Vacuum-Dried
Botulinum Toxin Type A Unit 100

KAMOMIS *Toxin*

Rediscover Your Youthful Confidence

KAMOMIS, vacuum-dried botulinum toxin excels over freeze-dried versions with enhanced stability, purity, and consistency, ensuring safer and more precise injections. Its user-friendliness and cost-effectiveness make it the top pick for medical and cosmetic applications requiring reliability and safety.

MAYPHARM

Clostridium Botulinum

Toxin Type A

Vacuum-Dried

Unit 100

Rediscover Your Youthful Confidence with KAMOMIS

POINT 1
Higher Purity

POINT 2
Greater Consistency

POINT 3
Enhanced Stability

KAMOMIS, the Vacuum-dried botulinum toxin offers significant advantages over freeze-dried alternatives. It boasts enhanced stability, higher purity, and greater consistency, reducing the risk of adverse reactions and improving safety. Additionally, it is easier to handle and reconstitute, contributing to more accurate injections, and often proves cost-effective due to increased product yield and reduced wastage. These benefits make vacuum-dried botulinum toxin the preferred choice for medical and cosmetic applications where reliability, safety, and precision are crucial.

KAMOMIS

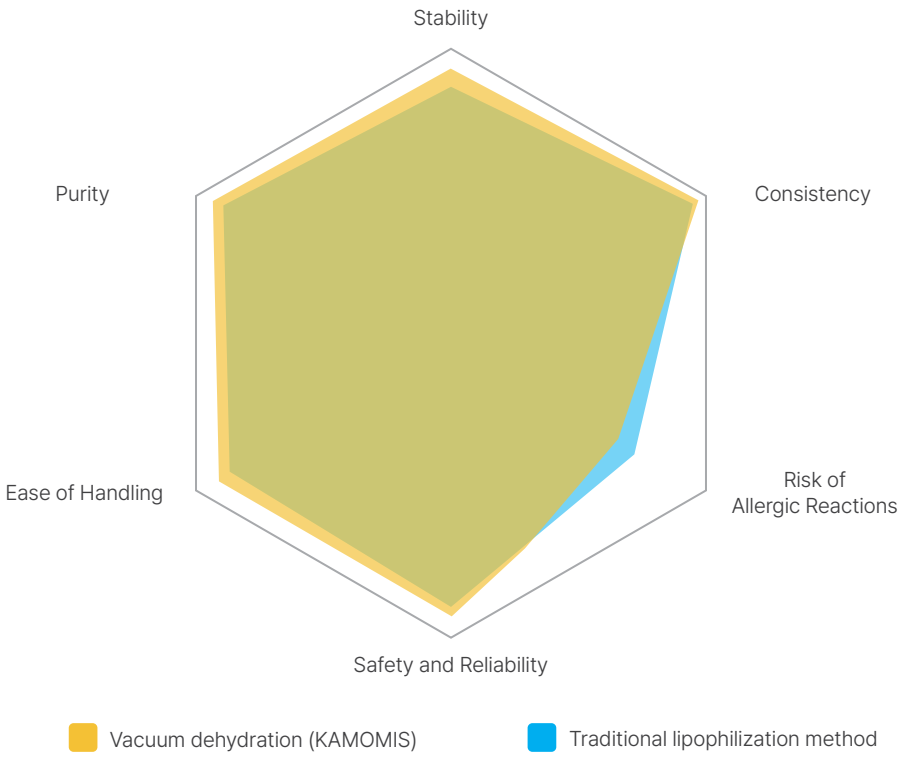
Vacuum-dried

PRODUCT A

Freeze-dried

While traditional botulinum toxin manufacturers rely on the conventional lyophilization method, Kamomis stands apart with its innovative approach, utilizing an upgraded technique known as vacuum dehydration. This cutting-edge process ensures minimal powder residue in each vial, a stark contrast to many other brands. The advantage of this is the reduction of denaturation issues, such as foaming or molecular breakage, when the product is diluted.

Performance



KAMOMIS, Vacuum-dried botulinum toxin offers several benefits over freeze-dried botulinum toxin, primarily in terms of stability, purity, and ease of handling:

Enhanced Stability: Vacuum drying involves removing moisture and other impurities in a controlled environment, resulting in a more stable product. This increased stability ensures that the botulinum toxin retains its potency for a longer period, reducing of the potency loss and ensuring reliable effectiveness over time.

Higher Purity: Vacuum drying typically produces botulinum toxin with fewer impurities and contaminants compared to freeze drying. This higher purity level is crucial for medical and cosmetic applications, as it keeps immunogenicity low and lowering the risk of resistance happen.

Consistency: Vacuum drying allows for more precise control over the drying process, leading to a consistent and uniform quality product. This consistency is essential in medical settings where precise dosing is critical for achieving desired therapeutic or cosmetic results.

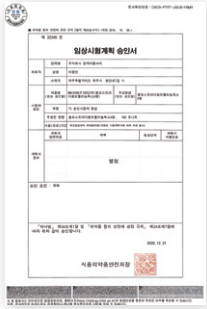
Ease of Handling: Vacuum-dried botulinum toxin is generally easier to handle and reconstitute, making it more convenient for healthcare professionals during preparation and administration. This ease of use can contribute to improved patient experiences and more accurate injections.

Reduced Risk of Allergic Reactions: Due to its higher purity and lower likelihood of impurities, vacuum-dried botulinum toxin carries a reduced risk of allergic reactions or adverse effects when compared to freeze-dried alternatives. This benefit adds to its safety and reliability.

Product Specification

GMP

COA



Clinical trial / IND

Active Ingredient	Clostridium Botulinum Toxin Type A
Contents	Clostridium botulinum toxin type A .....100 units Human Serum Albumin.....0.5mg Sodium chloride.....0.8mg
Appearance	A white or light yellow lyphilisate contained in a colorless and transparent vial and is a trantparent solution when dissolved in saline
Dosage	100 units
Effect	Temporary improvement of moderate to severe wrinkle line (such asglabellar lines) in adult patients
Mechanism	A temporary reduction in muscle activity for medical and aesthetic use
Storage Method	Refrigeration (2-8°c) To prevent bacterial contamination, the interior of the refrigerator should be kept sterile, and the vials clean

Injection site

Preparation before use

Diluent the product in preservative-free sterile saline solution.

※ 0.9% NaCl preservative-free sterile saline solution is recommended.

How to use

1. Dilute to 100U / 2.5 mL (4U / 0.1mL) with 0.9% preservative-free sterile saline solution.
2. Using a 30G needle, inject a total of 20U by injecting 0.1mL into five areas, two of each right and left corrugator muscle and one of the procerus muscle.

How to dillute

Saline Solution (0.9% NaCl)	Concentration (U/0.1mL)
1.0mL	10.0 U
2.0mL	5.0 U
4.0mL	2.5 U
8.0mL	1.25 U

※ This dilution is calculated based on an injection volume of 0.1 mL.
※ It is possible to increase or decrease the dosage according to the increase or decrease of the injection dose 0.05 mL (50% decrease in dose) to 0.15 ml (50% increase in dose)

Stability Test

KAMOMIS has shown excellent product stability through testing, assessing whether the quality of the product is maintained through changes over time.

Specification	Should be 80% ~ 125% of the labelled potency per vial.		
Initial	101.9%	98.3%	100.2%
1 month	98.4%	98.6%	100.6%
3 month	105.0%	98.4%	101.7%
6 month	99.3%	98.0%	96.2%
9 month	97.5%	100.2%	98.1%
12 month	95.6%	95.7%	95.1%

Pre-Clinical Study

Both the safety & efficacy of KAMOMIS have been successfully proven in a comparison study with company A's Product

Toxicity Test

Study Type	Test System	Route	Doses	
Single Dose	Rat	IM	0, 6, 30, 150	U/kg
	Monkey	IM	0, 8, 16, 32	U/kg
Repeated Dose	Rat	IM	0, 6, 30, 150	U/kg
	Monkey	IM	0, 8, 16, 32	U/kg
Embryo - Fetal Development	Rat	IM	0, 6, 30, 150	U/kg
	Monkey	IM	0, 8, 16, 32	U/kg

Safety Pharmacology

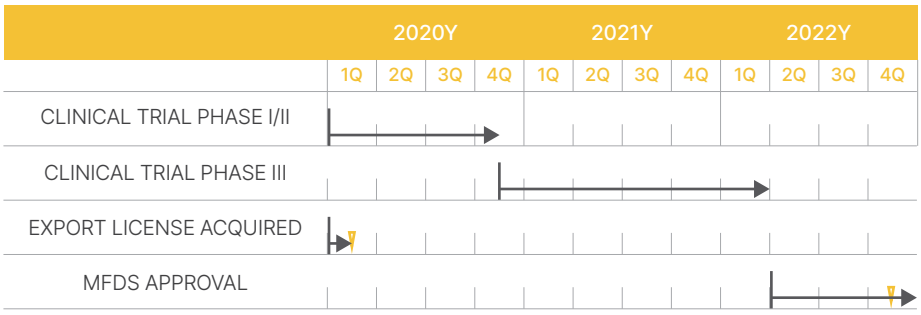
Study Type	Test System	Route	Doses	
Cardiovascular System	CHO hERG cells	in vitro	0, 0.125, 0.25, 0.5, 1	U/mL
Respiratory System	Rat	IM	0, 8, 16, 32	U/kg
Central Nervous System	Mouse	IM	0, 6, 30, 150	U/kg

Efficacy comparison

Study Type	Test System	Route	Doses		Comparison
Efficacy comparison	Mouse	IM	4, 12, 40	U/kg	Company A's Product

Clinical Trial Timeline

KAMOMIS is licensed for export and is currently headed towards the third phase of its clinical trial.



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