Valisure, LLC
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TEST REPORT

SAMPLE INFORMATION

Standard: ISO/IEC 17025:2005	**Report ID:** 191217319401	**Client ID**: 3194
Drug ID: Sirolimus	**Drug API (Label Claim):** 1 mg	**Release Claim**: Standard
Manufacturer: Zydus Cadilla 	**Drug Expiration:** 02/01/2021	**Order Date:** 12/17/2019
NDC: not known	**Lot:** M901984	**Receipt Date:** 12/26/2019

Standard: ISO/IEC 17025:2005	**Report ID:** 191217319402	**Client ID**: 3194
Drug ID: Sirolimus	**Drug API (Label Claim):** 1 mg	**Release Claim**: Standard
Manufacturer: BioCon/Swill Garnier Pvt 	**Drug Expiration:** 05/01/2021	**Order Date:** 12/17/2019
NDC: not known	**Lot:** BPSB19056	**Receipt Date:** 12/26/2019

Standard: ISO/IEC 17025:2005	**Report ID:** 191217319403	**Client ID**: 3194
Drug ID: Sirolimus	**Drug API (Label Claim):** 1 mg	**Release Claim**: Standard
Manufacturer: BioCon/Swill Garnier Pvt	**Drug Expiration:** 03/01/2021	**Order Date:** 12/17/2019
NDC: not known	**Lot:** BPSB19030	**Receipt Date:** 12/26/2019

DOSAGE ANALYSIS

DOSAGE ANALYSIS SUMMARY

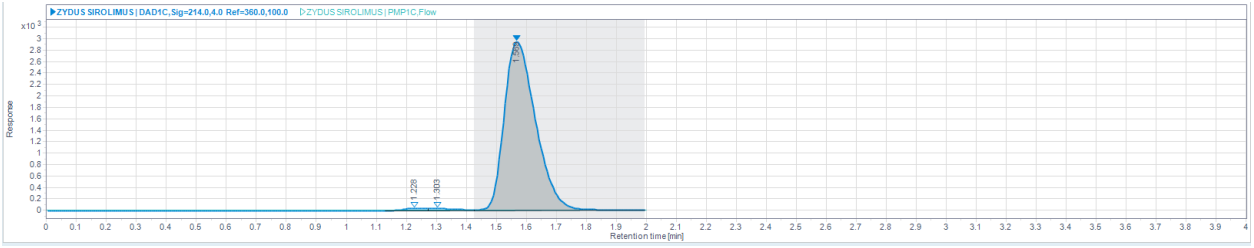
Dissolution Results: Varied (see below)	**Method:** HPLC (calibration r^2 = 0.998)
Replicates: 3 tablets	**Dosage:** Varied (see below)
Test Date: Ongoing	**Operator:** Shannon Williams
Analysis Date: 05/28/2020	**Analyst:** Kaury Kucera
Operator Notes: Non-sirolimus peaks observed in Biocon samples are consistent between tablets and are not observed in samples prepared from a certified reference standard. The anomalous peak is also observed to a very low degree in the Zydus sample.	**Approval Signature:** David Light, CEO 

DOSAGE RESULTS

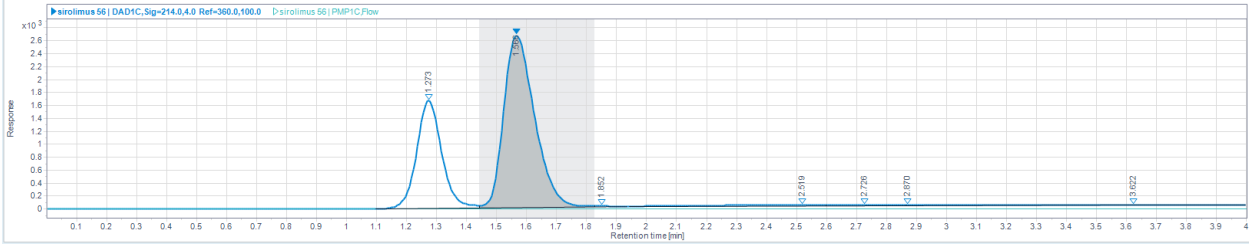
Valisure's results are for the analyzed material only and indicate that the medicinal product varies greatly in profile across labelled products. On average all have high doses of sirolimus. Biocon Lot BPSB19030 is closest to 1 mg per tablet. Of concern are anomalous peaks in Biocon samples that are not sirolimus.

Note: The United States Pharmacopeia does not specify dosage criteria for sirolimus drug products for regulatory purposes. The criteria for tacrolimus capsules is specified as 'not less than 93.0%' and 'not more than 105.0%' of the label claim of active ingredient.

Zydus Cadila Lot M901984, Sirolimus highlighted in grey
Dosage average: 117% or 1.17 mg sirolimus per tablet

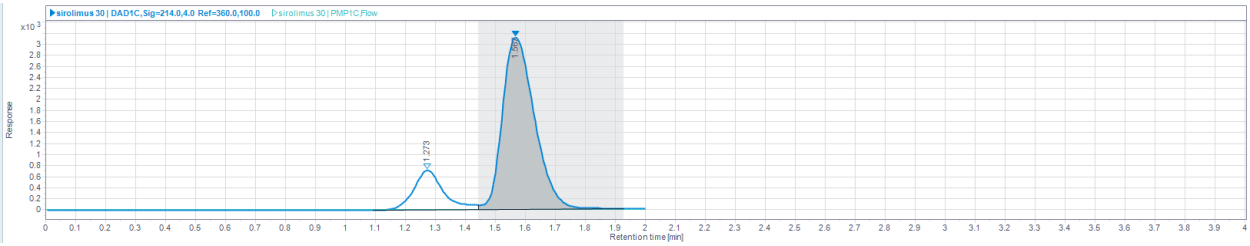


Biocon Lot BPSB19056, Sirolimus highlighted in grey
Dosage average: 110% or 1.1 mg sirolimus per tablet



Biocon Lot BPSB19030, Sirolimus highlighted in grey

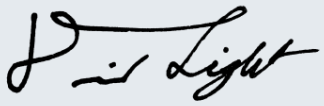
Dosage average: 105% or 1.05 mg sirolimus per tablet



Important Notice: The information in this document contains results from a chemical analysis performed on a subset of medicinal products from the same lot. The subset was designed to be representative of the entire lot. Valisure, LLC does not make, and specifically disclaims, any representations of warranties with regard to these results as they relate to other medicinal products, including, without limitation, any express or implied warranties, warranty of merchantability, warranty of performance, or warranty of fitness for a particular purpose. This information should not be reproduced without written approval from Valisure.

IMPURITY ANALYSIS

IMPURITY ANALYSIS SUMMARY

API: Sirolimus	**Method:** LC-HRMS
Nitrosamines **NDMA:** not detected **NDEA:** not detected **DMF:** not detected **NEIPA:** not detected **NDIPA:** not detected	**Replicates:** One tablets (n = 1) each sample
Test Date: 04/07/2020 - current	**Operator:** Qian Wu
Analysis Date: 05/28/2020	**Analyst:** Kaury Kucera, PhD
Operator Notes: Whole tablets were prepared in methanol.	**Approval Signature:** David Light, CEO 

IMPURITY RESULTS

To identify the anomalous peak observed in dosage analysis, Valisure did liquid chromatography-high resolution mass spectrometry analysis. This technique identifies all impurities that ionize in solution. No impurities or degradation products were observed in positive ionization mode using this technique. Impurities were observed in negative ionization mode that are unique to test samples and not observed in solvent or samples of reference standard samples. Rapamycin was identified in all samples confirming correct active ingredient.

It is reasonable that the anomalous Biocon peak is stearic acid or lactulose as these findings are unique to Biocon samples. Further research to confirm these findings is needed.

Sirolimus Biocon 56R		Sirolimus Biocon 30R		Sirolimus Zydus	
Library Hit	Library Score	Library Hit	Library Score	Library Hit	Library Score
Myristic acid	100	Myristic acid	100	Myristic acid	80.7
		Oleic acid	100	Oleic acid	100
Stearic acid	100	Stearic acid	98.8		
		Alpha-Lactose	90.7		
Lactulose	97.5	Lactulose	75.9		
				Sucrose	98.5
				Agistatin E	27.1
				Octadecanedioic acid	11.8

Note: this table shows mass-based library hits and the match score as percent probability of correct identification based on isotopic ratios and fragmentation patterns from analysis of certified reference standards for these materials.