

CERTIFICATE OF ANALYSIS

Product Name	Pioglitazone hydrochloride	Batch NO.	RY191125
Production date	2019.11.25	Expired Date	2021.11.24
CAS NO.	112529-15-4	Standard	Enterprise standard
Tests	Limits	Test results	
Appearance	White to White crystalline Powder, odourless, a little bitter taste	Conforms	
Solubility	Slightly soluble in ethanol, methanol, acetone and 0.1% dilute hydrochloric acid, almost insoluble in water, easily soluble in dimethylformamide	Conforms	
Melting point	190.0~198.0°C	192.0°C	
Identification	There should be max absorption at 221nm and 269nm	Conforms	
	Should be consistent with the infrared absorption spectrum of the reference	Conforms	
	Should be consistent with the retention time of the reference(HPLC)	Conforms	
	Should be positive	Positive	
Related substance	Any individual impurity $\leq 0.5\%$	$< 0.5\%$	
	The total impurities $\leq 1.0\%$	0.26%	
Loss on drying	$\leq 1.0\%$	0.32%	
Residue on ignition	$\leq 0.1\%$	0.08%	
Heavy metal	$\leq 1000\text{ppm}$	Conforms	
n-hexane	$\leq 0.029\%$	0.0%	
Assay	98.0%~102.0%	99.68%	
Conclusion: This batch meets enterprise standard.			

Tested by: Esther

Checked by: Alice

Approved by: Mich