

Analysis Certificate

Material: 95452 CILOSVITAE 100MGx28C CL	OT/OF: 281119	Batch: P005	Number Cert.: 2019/10733
Dosage Form: Tablets	Analyst: CPE		
Package Size: 28 Tablets (1 Blister)	Manufacture date: 11/11/19	Expiration Date: 11/2022	
Description: White, round tablet scored in one side. Approx.diameter 8 mm.			
	Method: 95452	rev.: 3	
Test	Specifications	Result	Units C. -

Description	Complies	Complies	Y /
Mass uniformity	(1)	Complies	Y /
Subdivision of tablets	(2)	Complies	Y /
Water	Not more than 5.0 %	2.2 %	Y /
Dissolution rate	Not less than 85.0% (Q=80), 60min		Y /
average		98.4 %	
values out of specifications	None	0	
Identification of Cilostazol			Y /
HPLC	t retention same as standard	Positive	
IR	Same as standard	Positive	
CILOSTAZOL	Between 95.0 and 105.0 %	99.7 %	Y /
Related substances			Y /
Impurity B	Not more than 0.2 %	0.026 %	
no. related substances >0.2 %	None	None	
Total related substances	Not more than 0.5 %	0.026 %	
Uniformity of dosage units (mass variation)			Y /
Result	(3)	Complies	
Acceptance value	AV<=15	1.25	
average content		99.70 %	
Blister Sealing	Complies	Complies	Y /
Packaging	Complies	Complies	Y /

CILOSTAZOL: 99.6 99.9 99.7
Dissolution rate: 98.1 98.8 97.9 100.4 98.2 97.1
Water: 2.2 2.2

Observaciones:

- (1) Not more than 2 of the individual masses of 20 deviates more than ± 7.5 % from the average mass and none deviates more than ± 15 %
 - (2) Not more than 1 of the individual masses of 30 deviates more than ± 15 % from the average mass and none deviates more than ± 25 %
 - (3) 1st level (n=10), AV<=15.0; 2nd level (n=30), AV<=15.0 and no individual content of the dosage unit deviates more than ± 25 % of the reference value (M).
- Cilostazol API Batch N.C Uriach 0000046730, Urquima F240-19006

Conform

Certificate aproved by a electronic signature:

Assumpció Vallmajor

Quality Control Manager
03/12/19 12:59:46