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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. 0000949	160830	Dr. Andreas Klamka +49-4 21-43 61-120	06.12.2016

Test Report

Lab code	**160830**
Sample code	Seal No. 0000949
Date of receipt	13.10.2016
Start date of testing	14.11.2016
Product name	WARFARIN-HUMANITY
Dosage form	film-coated tablets
Active ingredient	warfarin sodium
Strength	2.5 mg/tablet
Package size	10 tablets/package
Number of packages	10 packages
Type of primary container	blister
Type of secondary container	card board box
Storage conditions	room temperature, protected from light
Batch number	160052
Expiry date	01/2019
Manufacturing date	
Manufacturer	Celogen Generics Private Limited, India

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Aufsichtsratsvorsitzender:
Gerhard Zeitler

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Appearance			
	Method	visual	
	Specification:	white coloured, round shaped tablets, cross break line on one side and plain on other side	
	Result:	white coloured, round shaped, plain tablet	
	Conclusion:	does not comply	
Dissolution			
	Method:	STP No. FSTP/04/WAA of the manufacturer, effective date: 07.01.2015	
	Specification:	≥ 75 % (Q) of the labeled amount	
	Result:	S_1 (n = 6):	tablet 1 = 84.0 % tablet 2 = 90.7 % tablet 3 = 78.8 % tablet 4 = 49.4 % tablet 5 = 57.0 % tablet 6 = 83.8 %
	Conclusion:	does not comply	
Uniformity of dosage units			
	Method:	USP <905>, CU	
	Specification:	AV (L1) ≤ 15	
	Result:	AV (L1) = 15.7	
	Conclusion:	does not comply on L1	
Related substances			
	Method:	USP *Warfarin Sodium Tablets*	
	Specification:	warfarin related compound A	≤ 0.5 %
	Result:	warfarin related compound A	0.07 %
	Conclusion:	complies	
Identification			
warfarin sodium	*Method:*	USP *Warfarin Sodium Tablets*	
	Specification:	retention time conforms to reference standard	
	Result:	retention time and PDA spectra conform to reference standard	
	Conclusion:	complies	

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Assay

warfarin sodium	*Method:*	USP *Warfarin Sodium Tablets*
	Specification:	2.5 mg/tablet 95 – 105 % of the labeled amount
	Result:	2.20 mg/tablet, RSD = 0.23 % (n = 3); 88.0 % of the labeled amount
	Conclusion:	does not comply

Conclusion

Only the tests for identity and related substances comply with the specification of USP monograph *Warfarin Sodium Tablets*.

The manufacturer describes the product as a tablet with a one-sided cross break line. The tested product is a plain tablet without any break line.

The dissolution test does not comply on stage 1. Three out of six tablets showed dissolution rates below 80 % (Q + 5 %). Due to the fact that one tablet shows a result below 50 %, the product would not even pass stage 3.

The test for uniformity of dosage units (CU) does not comply on L1 with the specification of USP monograph *Warfarin Sodium Tablets*: AV = 15.7 instead ≤ 15.

The assay test shows a content of 88.0 % of the labeled amount. 95 - 105 % is specified in the USP monograph *Warfarin Sodium Tablets*.

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 *Warfarin Sodium Tablets* monograph might not be applicable for this product.

Dr. Konrad Horn
Head of Institute and
Managing Director

Dr. Andreas Klamka
Lab Manager