

Certificate of Analysis

Product Name	Pioglitazone Hydrochloride	Mfg. Date	2019.08.15
Batch No.	PBG2019081503	Testing Date	2019.08.16
Batch Quantity	150kg	Exp. Date	2021.08.14

Items		Specifications	Results
Appearance		White to off-white powder	White powder
Identification	IR	The IR absorption spectrum of the sample is corresponding to that of the reference standard	Complies
	Chloride	Positive	Complies
	HPLC	The retention time of the principle peak in the chromatogram of the sample corresponds to that of the reference standard	Complies
Residue on ignition		≤ 0.1%	0.05%
Water		≤ 0.5%	0.01%
Heavy metals		≤10 ppm	Complies
Related substances/HPLC			
Impurity A		≤0.15 ppm	0.03%
Impurity B		≤0.15 ppm	0.05%
Impurity C		< 0.15 PPM	Not detected
Single impurity		< 0.10 PPM	Not detected
Total impurities		< 0.5 PPM	0.08%
Assay (on dried basis) /HPLC		98.0-102.0%	98.44%
Conclusion		The product complies with the established specifications	

Storage:	Store in cool & dry place, keep away from strong light and heat.
Shelf Life:	2 years when properly stored.



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