

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Pioglitazone Hydrochloride

Batch No.: DR20130111	Piece: 100kg
Manufacture Date: 2013.01.11	Expiry Date: 2015.01.10

TESTS:

Items	Specification	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	Conforms
	Chloride :Positive	Conforms
	HPLC:The retention time of the principle peak in the chromatogram of the sample corresponds to that of the reference standard	Conforms
Residue on ignition	≤0.1%	0.03%
Heavy metals	≤10ppm	<10ppm
Water	≤0.5%	0.19%
Related substances/HPLC	ImpurityA ≤0.15%	0.02%
	ImpurityB ≤0.15%	ND
	ImpurityC ≤0.15%	ND
	Single impurity ≤0.10%	0.04%
	Total impurities ≤0.5%	0.09%
Assay (on dried basis)/HPLC	98.2%—102.0%	100.2%

Conclusion: The results conform with USP35.



Analyst: Joe Yu **Checker:** Agnes Zhong **QA.Manager:** Sun Wenhui

Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel:+86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 85335020

Website: http://www.dawnraypharma.com/