



Hangzhou Huarong Pharmaceutical Co., Ltd.

ADD: Room1101, Hakim International Building, Gongshu District,

Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

Website: www.huarongpharm.com

CERTIFICATE OF ANALYSIS

Product name	Sitagliptin phosphate monohydrate		
Batch No.	G00340-150702	Expiry date	Jun. 2017
Quantity	100 kg	Manu. date	Jul. 2015
CAS No.	654671-77-9	Ref. standard	In-house standard

Items	Specifications	Test results
Appearance	White to off-white crystalline powder	Conform
Solubility	Soluble in water and N,N- Dimethyl formamide, slightly soluble in methanol and insoluble in 2-propanol	Conform
Identification	HPLC RT	Conform
Water (by KF)	3.0~5.0%	3.6%
Phosphate content by potentiometry on anhydrous basis	18.0~22.0%	19.1%
Residue on ignition	$\leq 0.1\%$	0.01%
Heavy metals	$\leq 20\text{ppm}$	Conform
Related substances	Any individual impurity $\leq 0.1\%$	0.08%
	Total impurities $\leq 1.0\%$	0.2%
Chiral purity	S-isomer impurity $\leq 0.1\%$	$< 0.01\%$
Assay(by HPLC)	98.0~102.0%	100.1%

Storage: Preserve in well sealed container, store in cool and dried place, away from strong light and heat, when stored under above Condition, the retested date is 2 years away from manufactured date.

For and on behalf of
Hangzhou Huarong Pharmaceutical Co., Ltd.
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Authorized Signature(s)

*Means the document is under process
Product under patent is for R&D purpose.