lek
a Sandoz company

Lek Pharmaceuticals d.d.
Penicilin Production Plant

Perzonali 47
SI-2391 Prevalje, Slovenia
Phone +386 (0) 2 824 63 31
Fax +386 (0) 2 823 16 66

Quality Unit

Perzonali 47
SI-2391 Prevalje, Slovenia
Phone +386 (0) 2 824 63 43
Fax +386 (0) 2 823 17 75

CERTIFICATE OF ANALYSIS

Product: 6200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION

Number of MA: F-14358/09
Lot No: GE1922

Parameters	Specifications	Results
Colour of content	white to yellowish white	conforms
Appearance of content	crystalline powder	conforms
Colour and appearance of suspension	almost white to yellow, homogeneous	conforms
Water	<=8 5 %	5.3 %
pH	4 2 - 6 6	5.1
Filling	NLT 17 5 g	conforms
Identification, HPLC	amoxicillin	conforms
Identification HPLC	clavulanate potassium	conforms
Assay HPLC	360 0 - 480 0 mg/5ml amoxicillin, 400 0 mg/5ml	402 9 mg/5ml
Assay HPLC	51 30 - 71 25 mg/5ml clavulanic acid 57 00 mg/5ml (90 0 - 125 0%)	61 73 mg/5ml
Microbiological Quality- Ph Eur 5 1 4 Total aerobic microbial count (TAMC)	NMT 10exp 3/g	/*
Total yeasts and moulds count (TYMC)	NMT 10exp 2/g	/*

/* Not routinely tested Test is performed according to approved testing frequency

Electronically signed

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CERTIFICATE OF ANALYSIS

Product 5200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION

Number of MA F-14358/09
Lot No GE1922

Parameters	Specifications	Results
E Coli	absent/g	/*

Storage At a temperature below 30°C, in a dry place

Complies with specification of Marketing Authorisation

Quality Unit

Date 13 04 2016

Dunja Frece-Oderlap

/* Not routinely tested Test is performed according to approved testing frequency
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SANDOZ
a Novartis company

Issued by
Lek Pharmaceuticals d d
Verovskova 57
1526 Ljubljana
Slovenia
Tel +386 1 5802111
Fax +386 1 5683517
www lek si
Manufacturing License
800-30/2014-12

Ref 1306161048

Certificate of Conformity

Material Name	AMBILAN BID 457MG/5ML , 70ML POS-CL		
Trade Name	AMBILAN		
Strength/Potency	400 MG + 57 MG / 5 ML		
Dosage Form	POWDER FOR ORAL SUSPENSION		
Package Type	BOTTLE		
Package Size	1 PC x 70 ML		
Material No	5200112		
Sandoz Batch	GE1922		
Date of Manufacturing	APR-2016	Release date	13-JUN-2016
Expiry Date	APR-2019	Released Quantity	22224 PC
Manufacturer	Lek Pharmaceuticals d d		
Manufacturing site	Lek Pharmaceuticals d d Perzonali 47 2391 Prevalje Slovenia		

Components

Material Name	AMOKSIKLAV 2X S 457MG/5ML GR -P				
Material No	338834	Bulk Product		Batch No	GD8474
Total Bulk Quantity	402.8 KG				
Manufacturer	Lek Pharmaceuticals d d			License number	800-30/2014-12
Manufacturing Site	Lek Pharmaceuticals d d Perzonali 47 2391 Prevalje Slovenia				

Material Name	KALIJEV KLAV-D-ATB PHEUR PN100%-P				
Material No	784015	Active Pharm Ingredient		Batch No	B353065
Manufacturer	Lek d d Lendava plant API			License number	800-11/2013-6
Manufacturing Site	Lek d d Lendava plant API Tomini 2D 9220 Lendava Slovenia				

*Electronically signed according to Sandoz electronic signature standards

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Certificate of Conformity

Material name	AMBILAN BID 457MG/5ML, 70ML POS-CL		
Trade Name	AMBILAN		
Material No	5200112	Sandoz Batch	GE1922

Material Name	AMOKSICILIN TRIHIDR /PHUER USP			
Material No	315613	Active Pharm Ingredient	Batch No	B350174
Manufacturer	SANDOZ INDUSTRIAL PRODUCTS S			
Manufacturing Site	SANDOZ INDUSTRIAL PRODUCTS S A Crta Granollers Cardedeu 08520 LES FRANQUESES V Spain			
Manufacturer batch	B350174			

Certification Statement

I hereby certify that the above information is authentic and accurate This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP

Certificate comment

During the course of manufacturing and packaging there were no deviations that may influence the release of the product

Batch release authorized by* GABRIJELA OCEPEK, Head Release
Date 13-JUN-2016 08 48 28

*Electronically signed according to Sandoz electronic signature standards