

METAPHARMACEUTICAL

Lot: 9041117



浙江华海药业股份有限公司

HUHHAI ZHEJIANG HUHHAI PHARMACEUTICAL CO., LTD.

5 kg 他达拉非

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CERTIFICATE OF ANALYSIS

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Product Name	Tadalafil		
Batch No.	D5071-17-002	Batch Size	176.06kg
Batch Type	Commercial	Report Date	2017-3-6
Retest Date	2019-12	Storage Condition	Preserve in well-closed containers
Manufacture Date	2017-1-18	Manufacturing Site	Chuannan, Duqiao, Linhai, Zhejiang 317016, China
Reference	CEP(R0-CEP 2013-189-Rev 01)		
Test Items	Specifications	Results	
Appearance	White or off-white powder	Off-white powder	
Identification	(1) IR: IR spectrum is accordant with Tadalafil RS.	Conform	
	(2) Specific optical rotation: +78.0° to +84.0° (dried substance)	+79.5°	
Loss on drying	≤ 0.5%	0.1%	
Sulfated ash	≤ 0.1%	<0.1%	
Assay (HPLC)	97.5%~102.0% (dried substance)	99.5%	
*Impurities A, B and C (HPLC)	Impurity A≤ 0.15%	N.D	
	Unspecified impurities≤ 0.10%	N.D	
Related substances (HPLC)	Unspecified impurities≤ 0.10%	0.05%	
	Total impurities≤ 0.3%	0.05%	
Residual Solvents Test 1 (GC)	Methanol≤ 3000 ppm	88ppm	
**Genotoxic impurity (GC-MS)	Methyl chloroacetate≤37.5ppm	N.D	
Conclusion	Complies with CEP(R0-CEP 2013-189-Rev 01)		

* Impurity A: (6R,12aS)-6-(1,3-benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]-pyrido[3,4-b]indole-1,4-dione;

* Impurity B: (6S,12aS)-6-(1,3-benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]-pyrido[3,4-b]indole-1,4-dione;

* Impurity C: (6S,12aR)-6-(1,3-benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]-pyrido[3,4-b]indole-1,4-dione

**Genotoxic impurity: performed for the first three batches.

Signature: Zhang Xianhua (QC manager)

Issued Date: 2017.03.07

Signature: Wang Dongji (QA manager)

Issued Date: 2017.04.02

Q/ZHH QC-075-1