InphA
INSTITUT FÜR PHARMAZEUTISCHE UND ANGEWANDTE ANALYTIK
OFFICIAL MEDICINES CONTROL LABORATORY

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
144, Ak. Tsereteli Ave.
Tbilisi 0119
Georgia

Your reference	Our reference	Contact /Phone	Bremen,
Seal No. 0000934	160834	Dr. Jasna Seelbach +49-4 21-43 61-155	21.11.2016

Test Report

Lab code	**160834**
Sample code	Seal No. 0000934
Date of receipt	13.10.2016
Start date of testing	24.10.2016
Product name	Siltegra 100
Dosage form	Coated tablets
Active ingredient	Sildenafil
Strength	100 mg/tablet
Package size	4 tablets/package
Number of packages	25 packages
Type of primary container	blister
Type of secondary container	card board box
Storage conditions	Room temperature
Batch number	SM 511
Expiry date	04/2018
Manufacturing date	05/2015
Manufacturer	SR Medicare Pvt. Ltd., Maharashtra, India

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

Tel. +49 421 43 61 0
Fax +49 421 43 61 189

www.inpha.de
mail@inpha.de

Deutsche Bank AG
IBAN DE37 2907 0024 0355 6677 01
BIC DEUTDEDBBRE

USt-IdNr.: DE177639100

Amtsgericht Bremen
HRB 16583

Institutsleiter und Geschäftsführer:
Dr. Konrad Horn

Aufsichtsratsvorsitzender:
Gerhard Zeitler

DAkkS
Deutsche Akkreditierungsstelle
D-PL-13451-01-00

InphA
INSTITUT FÜR PHARMAZEUTISCHE UND ANGEWANDTE ANALYTIK
OFFICIAL MEDICINES CONTROL LABORATORY

Appearance			
	Method	visual	
	Specification:	no information available	
	Result:	Blue, rhombic, biconvex film coated tablet; no embossing	
	Conclusion:	not applicable	
Dissolution			
	Method:	USP *Sildenafil Tablets*	
	Specification:	≥ 80 % (Q) of the labeled amount	
	Result:	S_1 (n = 6):	tablet 1 = 88.4 % tablet 2 = 93.2 % tablet 3 = 84.9 % tablet 4 = 92.4 % tablet 5 = 81.7 % tablet 6 = 83.6 %
	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	
Related substances			
	Method:	USP *Sildenafil Tablets*	
	Specification:		
		Sildenafil N-oxide	≤ 0.20 %
		Any individual degradation product	≤ 0.20 %
		Total degradation products	≤ 0.50 %
	Result:		
		Sildenafil N-oxide	0.18 %
		Unknown degradation product 1	0.19 %
		Unknown degradation product 2	0.11 %
		Unknown degradation product 3	0.08 %
		Total degradation products	0.55 %
	Conclusion:	does not comply regarding the amount of total degradation products	

InphA
INSTITUT FÜR PHARMAZEUTISCHE UND ANGEWANDTE ANALYTIK
OFFICIAL MEDICINES CONTROL LABORATORY

Identification		
Sildenafil	*Method:*	USP *Sildenafil Tablets*
	Specification:	IR spectra conforms to reference standard
	Result:	IR spectra conforms to reference standard
	Conclusion:	complies
Sildenafil	*Method:*	USP *Sildenafil Tablets*
	Specification:	Retention time conforms to reference standard
	Result:	Retention time and PDA spectra conform to reference standard
	Conclusion:	complies
Assay		
Sildenafil	*Method:*	USP *Sildenafil Tablets*
	Specification:	100 mg/tablet 90 – 110 % of the labeled amount
	Result:	96,1 mg/tablet, RSD = 0.59 % (n = 3); 96 % of the labeled amount
	Conclusion:	complies

Conclusion

The tests performed comply with the specifications of USP monograph *Sildenafil Tablets* except the tests for *dissolution* (on stage S_1) and *related substances*.

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

The test for related substances does not comply. The result for total degradation products (0.55 %) exceeds the specified limit of ≤ 0.50 %.

InphA
INSTITUT FÜR PHARMAZEUTISCHE UND ANGEWANDTE ANALYTIK
OFFICIAL MEDICINES CONTROL LABORATORY

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

Dr. Konrad Horn
Head of Institute and
Managing Director

Dr. Jasna Seelbach
Lab Manager