


Certificate of Analysis

Product Name		
Psychiatry Calibrator Kit 2		
Catalog Number		Lot Number
C82911		23-031-B
Manufacture Date	Release Date	Expiration Date
2023-09-01	2023-09-01	2025-03-31

Document Reference	Version	Parameter Tested	Specification	Result	
WI070	17	Low Control Recovery	$\leq \pm 15\%$	Pass	
		Medium Control Recovery	$\leq \pm 15\%$	Pass	
		High Control Recovery	$\leq \pm 15\%$	Pass	
		Precision (%CV)	Aripiprazole	$\leq 10\%$	Pass
			Clozapine	$\leq 10\%$	Pass
			Olanzapine	$\leq 10\%$	Pass
			Quetiapine	$\leq 10\%$	Pass
	Risperidone	$\leq 5\%$	Pass		

This certifies that the Saladax Biomedical, Inc. manufactured item listed above has been produced, controlled, and has met all applicable specifications for release at the Bethlehem, PA facility in accordance with the procedures and requirements of the Saladax Quality Management System. Products are manufactured/assembled and tested in compliance to ISO 13485:2016 requirements.

Manufacturer Name and Address:	Saladax Biomedical, Inc. 116 Research Dr. Bethlehem, PA 18015 USA
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Released By (Quality Management):	Date:
	01 Sep 2023

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