BIOTON

SOP/O/71/E

CERTYFIKAT SERII KOŃCOWEGO PRODUKTU LECZNICZEGO

BATCH RELEASE CERTIFICATE / РАЗРЕШЕНИЕ НА ОТПУСК ЛЕКАРСТВЕННОГО ПРОДУКТА

Numer Certyfikatu: *Certificate No:* *Номер сертификата*	211/2024	**Data certyfikacji:** *Certification date* *Дата сертификации*	2024-10-25

Produkt: *Product* *Продукт*	Генсулин Р 100 ед./мл 3 мл	**Data ważności:** *Expiration date* *Срок годности*	09.2027
Numer serii: *Batch number* *№ серии*	57I2401E		
Kraj przeznaczenia: *Destination country* *Страна назначени:*	Украина		

Ilość certyfikowana *Certified Quantity of packs* *Количество для сертификации*	**2032 sztuk** *pieces* *штук*	**Próby archiwalne** *Archived samples* *Образцы в архив*	**12 sztuk** *pieces* *штук*
Ilość zwolniona do obrotu *Quantity of packs released for distribution* *Количество отпущенное в оборот*	**2020 sztuk** *pieces* *штук*		

Niniejszym certyfikuję, że wszystkie etapy wytwarzania produktu końcowego produktu leczniczego zostały przeprowadzone w pełnej zgodności z wymaganiami Dobrej Praktyki Wytwarzania oraz wymaganiami pozwolenia (pozwoleń) i dokumentacji dotyczącej wprowadzania do obrotu produktu leczniczego docelowego kraju przeznaczenia.

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country.

Настоящим подтверждаю, что все этапы производства этой партии готового продукта были выполнены в полном соответствии с требованиями GMP и требованиями разрешения на продажу в стране назначения..

UWAGI: *05-GW-10-R-UKR*
Comments
Комментарии

QUALIFIED PERSON
2024-10-25
Beata Cieślik

Osoba Wykwalifikowana: ______________________
Qualified Person

podpis pieczątka i data (signature, stamp and date; подпись, печать и дата)

Firma spółki
BIOTON Spółka Akcyjna
Kapitał zakładowy
1.717.284.000,00 PLN
(kapitał wpłacony 1.717.284.000,00 PLN)

Siedziba i adres spółki
ul. Starościńska 5
02-516 Warszawa
NIP 521-008-25-73
REGON 001384592

Adres do korespondencji
Macierzysz, ul. Poznańska 12
05-850 Ożarów Mazowiecki
Tel. +48 22 721 40 00
www.bioton.pl

Sąd Rejestrowy
Wpis do Rejestru Przedsiębiorców prowadzonego przez Sąd Rejonowy
dla m.st. Warszawy w Warszawie,
XIII Wydział Gospodarczy Krajowego Rejestru Sądowego, KRS 0000214072

Вх. ан № 2507 від 11.11.2024

BIOTON

QUALITY CERTIFICATE.

Certificate No:	**2052/2024/C**	Date of analysis:.	**2024-10-23**
Product:	**Gensulin R 100 IU/ml, solution for injections Recombinant Human Insulin 100 IU/ml cartridge of 3 ml №5 in blister and carton**	Date of manufacture:	**09.2024**
Batch No:	**57I2401E**	Expiration date:	**09.2027**
Size of series:	**43 400 pcs**		
Producer:	BIOTON S.A.		
	Number of Registration certificate: **UA/1613/01/01**		

Name, address and authorisation number manufacturing and quality control site	BIOTON S.A Poland ul. Starościńska 5, 02-516 Warszawa 104/0026/15 Macierzysz , ul. Poznańska 12, 05-850 Ożarów Mazowiecki
Product line number:	M4
Temperature requirements:	from 2°C to 8°C

TEST		REQUIREMENTS	RESULTS
Appearance		A colourless, transparent liquid	A colourless, transparent liquid
Visible particles		Free from particulate contamination	Free from particulate contamination
Extractable volume		Not less than 100% of the declared volume	103%
pH		7.0 – 7,6	7.2
Identification	Human insulin	The position of the peak in the chromatogram corresponds to that of the principal peak in the chromatogram of the standards	The position of the peak in the chromatogram corresponds to that of the principal peak in the chromatogram of the standards
	m-cresol	The position of the peak in the chromatogram corresponds to that of the principal peak in the chromatogram of the standards	The position of the peak in the chromatogram corresponds to that of the principal peak in the chromatogram of the standards
Impurities with molecular masses greater than that of insulin		Not more than 1.0%	0.1%
Related proteins	21A desaminoinsulin	Not more than 1.0%	0.3%
	Total (without desaminoinsulin)	Not more than 2.0%	0.9%
Assay	Total zinc	Not more than 40.0 µg/100 IU of insulin	11.4 µg/100 IU of insulin
	Human insulin	95.0 - 105.0 IU/ml (95.0 -105.0% of the declared amount of insulin)	101.9 IU/ml (101.9 %)
	m-cresol	2.5 – 3.5 mg/ml	3.1 mg/ml
Sterility		Sterile	Sterile
Bacterial endotoxins		Less than 80 IU per 100 IU of insulin	Less than 80 IU per 100 IU of insulin
Particulate contamination	Sub-visible particles	Particles ≥ 10 µm not more than 6000 per container	Particles ≥ 10 µm: 22 per container
		Particles ≥ 25 µm not more than 600 per container	Particles ≥ 25 µm: 0 per container

We hereby confirm that all stages of production of this batch of finished product have been manufactured (including packaging / labeling), and its quality control has been carried out in full compliance with GMP and marketing authorization requirements in the country of destination. It meets requirements of Ph. Eur

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QUALIFIED PERSON
2024-10-24
Beata Cieślik
date and signature

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Size of series:	**43 400 pcs**		
Producer:	BIOTON S.A.		
	Number of Registration certificate: **UA/1613/01/01**		

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2024-10-24
Beata Cieślik

QUALIFIED PERSON _____
date and signature