

CERTIFICATE OF ANALYSIS

Product	Prasugrel Hydrochloride		
Batch No.	20121212	Mfg.Date.	Dec.12, 2012
Approval Date	Jan. 9, 2013	Exp.Date.	Dec.11, 2014
ITEMS	SPECIFICATIONS		RESULTS
Appearance	White or almost white crystalline powder		White crystalline powder
Identification	Complies with the requirements		Conforms
	The IR absorbtion spectra obtained is in concordance with the reference standard		Conforms
	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation		Conforms
pH	2.5~3.5		2.85
Related compounds	Single impurity ≤0.5%		0.32%
	Total impurity ≤1.0%		0.55%
Residual solvents	Complies with the requirements		Conforms
Loss on drying	≤0.5%		0.15%
Residue on ignition	≤0.1%		0.03%
Heavy metals	≤20ppm		<10ppm
Purity(HPLC)	98.5%~101.5%		99.5%
	(calculated by dried C ₂₀ H ₂₀ FNO ₃ S·HCl))		
Conclusion: The product conform to the in-house specification			
Chief of QC: Li de Checker: Zhang Dechen Analyst: Liu Zhiyong			