02739

T.R. MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
MARKETING AUTHORIZATION CERTIFICATE

04.09.2006 dated and 208/78 numbered marketing authorization certificate for human medicinal product named **POLİFLEKS 20% MANNİTOL SOLUTION IN WATER FOR IV INFUSION,** has been granted to **POLİFARMA İLAÇ SAN. VE TİC. A.Ş.** company.

Attachment: Certificate
License ID: 14096
This license is valid in the presence of the attached certificate.

//seal and signature//
Assoc. Prof. Dr.Tolga KARAKAN
Head of the Agency

This isto certify that the above translation from Turkish to English is true and accurate.
Atilla ÖZYILMAZ
İşbu Tercüme aslına uygun olarak tarafımdan yapılmıştır.
Yeminli Mütercim

01 Şubat 2024

T.R.
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

License ID: 14096

This certificate has been issued as the annex of the license issued on **04.09.2006** and with the number of **208/78** for the human medicinal product named **POLİFLEKS 20% MANNİTOL SOLUTION IN WATER FOR IV INFUSION.**

PRESCRIPTION/NONPRESCRIPTION:	PRESCRIPTION
TYPE OF PRESCRIPTION:	WHITE PRESCRIPTION
MARKETING AUTHORIZATION HOLDER:	POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
NAME OF DRUG SUBSTANCE:	MANNITOL
MANUFACTURING SITE FOR SOLVENT:	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. ERGENE/TEKİRDAĞ
MANUFACTURING SITE:	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. ERGENE/TEKİRDAĞ
PRIMARY PACKAGING PLACE:	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. ERGENE/TEKİRDAĞ
SECONDARY PACKAGING PLACE:	POLİFARMA İLAÇ SAN. VE TİC. ERGENE/TEKİRDAĞ
BATCH RELEASE SITE: INCLUDING BATCH CONTROL ANALYSIS SITE	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. ERGENE/TEKİRDAĞ
SHELF LIFE (MONTHS):	24 MONTHS
STORAGE TEMPERATURE (°C):	AT ROOM TEMPERATURE BELOW 25°C
PACKAGE DESCRIPTION:	PVC WITH TWO OUTLETS AND PORT SYSTEM MODIFIED POLYPROPYLENE (PP) SOLUTION IN A HEAT-CLOSED PLASTIC BAG (WITH/WITHOUT SET)
PACKAGE SIZE:	100 ML, 150 ML, 250 ML 500 ML AND 1000 ML
LICENSE FEE:	16.05.2002/30020000119 10.06.2022/03DMY0000022
ANALYSIS FEE:	16.04.2004/ 253450 27.01.2004/898457 26.01.2004/446924

The results of the scientific examination were found to be appropriate and the licence remains valid.

//signature //
Dr. Asim HOCAOĞLU
Vice President of the Agency

02739

01 Şubat 2024

02739

T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

RUHSATNAME

04.09.2006 tarih ve 208/78 sayılı bu Ruhsatname **POLİFLEKS % 20 MANNİTOL SUDAKİ IV İNFÜZYON İÇİN ÇÖZELTİ** isimli beşeri tıbbi ürün için **POLİFARMA İLAÇ SAN. VE TİC. A.Ş.** firması adına tahsis edilmiştir.

Eki : Sertifika
Ruhsatname ID : 14096
İş bu Ruhsatname eki sertifika ile geçerlidir.

Doç. Dr. Tolga KARAKAN
Kurum Başkanı

İşbu Tercüme aslına uygun olarak tarafımdan yapılmış Yeminli Mütercim

BAKIRKÖY 55. NOTERLİĞİ
İmza Yetkili
01 Şubat 2024

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

02739

Ruhsatname ID : 14096

Bu sertifika **04.09.2006** tarih ve **208/78** sayılı Ruhsatname eki olarak **POLİFLEKS % 20 MANNİTOL SUDAKİ IV İNFÜZYON İÇİN ÇÖZELTİ** isimli ilaç için ruhsatname aslı zayii olduğundan 28.07.2022 tarihinde yeniden düzenlenmiştir.

REÇETELİ / REÇETESİZ	:	REÇETELİ
REÇETE TÜRÜ	:	BEYAZ REÇETE
RUHSAT SAHİBİ	:	POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
ETKİN MADDE ADI	:	MANNİTOL
ÜRETİM YERİ	:	POLİFARMA İLAÇ SANAYİ VE TİCARET A.Ş. ERGENE/TEKİRDAĞ
PRİMER AMBALAJLAMA YERİ	:	POLİFARMA İLAÇ SANAYİ VE TİCARET A.Ş. ERGENE/TEKİRDAĞ
SEKONDER AMBALAJLAMA YERİ	:	POLİFARMA İLAÇ SANAYİ VE TİCARET A.Ş. ERGENE/TEKİRDAĞ
SERİ KONTROL ANALİZ YERİ İÇEREN SERİ SERBEST BIRAKMA YERİ	:	POLİFARMA İLAÇ SANAYİ VE TİCARET A.Ş. ERGENE/TEKİRDAĞ
RAF ÖMRÜ(AY)	:	24 AY
SAKLAMA SICAKLIĞI (^{0}C)	:	25 °C'NİN ALTINDAKİ ODA SICAKLIĞINDA
AMBALAJ TANIMI	:	AĞZI ISI İLE KAPATILMIŞ PLASTİK TORBA İÇERİSİNDE İKİ ÇIKIŞI BULUNAN PVC VE PORT SİSTEMİ DEĞİŞTİRİLMİŞ POLİPROPİLEN (PP) TORBADA ÇÖZELTİ (SETLİ/SETSİZ)
AMBALAJ BOYUTU	:	100 ML, 150 ML, 250 ML, 500 ML VE 1000 ML
RUHSAT HARCI	:	16.05.2002/30020000119 10.06.2022/03DMY0000022
ANALİZ HARCI	:	16.04.2004/253450 27.01.2004/898457 26.01.2004/446924

Bilimsel inceleme sonuçları uygun bulunmuş olup ruhsatname geçerliliğini korumaktadır.

Dr. Asım HOCAOĞLU
Kurum Başkan Yardımcısı

İşbu Tercüme aslına uygun olarak tarafımdan yapılmış Yeminli Mütercim

BAKIRKÖY 55. NOTERLİĞİ İmza Yetkili

01 Şubat 2024

REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL
DEVICES AGENCY OF TÜRKİYE

Certificate No: TR/GMP/2024/151

CERTIFICATE OF GMP COMPLIANCE OF MANUFACTURER

Part 1

Issued following an inspection in accordance with current Good Manufacturing Practice Guidelines, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use* and the Law No 1262 on Pharmaceutical and Medicinal Preparations. These regulations are in line with the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/s) and the Directives of the European Commission.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer's Name	: POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Head Office / Correspondence Address	: Vakıflar OSB Mah. Sanayi Cad. No:22/1 Ergene/TEKİRDAĞ
Site Address	: Vakıflar OSB Mahallesi Sanayi Caddesi No:22/1 Ergene/TEKİRDAĞ
Manufacturing Authorization Date	: TR/ÜY/2019/11-10
Manufacturing Authorization Number	: 01.11.2024

Has been inspected in accordance with current Good Manufacturing Practice Guidelines, the Regulation on Manufacturing Plants of Medicinal Products for Human Use, the Law No 1262 on Pharmaceutical and Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 19-23.02.2024, it is considered that it complies with the requirements of Good Manufacturing Practice (GMP).

This certificate reflects the status of the manufacturing site at the time of the inspection, and Turkish Medicines and Medical Devices Agency should be consulted to verify compliance of the manufacturing site with GMP requirements if more than 3 years have elapsed since the date of inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified by Turkish Medicines and Medical Devices Agency upon request.

**This regulation is aligned with European Union Directive Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, and Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

Eray KAPLAN
Vice President of the Agency

■ Human Medicinal Products

1 - MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS	
If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.	
1.1	**Sterile Products**
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for cardioplegia - Bladder irrigation - Solution for infusion - Solution for peritoneal dialysis - Irrigation solution - Emulsion for infusion 1.1.2.3 Small volume liquids - Emulsion for injection/infusion - Eye drops, emulsion
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use - Inhalation solution
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.2 Cell therapy products 1.3.2.6 Human or animal extract derived products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological (sterility)
	1.6.2 Microbiological (non-sterility)
	1.6.3 Chemical/Physical
	1.6.4 Biological testing

Any restrictions or clarifying remarks related to the scope of this certificate:

1.1.2.1 Applicable to PVC bag, polypropylene bag, glass bottle and polypropylene bottle.

1.1.3 It has been found appropriate to allow parametric release activity for products named "Polifleks %0,9 İzotonik Sodyum Klorür I.V. İnfüzyon için Çözelti", "Polifleks %5 Dekstroz Sudaki I.V. İnfüzyon İçin Çözelti", "Polifleks Laktatlı Ringer I.V. İnfüzyon İçin Çözelti" (PP Torba) and "Polifleks İzolen Dengeli Elektrolit İ.V. İnfüzyon İçin Çözelti" (PP Torba).

1.3.2.2 Valid for batch release activities including batch control analyses for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.

1.5.1.5: The inhalation solution is in an aluminum bottle primary packaging.

1.6.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.

Eray KAPLAN
Vice President of the Agency

2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products

Any restrictions or clarifying remarks related to the scope of this certificate:
2.1.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.
2.2.3.2 It is valid for batch release activities that include batch control analyzes for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml iM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.

■ Human Investigational Medicinal Products (for Phase I, II, III Clinical trials)

1 - MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS	
If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.	
1.1	**Sterile Products**
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids - Solution for cardioplegia - Bladder irrigation - Solution for infusion - Solution for peritoneal dialysis - Irrigation solution - Emulsion for infusion 1.1.2.3 Small volume liquids - Emulsion for injection/infusion
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use - Inhalation solution
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.2 Cell therapy products 1.3.2.6 Human or animal extract derived products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological (sterility)
	1.6.2 Microbiological (non-sterility)
	1.6.3 Chemical/Physical
	1.6.4 Biological testing

Eray KAPLAN
Vice President of the Agency

Any restrictions or clarifying remarks related to the scope of this certificate:
1.1.2.1 Applicable to PVC bag, polypropylene bag, glass bottle and polypropylene bottle.
1.1.3 It has been found appropriate to allow parametric release activity for products named "Polifleks %0,9 İzotonik Sodyum Klorür I.V. İnfüzyon için Çözelti", "Polifleks %5 Dekstroz Sudaki I.V. İnfüzyon İçin Çözelti", "Polifleks Laktatlı Ringer I.V. İnfüzyon İçin Çözelti" (PP Torba) and "Polifleks İzolen Dengeli Elektrolit İ.V. İnfüzyon İçin Çözelti" (PP Torba).
1.3.2.2 Valid for batch release activities including batch control analyses for "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products.
1.5.1.5: The inhalation solution is in an aluminum bottle primary packaging.
1.6.4 "CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Flakon ve CoronaVac 600SU/0,5ml IM Enjeksiyonluk Süspansiyon içeren Kullanıma Hazır Enjektör" products are valid for serial control analysis.

11.11.2024 TR/GMP/2024/151

Eray KAPLAN
Vice President of the Agency