

S3-1

2 vials
+ 1 vial

= 3 vials

Brought

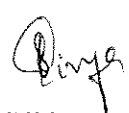


Sai Mirra

SAI MIRRA INNOPHARM PVT. LTD.
288 & 299, SIDCO ESTATE, CHENNAI - 600 098.

WORKING STANDARD REPORT	
NAME OF THE MATERIAL	SITAGLIPTIN PHOSPHATE MONOHYDRATE
EVALUATED WITH	WORKING STANDARD (WS-SIT-0002)
SOURCE	MSN PHARMACHEM PVT.LTD
DATE OF STANDARDISATION	08/09/2014
VALIDITY PERIOD	08/09/2015
WORKING STANDARD NUMBER	WS-SIT-0003
WORKING STANDARD A.R.NO.	SMWS0042/14
DIRECTIONS FOR USE	Use as such
STORAGE CONDITION	Store in air tight container at room temperature.
REFERENCE : INHOUSE	
Tests selected for comparison	

S.No	TEST PARAMETER	RESULT	SPECIFICATION
1.	Description	White crystalline powder	White to off-white crystalline powder
2.	Identification IR Spectrum	The infrared absorption spectrum obtained with the sample is concordant with the infrared absorption spectrum obtained with that of Sitagliptin Phosphate Monohydrate standard.	The infrared absorption spectrum of the sample should concordant with the infrared absorption spectrum obtained with that of Sitagliptin Phosphate Monohydrate standard.
3.	Water	3.67%	Between 3.0 and 5.0 %w/w
4.	Assay (On anhydrous basis)	99.76%	Between 98.0 and 102.0 %w/w
5.	Purity	96.10%	-

REMARKS: The working standard is comparable with the Certified Working Standard as per the above tests and is suitable to use as a substitute.

Tested by:  S.Divya Chemist-QC Date : 08/09/2014	Checked by:  S.Hemalatha Senior Chemist-QC Date : 08/09/2014	Approved by:  K.Rama AGM-QC Date : 08/09/2014
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