMA THE TOXIN™ showed a low incidence of adverse events and no adverse drug reactions.
No clinically significant changes related to safety were observed in the results
of laboratory tests, vital signs, and physical examinations.

	JETEMA THE TOXIN™ (N=10)			Product B (N=10)		
	N (%)	Events	(95% CI)	N (%)	Events	(95% CI)
TEAE (Treatment Emergent Adverse Events)	1 (10.00)	1 (severity: mild)	(0.00, 28.59)	3 (30.00)	6 (severity: mild)	(1.60, 58.40)
ADR (Adverse Drug Reactions)	0 (0.00)	0	(-)	0 (0.00)	0	(-)
SAE (Serious Adverse events)	0 (0.00)	0	(-)	0 (0.00)	0	(-)

A randomized, double-blind, active-control, single-center, phase I clinical trial for comparative safety evaluation of 20 Units dose of JTM201 (JETEMA THE TOXIN™) or Botox® Injection for 12 weeks in adults who need moderate to severe glabellar line improvement
Name of Investigational Institution: Chung-Ang University Hospital / Study duration: Oct 13, 2020 to Jan 19, 2021



Dilution Table

Diluent added to 100 Units/vial (0.9% normal saline)	Resulting dose per 0.1mL
1.0 mL	10.0 units
2.0 mL	5.0 units
2.5 mL	4.0 units
4.0 mL	2.5 units
8.0 mL	1.25 units

Note: These dilutions are calculated for an injection volume of 0.1mL. A decrease or increase in the dose is also possible by administering a smaller or larger injection volume (i.e., 0.05mL (50% decrease in dose) or 0.15mL (50% increase in dose)).

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Contact Information

Email global@jetema.com

www.jetema.com

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