

Certificate of Analysis for Analytical Working Standard (AWS)Name of the Analytical Working Standard (AWS) : **SITAGLIPTIN PHOSPHATE MONOHYDRATE**Manufacturer's / Supplier's Name: **Lianyungang Jari Pharmaceutical Co. Ltd**Batch/Lot Number : **WS-20141222**PurRef. Number : **9618**Date of Manufacturing : **DEC,2014**Date of Expiry : **-**Date of Standardization : **-**Retest Date : **NOV,2016**Reference Standard Used : **WS**Batch /Lot Number : **-**Reference of Methods of Analysis : **FP-059**

Sl. No.	Tests	Specifications	Results
01.	Description	White to off white crystalline powder.	White crystalline powder.
02.	Identification : By IR Spectroscopy	Conforms by IR spec.	Conforms.
03.	Water	Between 3% and 5%	3.4 %
04.	Related Substances: i) Single maximum unknown impurity ii) Total impurities	i) Not more than 0.10%. ii) Not more than 1.0%.	i) 0.09 %. ii) 0.2 %.
05	Chiral Purity (S-isomer)	NMT 1.0 %	0.20
05.	Assay (on anhydrous basis)	Not less than 98.0% and not more than 102.0% of Sitagliptin Phosphate.	100.3 % (as Sitagliptin Phosphate)
	Assay (as is basis)	For Record.	96.9 % (as Sitagliptin Phosphate)

Comments: Qualified for use as working standard.

	Name	Designation	Sign & Date
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