

CERTIFICATE OF ANALYSIS

Product Name	Calcium (3R,5R)-7-(2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl)-3,5-dihydroxyheptanoate trihydrate (technical)	Batch NO.	RY190212
Production date	2019.02.12	Expired Date	2021.02.11
CAS NO.	344423-98-9	Standard	USP39 standard
Tests	Limits	Test results	
Appearance	A white or almost white crystalline powder	Conforms	
Identification	IR: similar to reference substance	Conforms	
Water	3.5%~5.5%	4.88%	
Related substances 1	Impurity RRT0.58≤0.15%	N.D.	
	Impurity RRT0.86≤0.30%	N.D.	
	Impurity RRT0.94≤0.30%	N.D.	
	Impurity RRT1.1≤0.30%	N.D.	
	Impurity RRT1.45≤0.10%	N.D.	
	Impurity RRT1.9≤0.15%	N.D.	
	Impurity RRT2.0≤0.15%	N.D.	
	Impurity RRT2.08≤0.15%	N.D.	
	Impurity RRT2.18≤0.15%	N.D.	
	Impurity RRT2.75≤0.15%	N.D.	
	The single impurity≤0.10%	0.09%	
	The total impurities≤1.50%	0.09%	
Related substances 2	Impurity RRT0.80≤0.30%	N.D.	
	Impurity RRT0.90≤0.30%	N.D.	
	Impurity RRT1.20≤0.30%	N.D.	
	Impurity RRT2.10≤0.20%	N.D.	
	The single impurity≤0.10%	0.08%	
	The total impurities≤1.0%	0.24%	
Enantiomers	≤0.30%	N.D.	
Assay (anhydrous)	98.0%~102.0%	100.4%	
Conclusion: This batch meets USP39 standard.			

Tested by: Esther

Checked by: Alice

Approved by: Mich

