

CERTIFICATE OF ANALYSIS

Product Name	Clopidogrel Bisulfate FORM 1	Batch NO.	RY190103
Production date	2019.01.03	Expired Date	2021.01.02
CAS NO.	113665-84-2	Standard	USP40 standard
Tests	Limits	Test results	
Appearance	A white to almost white powder	Conforms	
Identification	The IR absorption spectrum of sample responds to that of USP clopidogrel bisulfate CRS	Conforms	
	The RT of the major peak in the chromatogram of the sample corresponds to that of the reference standard.	Conforms	
	Positive reaction for sulfate	Conforms	
Loss on drying	≤0.5%	0.07%	
Residue on ignition	≤0.10%	0.05%	
Residual solvents	Isopropyl acetate≤5000ppm	240ppm	
	methanol≤3000ppm	322ppm	
	Toluene≤880ppm	N.D.	
	Dichloromethane≤600ppm	N.D.	
	Tetrahydrofuran≤720ppm	N.D.	
	Isopropanol≤5000ppm	108ppm	
	Diisopropyl ether≤1000ppm	N.D.	
	Acetone ≤5000ppm	169ppm	
Related substances	Clopidogrel related compound A≤0.20%	<0.03%	
	Clopidogrel related compound B≤0.30%	0.06%	
	Clopidogrel related compound C≤1.0%	<0.03%	
	Any other impurity ≤0.10%	0.04%	
	Total impurities≤0.50%	0.10%	
Assay	97%~101.5%	100.1%	
Conclusion: This batch meets USP standard.			
Remark: Type I crystalline			



Tested by: Esther

Checked by: Alice

Approved by: Mich