

济南健丰化工有限公司
JINAN JIANFENG CHEMICAL CO.LTD.

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CERTIFICATE OF ANALYSIS

Product: Nateglinide
Batch No:20110305
Quantity: 25 kgs
Manufacturing Date:20110305
Expiry Date : 20130305
Test standard: Enterprise standard



Test	Standard	Results
Description	white or off-white crystalline powder	white powder
Melting point(°C)	137-141	137.3-138.4
Optical rotation(°)	-16.5-20.5	-18.6-19.3
Chloride	≤0.02%	0.006%
Single substance	≤0.5%	0.2%
Total substance	≤1.0%	0.45%
L-isomer	≅0.5%	0.06%
Total isomer	≤1.0%	0.13%
Loss on Drying	≅0.5%	0.30%
Residue on ignition	≅0.2%	0.08%
Heavy metal	≤0.002%	complies
Chlorobenzene	≤0.005%	0.0009%
Assay (by HPLC)	≥99.0%	99.53%

Conclusion :Conform to Enterprise standard

Exam

Analyst

Checker