TOXPIA

Clostridium botulinum toxin Type A complex

HJ corporations

What is TOXPIA?

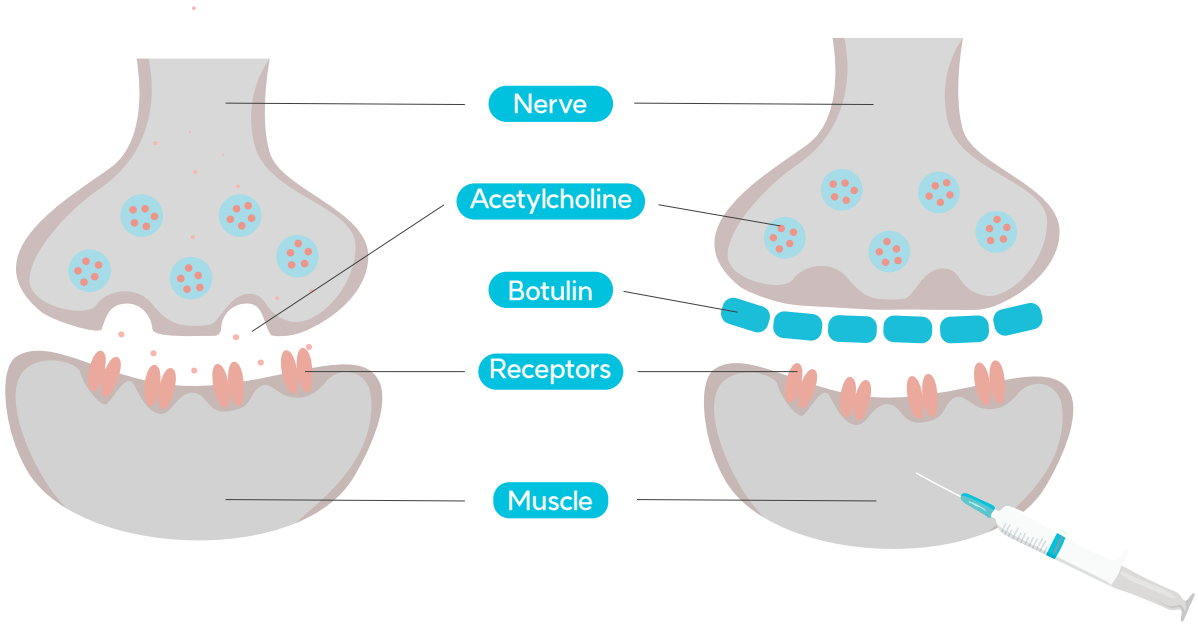
Toxpia is a Clostridium Botulinum Toxin Type A, which is manufactured and distributed by **HJ Corporations.**

Classification	Medicine
Active Ingredient	Clostridium botulinum toxin type A
Contents(1vial)	Clostridium botulinum toxin type A 100 units Human Serum Albumin 0.5 mg Sodium chloride 0.9 mg
Appearance	A white or light yellow lyophilisate contained in a colorless and transparent vial and is a transparent solution when dissolved in saline.
Effect	Temporary improvement of moderate to severe wrinkle lines (such as glabella lines) for adult patients
Mechanism	A temporary reduction in muscle activity for medical and aesthetic use

How does TOXPIA Work?

The botulinum toxin shot blocks the release of acetylcholine*.
This way, the muscles are relaxed, reducing unwanted wrinkles.

*Acetylcholine is the chemical signal which causes muscles to contract.



Normal process

After botulin injection

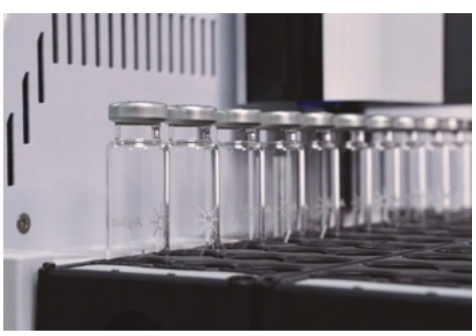
Our Manufacturing Process

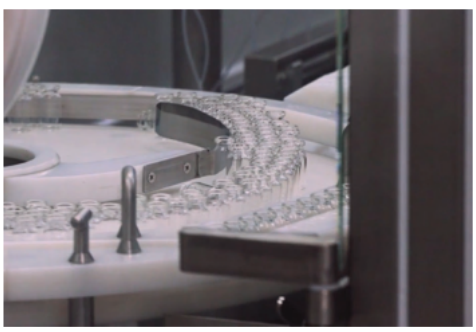
CULTURE > PURIFICATION > FILLING

VACUUM DRYING > INSPECTION > PACKAGING

Our Manufacturing Plant





/ Our Certificates /

문서확인번호 : Z7FJ-JKOK-D0QU-TTBQ

제 1 호

[V] 의약품 [V] 제조판매
[ ] 의약외품 [ ] 수입
품목허가증

업종	의약품	업허가번호 : (업신고번호)	98 / (구)
제품명	비에녹스주(클로스트리디움보툴리눔독소형)(수출용)	의약품분류	[V] 전문 [ ] 일반 [ ] 희귀 [ ] 신약
원료약품(원자재) 및 분량	별첨	의약외품 분류번호	
성상	별첨		
제조방법	별첨		
효능 · 효과	별첨		
용법 · 용량	별첨		
사용상의 주의사항	별첨		
포장단위	1 바이알/상자(1바이알(100 유니트))		
저장방법 및 사용(유효)기간	밀봉용기, 냉장(2-8℃) 보관 제조일로부터 36개월		
기준 및 시험방법	별첨		
제조소	별첨		
허가조건	수출용에 한함	비고기한	

「약사법」 제31조 · 제42조 및 「의약품 등의 안전에 관한 규칙」 제13조제1항 · 제20조제2항, 같은 규칙 제59조에 따라 위와 같이 허가합니다.

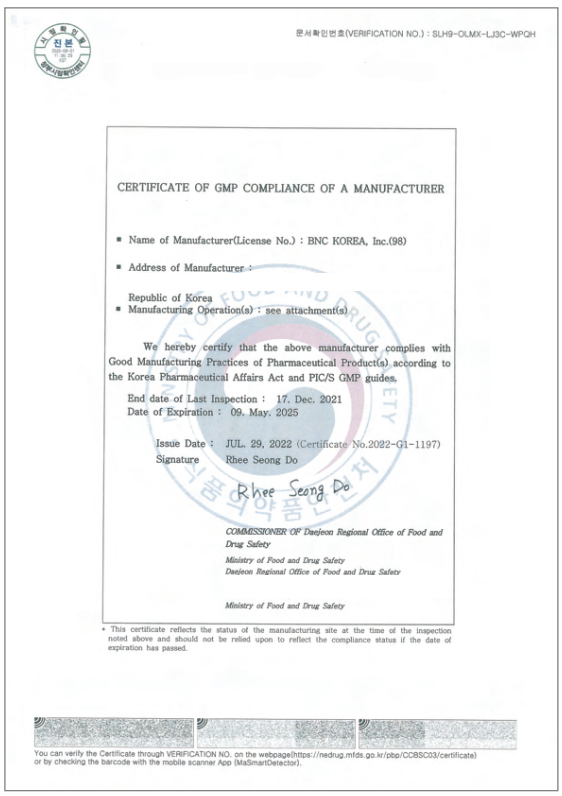
수출용.

2020. 1. 13

식 품 의 약 품 안 전 처 장

품목기준코드 202000204

※ 본 증명서는 안대넷으로 발급되었으며, 홈페이지(https://nedrug.mfds.go.kr)의 발급번호를 통하여 위변조 여부를 확인할 수 있습니다.
또한, 문서하단의 바코드로도 신뢰확인(스캐너용 문서확인프로그램)을 하실 수 있습니다.



문서확인번호(VERIFICATION NO.) : SLH9-OLMX-LJ3C-WPQH

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

- Name of Manufacturer(License No.) : BNC KOREA, Inc.(98)
- Address of Manufacturer :

Republic of Korea
- Manufacturing Operation(s) : see attachment(s)

We hereby certify that the above manufacturer complies with Good Manufacturing Practices of Pharmaceutical Product(s) according to the Korea Pharmaceutical Affairs Act and PIC/S GMP guides.

End date of Last Inspection : 17. Dec. 2021
Date of Expiration : 09. May. 2025

Issue Date : JUL. 29, 2022 (Certificate No.2022-G1-1197)
Signature Rhee Seong Do

Rhee Seong Do

COMMISSIONER OF Daejeon Regional Office of Food and Drug Safety
Ministry of Food and Drug Safety
Daejeon Regional Office of Food and Drug Safety

Ministry of Food and Drug Safety

* This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if the date of expiration has passed.

You can verify the Certificate through VERIFICATION NO. on the webpage(https://nedrug.mfds.go.kr/pbp/CCBSC03/certificate) or by checking the barcode with the mobile scanner App (MaSmartDetector).

BNC Biotechnology Next Challenge KOREA

Issuing Date: 2022.12.16
Revision No.: 00
Revision Date: 2022.12.16

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY INFORMATION

Product Name TOXPIA Injection (Clostridium Botulinum Toxin Type A)

Recommended use of the chemical and restrictions on use

Recommended Use Temporary improvement of moderate to severe glabellar wrinkles due to activities of the corrugator and/or procerus muscles in adults between the ages of 19 and 65

Uses advised against No information available

Supplier's details

Name BNC KOREA, Inc.

Address

Tel

2. HAZARDS IDENTIFICATION

Classification

Reproductive Toxicity Category 2

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word Warning

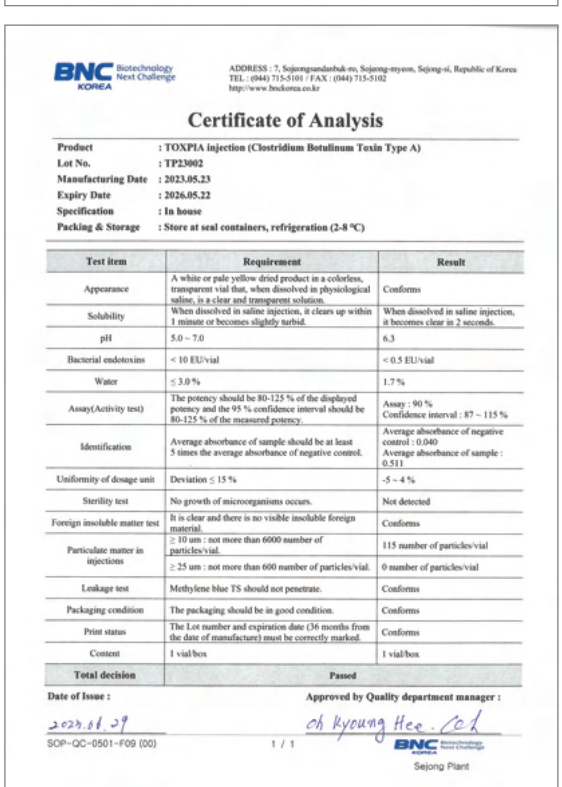
Hazard Statements

• Suspected of damaging fertility or the unborn child

Appearance A white or slightly yellow dried product in a clear colorless vial and clear transparent solution when dissolved in saline.

Odor None

1 / 11



BNC Biotechnology Next Challenge KOREA

ADDRESS : 7, Sojeongnamdeok-ro, Sojeong-myeon, Sejong-si, Republic of Korea
TEL : (044) 715-5101 / FAX : (044) 715-5102
http://www.bnckorea.co.kr

Certificate of Analysis

Product : TOXPIA injection (Clostridium Botulinum Toxin Type A)
Lot No. : TP23002
Manufacturing Date : 2023.05.23
Expiry Date : 2026.05.22
Specification : In house
Packing & Storage : Store at seal containers, refrigeration (2-8 ℃)

Test item	Requirement	Result
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.	Conforms
Solubility	When dissolved in saline injection, it clears up within 1 minute or becomes slightly turbid.	When dissolved in saline injection, it becomes clear in 2 seconds.
pH	5.0 ~ 7.0	6.3
Bacterial endotoxins	< 10 EU/vial	< 0.5 EU/vial
Water	≤ 3.0 %	1.7 %
Assay(Activity test)	The potency should be 80-125 % of the displayed potency and the 95 % confidence interval should be 80-125 % of the measured potency.	Assay : 90 % Confidence interval : 87 ~ 115 %
Identification	Average absorbance of sample should be at least 5 times the average absorbance of negative control.	Average absorbance of negative control : 0.040 Average absorbance of sample : 0.511
Uniformity of dosage unit	Deviation ≤ 15 %	-5 ~ 4 %
Sterility test	No growth of microorganisms occurs.	Not detected
Foreign insoluble matter test	It is clear and there is no visible insoluble foreign material.	Conforms
Particulate matter in injections	≥ 10 um : not more than 6000 number of particles/vial.	115 number of particles/vial
	≥ 25 um : not more than 600 number of particles/vial.	0 number of particles/vial
Leakage test	Methylene blue TS should not penetrate.	Conforms
Packaging condition	The packaging should be in good condition.	Conforms
Print status	The Lot number and expiration date (36 months from the date of manufacture) must be correctly marked.	Conforms
Content	1 vial/box	1 vial/box
Total decision	**Passed**	

Date of Issue : 2023. 6. 29

Approved by Quality department manager : Oh Kyoung Hee

SOP-QC-0501-F09 (00) 1 / 1

BNC Biotechnology Next Challenge Sejong Plant

Why TOXPIA?

1 Stability Test

Toxpia's excellent product stability has been proven through clinical trials.

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%

2 Vacuum-Drying Method

Toxpia is manufactured through the vacuum-drying method, which is the latest techonlogy that is used for manufacturing botulinum toxin.

Toxpia-Vacuum-Drying Method

Freeze-Drying Method

As you can see in the picture above, there is no powder residue in the vial of the toxin that is manufactured using vacuum-drying method.
This increases the purity of the product while minimizing the denaturalization of protein as the risk of foaming during the dilution process is significantly reduced.

3 Quick Response Time

It is proven to be responsive within 72 hours after injection*.

* This may vary as per individual.

PRE – Clinical Study

Both the safety & efficacy of TOXPIA 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, 1.5, 3, 6	U/kg
	Monkey	IM	0, 2, 4, 16	U/kg
Embryo – Fetal Development	Rat	IM	0, 1, 3, 9	U/kg
	Rabbit	IM	0, 0.1, 0.2, 0.4	U/kg

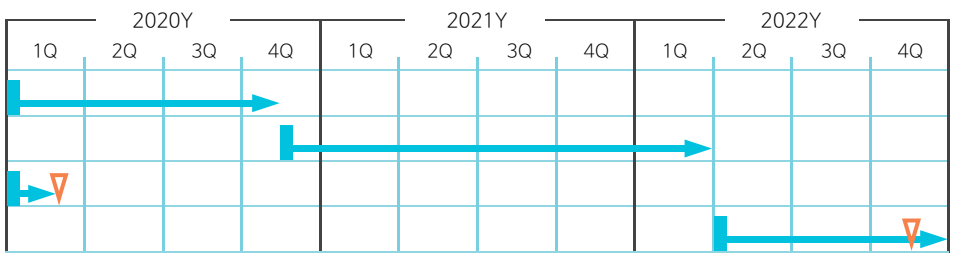
Safety Pharmacology				
Study Type	**Test System**	**Route**	**Doses**	
Cardiovascular System	CHO hERG cells	in vitro	0, 0.125, 0.25, 0.5, 1	U/mL
Respiratory System	Rat	IM	0, 1.5, 3, 6	U/kg
Central Nervous System	Mouse	IM	0, 4.5, 3, 6	U/kg

Efficacy Comparison – Company A's product				
Study Type	**Test System**	**Route**	**Doses**	
Efficacy test	Mouse	IM	4, 12, 40	U/kg

Clinical Trial Timeline

TOXPIA is licensed for export and is completed the third phase of its clinical trial.

CLINICAL TRIAL PHASE Ⅰ/Ⅱ
CLINICAL TRIAL PHASE Ⅲ
EXPORT LICENSE ACQUIRED
MFDS APPROVAL



Clostridium botulinum toxin Type A complex

TOXPIA

toxpia.com

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