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INSTITUT FÜR PHARMAZEUTISCHE UND ANGEWANDTE ANALYTIK
OFFICIAL MEDICINES CONTROL LABORATORY

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Ministry of Health, Labour and Social Affairs of Georgia
LEPL State Regulation Agency for Medical Activities
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Your reference	Our reference	Contact /Phone	Bremen,
Seal No. 0000945	160832	Dr. Andreas Klamka +49-4 21-43 61-120	08.12.2016

Test Report

Lab code	**160832**
Sample code	Seal No. 0000921
Date of receipt	13.10.2016
Start date of testing	24.10.2016
Product name	CAPTOPRIL
Dosage form	tablets
Active ingredient	captopril
Strength	25 mg/tablet
Package size	30 tablets/package
Number of packages	4 packages
Type of primary container	blister
Type of secondary container	card board box
Storage conditions	
Batch number	1415123
Expiry date	12/2018
Manufacturing date	
Manufacturer	GAMA LTD, Georgia

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Amtsgericht Bremen
HRB 16583

Institutsleiter und Geschäftsführer:
Dr. Konrad Horn

Aufsichtsratsvorsitzender:
Gerhard Zeitler

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Appearance			
	Method	visual	
	Specification:	no information available	
	Result:	white, round, plain tablets with one-sided imprint of the company logo	
	Conclusion:	not applicable	
Dissolution			
	Method:	USP *Captopril Tablets*	
	Specification:	≥ 80 % (Q) of the labeled amount	
	Result:	S_1 (n = 6):	tablet 1 = 123.6 % tablet 2 = 112.4 % tablet 3 = 127.2 % tablet 4 = 124.6 % tablet 5 = 125.2 % tablet 6 = 133.4 %
	Conclusion:	complies	
Uniformity of dosage units			
	Method:	USP <905>, MV	
	Specification:	AV (L1) ≤ 15	
	Result:	AV (L1) = 12.9	
	Conclusion:	complies	
Related substances			
	Method:	USP *Captopril Tablets*	
	Specification:	according BP *Captopril tablets*: limit of captopril disulfide	≤ 3 %
	Result:	captopril disulfide	≥ 3 %
	Conclusion:	does not comply	
Identification			
captopril	*Method:*	Assay according to USP *Captopril Tablets*	
	Specification:	retention time and PDA spectra conform to reference standard	
	Result:	retention time and PDA spectra conform to reference standard	
	Conclusion:	complies	

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Assay

captopril	*Method:*	USP *Captopril Tablets*
	Specification:	25 mg/tablet 90 – 110 % of the labeled amount
	Result:	23.2 mg/tablet, RSD = 0.68 % (n = 3); 92.9 % of the labeled amount
	Conclusion:	complies

Conclusion

The test for related substances (limit of captopril disulfide) does not comply. The test was performed according to the method described in the USP monograph *Captopril Tablets* by using a BP reference standard. The USP monograph provides a formula for calculating the content of captopril disulfide. Due to a missing content of the BP reference substance, we decided to use the method of comparing the peak areas of captopril disulfide (test solution vs. reference solution) as described in the BP monograph.
Regarding the results of the dissolution testing, the USP method with its very unspecific wavelength of 205 nm used for the UV-detection, might lead to unusual high results.

Explanatory Note

It has to be noted that the submitted sample is not labeled as to comply with USP. Therefore, the methods and specifications of the USP *Captopril Tablets* monograph might not be applicable for this product.

Dr. Konrad Horn
Head of Institute and
Managing Director

Dr. Andreas Klamka
Lab Manager