



Certificate of analysis

Product name: Pramipexole Dihydrochloride Monohydrate

Cas number: 191217-81-9

Molecular Formula: $C_{10}H_{17}N_3S_2(HCl) \cdot H_2O$

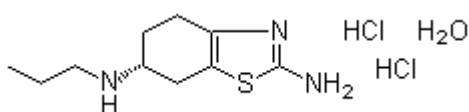
Molecular Weight: 302.26

Date of production: May. 30, 2018

Batch No: 20180530

Exp Date: May. 29, 2020

Chemical structure:



Items	Specifications	Results
Appearance	white or off-white crystalline powder	Conforms
Sloubility	Freely soluble in water, soluble in methanol, sparingly soluble or slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.	Conforms
Identufication	HNMR IR HPLC	Conforms
Appearance of solution	The solution is clear and not more intensely colored than reference solution Y6	
Related substances	Impurity A $\leq 0.15\%$ Impurity B $\leq 0.15\%$ Impurity C $\leq 0.15\%$ Impurity D $\leq 0.5\%$ Unspecified impurity $\leq 0.10\%$ Total impurities $\leq 0.5\%$	0.05% N.D N.D 0.05% 0.15% 0.04%
Heavy metals	$\leq 10\text{ppm}$	Conforms
Water	5.0%~7.0%	5.8%
Sulfated ash	$\leq 0.1\%$	0.07%
Assay	99.0%~101.0% (on anhydrous basis)	99.3%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F