WIZMEDI

WIZTOX inj

100 UNITS

Clostridium Botulinum Toxin **Type A**
Purified Neurotoxin Complex

EFFICACY

WIZTOX inj. is strictly controlled
for safety and
high & stable potency

HIGH PURITY

WIZTOX inj. has
purity of 99%

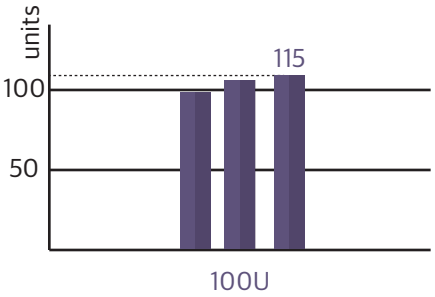
POTENCY& STABILITY

Classification	Medicine
Active Ingredients	Clostridium Botulinum Toxin Type A
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.
Dosage	100 units
Assay (Activity test)	87~115%
Molecular weight	900kDa
pH	6.0±0.5
Storage	2~8℃
Expiration	36 months from date of manufacture

ACTIVITY TEST

WIZTOX inj keeps stabilized potency of each vial by its own strict quality control system.

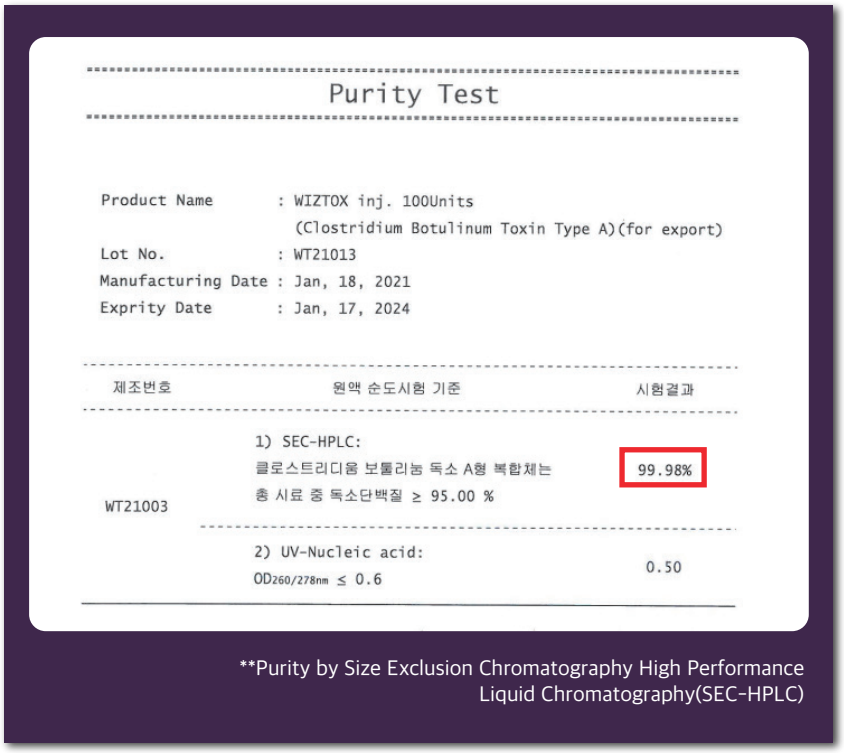
Specifications	MFDS	WIZTOX inj
WIZTOX inj 100U	80 - 125	90 - 115



Ref. In-house

HIGH PURITY

WIZTOX inj is botulinum toxin with high purity.



Purity Test

Product Name : WIZTOX inj. 100Units
(Clostridium Botulinum Toxin Type A)(for export)
Lot No. : WT21013
Manufacturing Date : Jan, 18, 2021
Exprity Date : Jan, 17, 2024

제조번호	원액 순도시험 기준	시험결과
WT21003	1) SEC-HPLC: 클로스트리디움 보툴리눔 독소 A형 복합체는 총 시료 중 독소단백질 ≥ 95.00 %	99.98%
	2) UV-Nucleic acid: $OD_{260/278nm}$ ≤ 0.6	0.50

**Purity by Size Exclusion Chromatography High Performance Liquid Chromatography(SEC-HPLC)

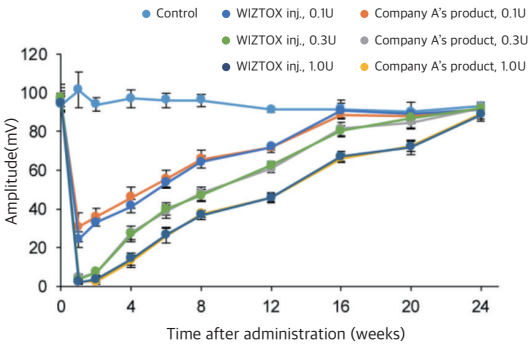
Using Size Exclusion Chromatography High performance liquid chromatography(SEC-HPLC), undiluted toxin complex solution was analyzed which resulted in purity of over **99%**.

EFFICACY

According to efficacy test in mouse,

WIZTOX inj shows equivalent efficacy compared to Company A's product.

Group	Test System	Route	Doses(U/kg)
Control	Mouse	IM	None
WIZTOX inj	Mouse	IM	4
			12
Company A's product			40



PRE-CLINICAL STUDY

Both the safety & efficacy of WIZTOX inj are proved in various pre-clinical studies.

	Study Type	Test System	Route	Doses(U/kg)
Toxicity Test	Single Dose	Rat Monkey	IM	0, 6, 30, 150 0, 8, 16, 32
	Repeated Dose	Rat Monkey	IM	0, 1.5, 3, 6 0, 2, 4, 16
	Embryo-Fetal Development	Rat Monkey	IM	0, 1, 3, 9 0, 0.1, 0.2, 0.4

	Study Type	Test System	Route	Doses
Safety Pharmacology	Cardiovascular System	CHO hERG cells	in vitro	0, 0.125, 0.25, 0.5, 1 U/mL
	Respiratory System	Rat	IM	0, 1.5, 3, 6 U/kg
	Central Nervous System	Mouse	IM	0, 1.5, 3 6 U/kg

WIZTOX inj

Reconsititution and Dilution Technique

1. To dissolve this dried drug, sterilized saline without preservatives is used. The recommended diluent is 0.9 % sodium chloride solution.

2. Put an adequate amount of diluent into an adequately sized syringe.

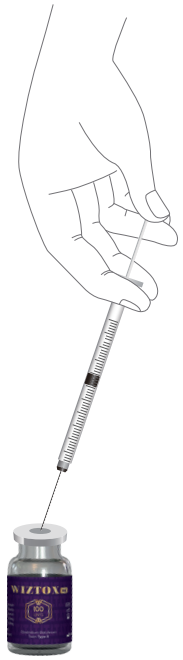
3. Generation of bubbles or any other similar turbulences may result in denaturation of the drug, so the diluent should be injected slowly into the vial. If the diluent was not injected into the vial in a vacuum state, the vial must be disposed of.

4. Record the diluted date and time on the label, and use the solution within 24 hours of dissolution.

5. The diluted solution should be refrigerated (2-8℃).

* The dissolved solution should be transparent without any visible foreign matters. Parenteral agents should be checked carefully for any foreign matters or discolorations before administration.

* Since no preservatives are included in this drug or the diluent, 1 vial should be used for only 1 patient.



[Dilution Table]

Added diluent	Resulting dose(U/0.1mL)
0.9% Sodium Chloride (mL)	WIZTOX inj 100U
1.0mL	10.0 U
2.0mL	5.0 U
4.0mL	2.5 U
8.0mL	1.25 U

Note. The diluent is calculated based on 0.1 mL injection dose. The administration dose can also be controlled by increasing the injection dose. 0.05 mL (50 % decrease from the administration dose)~0.15 mL (50 % increase from the administration)

Ref. WIZTOX inj. Product Information

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MADE IN KOREA

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