

Spanish Agency of Medicines and Medical Devices

CERTIFICATE NUMBER : *ES/002HV/20*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Spain confirms the following:

The manufacturer : ***Gensenta Ilaç Sanayi ve Ticaret A.S.***

Site address : ***Diger Ilaçar Ünitesi, Sanayi Caddesi No. 13, Bahçelievler-Yenibosna, Istanbul, 34196, Turkey***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-07-23** , it is considered that it complies with :

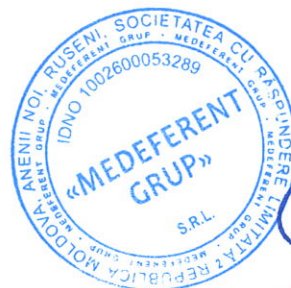
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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 more than three years have elapsed since the date of that 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 in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.



Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	1.1.1 <i>Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates
1.5	Packaging
	1.5.2 <i>Secondary packaging</i>
1.6	Quality control testing
	1.6.1 <i>Microbiological: sterility</i> 1.6.3 <i>Chemical/Physical</i>

2020-01-10

Name and signature of the authorised person of the
Competent Authority of Spain

Confidential
Spanish Agency of Medicines and Medical Devices
Tel: **Confidential**
Fax: **Confidential**



[Handwritten signature]

BARCOD	BRUN ADI	ETIKIN MAUDE	ATC KODU	RUHSAT SAHIBI	RUHSAT TARİHİ	RUHSAT NUMARASI	DEĞİŞİKLİK	Bu maddede değişiklik yapılan ürün	DEĞİŞİKLİK TARİHİ
8699540170223	ALITZEM SR 120 MG KAPSUL, 120 ADET	diyuozem bel	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	19/07/1991	153998			
8699540170216	ALITZEM SR 120 MG KAPSUL, 60 ADET	diyuozem bel	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	19/07/1991	153998			
8699540170261	ALITZEM SR 180 MG MİKROPELLET KAPSUL, 30 ADET	diyuozem bel	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	13/05/1997	182665			
8699540170230	ALITZEM SR 90 MG MİKROPELLET KAPSUL, 30 ADET	diyuozem bel	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	13/05/1997	182660			
8699540170209	ALITZEM SR 120 MG KAPSUL, 30 ADET	diyuozem	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	19/07/1991	153998			
8699540170254	ALITZEM SR 60 MG KAPSUL, 30 ADET	diyuozem bel	C09D301	NOBEL İLAÇ SAN. VE TİC. A.Ş.	10/10/1992	161995			
8699540170426	DLKOR SR 120 MG MİKROPELLET KAPSUL, 120 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172464			
8699540170419	DLKOR SR 120 MG MİKROPELLET KAPSUL, 30 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172464			
8699540170501	DLKOR SR 180 MG MİKROPELLET KAPSUL, 60 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172464			
8699540170228	DLKOR SR 60 MG MİKROPELLET KAPSUL, 120 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172464			
8699540170204	DLKOR SR 60 MG MİKROPELLET KAPSUL, 30 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172463			
8699540170211	DLKOR SR 90 MG MİKROPELLET KAPSUL, 30 ADET	diyuozem bel	C09D301	UL KAR KİMYA SAN. VE TİC.	15/08/1995	172463			
8699540170303	DLITZEM 30 MG TABLET, 48 ADET	diyuozem bel	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	28/05/1997	182558			
86995401703014	DLITZEM 30 MG TABLET, 48 ADET	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	09/04/1987	141670	ürün adı güncelleme	24/09/2021	
86995401703016	DLITZEM 120 MG UZATILMIŞ SALIMLI TABLET, 48 ADET	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	10/04/1987	141670	ürün adı güncelleme	24/09/2021	
86995401703205	DLITZEM 240 MG UZATILMIŞ SALIMLI TABLET, 16 ADET	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	13/03/1992	159298	ürün adı güncelleme	24/09/2021	
86995401703084	DLITZEM SR 90 MG UZATILMIŞ SALIMLI TABLET, 48 ADET	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	19/08/1984	188972	ürün adı güncelleme	24/09/2021	
86995401791760	DLITZEM 4,25 MG HYOFETİZE ENJEKSİYONLUK TOZ, 1 AMPUL	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	17/11/1992	169718	ürün adı güncelleme	24/09/2021	
8699540100052	KARITAZEM 60 MG TABLET, 50 TABLET	diyuozem bel	C09A03	SAVOVEL İLAÇ SAN. VE TİC.	12/10/1990	153661			
8699540039042	LOC AFEN 2 KRREM, 30 GRAM	diyuozem hidroklorür	C05A03	İLKO İLAÇ SAN. VE TİC. A.Ş.	08/08/2017	2017263			
869954008010219	PRECIAZEM 60 MG KONTROLLÜ SALIMLI MİKROPELLET KAPSUL, 50 ADET	diyuozem hidroklorür	C09D301	İE ULGA V İLAÇ SAN. TİCARETİ	02/08/1992	168054			
8699540170048	PROGOR 12MG KONTROLLÜ SALIMLI MİKROPELLET KAPSUL, 28 ADET	diyuozem bel	C09D301	GALPHEFARMA MEDİKAL	11/09/10/2000	108974			
8699540170055	PROGOR 24MG KONTROLLÜ SALIMLI MİKROPELLET KAPSUL, 28 ADET	diyuozem bel	C09D301	GALPHEFARMA MEDİKAL	11/09/10/2000	108975			
8699540170062	PROGOR 36MG KONTROLLÜ SALIMLI MİKROPELLET KAPSUL, 28 ADET	diyuozem bel	C09D301	GALPHEFARMA MEDİKAL	11/09/10/2000	108976			
8699540170079	TIACARD 25MG ENJEKSİYONLUK İZOMERİZASYONLUK COZEĞİTTİHAZIRLAMAK İÇİN 1	diyuozem hidroklorür	C09D301	VEM İLAÇ SAN. VE TİC. A.Ş.	01/08/2018	20180428			
869954017009519	PROGOR 300 MG KONTROLLÜ SALIMLI MİKROPELLET KAPSUL	diyuozem hidroklorür	C09D301	GALPHEFARMA MEDİKAL	11/09/10/2000	108664	ribelidil ürün ekleme	17/08/2018	
869954017009519	DLITZEM 240 MG UZATILMIŞ SALIMLI TABLET, 32 ADET	diyuozem hidroklorür	C09D301	GENSENTİA İLAÇ SANAYİ VE TİC.	19/08/1998	188972		24/09/2021	



[Handwritten signature]