



QUALITY ASSURANCE

Raw Material Quality Report

Date: 18-09-2014

Item Name: Linagliptin

Manufacturer: Beijing Huikang Boyuan Chemical Tech Co, China

L/C. No. (If any): - Ledger No / Page No: 07/195

Batch No. 140730 Lot No. -

Mfg. Date: 07-2014 Exp. Date: 07-2016

Quantity Received: 1x2 kg Received on: 12-09-2014

Sampled by: Anees Sampled on: 16-09-2014 Quantity of Sample: 5 gm

Date of Test: 18-09-2014 Date of Retest: 18-09-2015 Q.C. No. 35636/R-14

TEST	SPECIFICATION	RESULTS / REMARKS	
PHYSICAL CHECKS			
Physical Form & Colour	Yellow to off white powder	As/sp	Complies
Loss on drying: at 105°C	NMT 1.0%	0.75%	Complies
Residue on ignition	NMT 0.10%	0.06%	Complies
Heavy Metals	NMT 10ppm	LT10 ppm	Complies
CHEMICAL ANALYSIS			
Identification test of by IR Spectrum by HPLC	Should comply with standard spectrum The retention time of sample and standard peaks should be comparable	As/Sp	Complies
Related Substance by HPLC			
Single Impurity	NMT 0.50%	LT 0.50%	Complies
Total Impurity	NMT 1.0%	0.46% as/coa	Complies
ASSAY			
Linagliptin	98.0-----102.0%. OAB	97.85% As is 98.60% OAB	Complies

Overall Remarks:

OK

Quality Control Officer

Date 18-9-14

Executive Quality Control

Date 18-9-14

Manager Quality Control

Date

18/9/14