

**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 0906161131

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	GG8544	
Date of Manufacturing	MAY-2016	Release date 09-JUN-2016
Expiry Date	MAY-2019	Released Quantity 22080 PC
Manufacturer	Lek Pharmaceuticals d d	
Manufacturing site	Lek Pharmaceuticals d d Perzonal 47 2391 Prevalje Slovenia	

Components

Material Name	AMOKSIKLAV 2X S 457MG/5ML GR.-P	
Material No	338834 Bulk Product	Batch No GG4349
Total Bulk Quantity	402.6 KG	
Manufacturer	Lek Pharmaceuticals d d	License number 800-30/2014-12
Manufacturing Site	Lek Pharmaceuticals d d Perzonal 47 2391 Prevalje Slovenia	

Material Name	KALIJEV KLAV-D-ATB PHEUR PN100%-P	
Material No	784015 Active Pharm. Ingredient	Batch No B358022
Manufacturer	Lek d d Lendava plant API	License number 800-11/2013-6
Manufacturing Site	Lek d d Lendava plant API Trninski 2D 9220 Lendava Slovenia	

**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 C906161131

Certificate of Conformity

Material name	AMBILAN BID 457MG/5ML, 70ML POS-CL		
Trade Name	AMBILAN		
Material No	5200112	Sandoz Batch	GG8544

Material Name	AMOKSICILIN TRIHIDR /PHUER USP		
Material No	315613	Active Pharm Ingredient	Batch No B358436
Manufacturer	SANDOZ INDUSTRIAL PRODUCTS S		
Manufacturing Site	SANDOZ INDUSTRIAL PRODUCTS S A C/ta Granollers Cardener 08520 LES FRANQUESES V Spain		
Manufacturer batch	B358436		

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 09-JUN-2016 09:30:49





a Sandoz company

Lek Pharmaceuticals d.d.
Penicilin Production Plant

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

Quality Unit

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

CERTIFICATE OF ANALYSIS

Product 5200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION

Number of MA F-14358/09
Lot No GG8544

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	$\leq 8.5\%$	5.1%
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	411.6 mg/5ml
Assay HPLC	51.30 - 71.25 mg/5ml clavulanic acid 57.00 mg/5ml (90.0 - 125.0%)	63.98 mg/5ml
Microbiological Quality Ph Eur 5.1.4 Total aerobic microbial count (TAMC)	NMT 10exp 3/g	1*
Total yeasts and moulds count (TYMC)	NMT 10exp 2/g	1*

1* Not routinely tested. Test is performed according to approved testing frequency.
Electronically signed

Page 1 of 2



a Sandoz company

Lek Pharmaceuticals d.d.
Penicilin Production Plant

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

Quality Unit

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

CERTIFICATE OF ANALYSIS

Product 5200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION

Number of MA F-14358/09
Lot No GG8544

Parameters	Specifications	Results
E Coli	absent/g	1*
Storage	At a temperature below 30°C, in a dry place	
Complies with specification of Marketing Authorisation		
Date	30.05 2016	Quality Unit Dunja Frece-Oderlap

1* Not routinely tested Test is performed according to approved testing frequency
Electronically signed

Page 2 of 2