

InphA GmbH · Emil-Sommer-Str. 7 · 28329 Bremen · Germany

**Ministry of Health, Labour and Social Affairs
of Georgia
LEPL State Regulation Agency for Medical
Activities
Attn: Gia Tvalavadze
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Tbilisi 0119
Georgia**

Your reference
Seal No. 0000945

Our reference
160825

Contact /Phone
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Bremen,
07.12.2016

Test Report

Lab code	160825
Sample code	Seal No. 0000945
Date of receipt	13.10.2016
Start date of testing	11.11.2016
Product name	SALUFON-HUMANITY
Dosage form	film-coated tablets
Active ingredient	cetirizine hydrochloride
Strength	10 mg/tablet
Package size	20 tablets/package
Number of packages	5 packages
Type of primary container	blister
Type of secondary container	card board box
Storage conditions	room temperature
Batch number	6625
Expiry date	10/2018
Manufacturing date	
Manufacturer	Unimax Laboratories, India

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Amtsgericht Bremen
HRB 16583

Institutsleiter und Geschäftsführer:
Dr. Konrad Horn

Aufsichtsratsvorsitzender:
Gerhard Zeitler

Appearance

<i>Method</i>	visual
<i>Specification:</i>	white to off white, round, biconvex, film coated tablets
<i>Result:</i>	white to off white, round, biconvex, film coated tablets
<i>Conclusion:</i>	complies

Dissolution

<i>Method:</i>	USP <i>Cetirizine Hydrochloride Tablets</i>		
<i>Specification:</i>	$\geq 80 \%$ (Q) of the labeled amount		
<i>Result:</i>	S_1 (n = 6):	tablet 1 = 67.2 %	
		tablet 2 = 71.5 %	
		tablet 3 = 75.0 %	
		tablet 4 = 76.2 %	
		tablet 5 = 68.6 %	
		tablet 6 = 64.8 %	
<i>Conclusion:</i>	does not comply on stage S_1		

Uniformity of dosage units

<i>Method:</i>	USP <905>, CU
<i>Specification:</i>	AV (L1) ≤ 15
<i>Result:</i>	AV (L1) = 4.2
<i>Conclusion:</i>	complies

Related substances

<i>Method:</i>	USP <i>Cetirizine Hydrochloride Tablets</i>	
<i>Specification:</i>	cetirizine lactose	≤ 0.5 %
	cetirizine ethanol	≤ 0.4 %
	any unspecified degradation product	≤ 0.2 %
	total impurities	≤ 1 %
<i>Result:</i>	cetirizine lactose	n.d.
	cetirizine ethanol	n.d.
	unspecified impurity 1	0.08 %
	unspecified impurity 2	0.61 %
	unspecified impurity 3	1.24 %
	unspecified impurity 4	0.15 %
	unspecified impurity 5	0.14 %
	unspecified impurity 6	0.26 %
	unspecified impurity 7	0.05 %
	unspecified impurity 8	0.04 %
	unspecified impurity 9	0.07 %
	unspecified impurity 10	0.06 %
	unspecified impurity 11	0.21 %
	total impurities	2.91 %
<i>Conclusion:</i>	does not comply	

Identification

cetirizine hydrochloride	<i>Method:</i>	USP <i>Cetirizine Hydrochloride Tablets</i>
	<i>Specification:</i>	retention time conforms to reference standard
	<i>Result:</i>	retention time and PDA spectra conform to reference standard
	<i>Conclusion:</i>	complies

Assay

cetirizine hydrochloride	<i>Method:</i>	USP <i>Cetirizine Hydrochloride Tablets</i>
	<i>Specification:</i>	10 mg/tablet 90 – 110 % of the labeled amount
	<i>Result:</i>	9.86 mg/tablet, RSD = 0.44 % (n = 3); 98.6 % of the labeled amount
	<i>Conclusion:</i>	complies

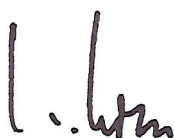
Conclusion

The dissolution test does not comply on stage 1. All six tablets showed dissolution rates below 85 % (Q + 5 %).

The test for related substances does not comply. The result for total degradation products (2.91 %) exceeds the specified limit of ≤ 1 % and four unspecified impurities (unspecified impurity 2, 3, 6 and 11) exceed the specified limit of ≤ 0.2 %.

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 *Cetirizine Tablets* monograph might not be applicable for this product.



Dr. Konrad Horn
Head of Institute and
Managing Director



Dr. Andreas Klamka
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