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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	160825	Dr. Andreas Klamka +49-4 21-43 61-120	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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Appearance		
	Method	visual
	Specification:	white to off white, round, biconvex, film coated tablets
	Result:	white to off white, round, biconvex, film coated tablets
	Conclusion:	complies
Dissolution		
	Method:	USP *Cetirizine Hydrochoride Tablets*
	Specification:	≥ 80 % (Q) of the labeled amount
	Result:	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 %
	Conclusion:	does not comply on stage S_1
Uniformity of dosage units		
	Method:	USP <905>, CU
	Specification:	AV (L1) ≤ 15
	Result:	AV (L1) = 4.2
	Conclusion:	complies

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Related substances

	Method:	USP *Cetirizine Hydrochoride Tablets*	
	Specification:	cetirizine lactose	≤ 0.5 %
		cetirizine ethanol	≤ 0.4 %
		any unspecified degradation product	≤ 0.2 %
		total impurities	≤ 1 %
	Result:	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 %
	Conclusion:	does not comply	

Identification

cetirizine hydrochloride	*Method:*	USP *Cetirizine Hydrochoride Tablets*
	Specification:	retention time conforms to reference standard
	Result:	retention time and PDA spectra conform to reference standard
	Conclusion:	complies

Assay

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

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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
Lab Manager