

28.02.2017

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YERLİ TIBBİ MÜSTAHZARLAR RUHSATNAMESİ	
Ruhsat harcı makbuzunun	
Tarih	Numarası
05.2006 / 2709	07.2006 / 11481

26.07.2006 / 11481

04.09.2007 / F00866

..satılmasına müsaade edilmiştir.

Dr. Mahmud TOKAÇ

listesat ratiunm

Preparatın raf ömrü 24 aydır.
(25 °C'nin altındaki oda sıcaklığında)

11 Ekim 2007

Ambalaj: Kutuda, 5 adet herbiri 5ml solüsyon içeren renksiz
otopul cam ampulde.

11 Ekim 2007

Beş yıllık bilimsel inceleme
süresinin başlangıç tarihi.....olup
tastadik edilmiştir

11 Ekim 2007

Preparatın raf

ömrü 36 aydır.

(25 °C'nin altındaki oda sıcaklığında) 06.05.2009

Bilimsel inceleme sonuçları uygun
bulunmuş olup ruhsatname
sürekliliğini korumaktadır

03.14

RUHSATNAMEDE KAYITLI
REPARATIN RUHSAT SAHİBİ
FİRMA ÜNVANININ
VEM İLAÇ SAN VE TİC A.Ş.
YARAK DEĞİŞTİRİLMESİ UYGUN
BULUNMUŞTUR

11.01.2016

İş bu ruhsatnamede kayıtlı preparatın üretim, primer/sekonder
ambalajlama ve seri kontrol/analizini içeren seri serbest
bırakma yerine alternatif olarak "Yem İlaç San. ve Tic.A.Ş.
Kapaklı/TEKİRDAĞ" eklennmiştir. 13.06.2013

İş bu ruhsatnamede kayıtlı
müstahzarın adının bundan
böyle "Yem İlaç San. ve Tic.A.Ş." olarak değiştirilmesi
uygun bulunmuştur. 13.06.2013

13.06.2013

19 SUB 2018

NO 307



It was approved to change the primary package of this drug product as one point cut (OPC) hereby with this license.
28 February 2017

Volume number

212

Layer number

83

**T.R.
TURKISH MINISTRY OF HEALTH
DOMESTIC MEDICAL PREPARATION LICENSE**

Analysis charge receipt

Date Number

15.05.2006 / 2709

26.07.2006 / 11481

License charge receipt

Date Number

04.09.2007 / F00866

It is allowed that the product formulated by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ./ANKARA, manufactured by İDOL İLAÇ DOLUM SAN. VE TİC. A.Ş /İSTANBUL and called “EPITOIN 250 mg/5 ml I.M./I.V Solution For Injection, Ampoule” (Phenytoin sodium) can be sold as prescription drug by VEM İLAÇ SAN. VE TİC. LTD. ŞTİ / ANKARA.

Signed by Dr. Mahmut TOKAÇ
General Manager

Signed by Prof. Dr. Nihat TOSUN
Acting Deputy Undersecretary

11 October 2007

Shelf life of this drug product is 24 months. (At room temperature below 25°C). 11 October 2007

In box, in autopul colorless glass ampoule with 5 ml solution (5 units). 11 October 2007

Starting date of five-year scientific examination period is 11 October 2007 and it is confirmed.

Shelf life of this drug product is 36 months. (At room temperature below 25°C). 06 May 2009

The scientific research results has been approved and the marketing authorisation maintains its validity. 20 March 2014

It was approved to change the company title of registered product hereby with this license as “Vem İlaç San. ve Tic. A.Ş.”. 11 January 2016

It was approved to add “Vem İlaç San. ve Tic. A.Ş. KAPAKLI/TEKİRDAĞ” as alternative to the current release site including manufacture, primary/secondary packaging and batch control/analysis of the product registered hereby with this certificate. 13 June 2017

It was approved to change the name of hereby registered product as “EPITOİN 250 mg/5 ml I.M./I.V Solution For Injection, Ampoule”. 17 May 2018