



浙江华海药业股份有限公司

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CERTIFICATE OF ANALYSIS

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Product Name	Tadalafil		
Batch No.	D5071-17-006	Batch Size	164.56kg
Batch Type	Commercial	Report Date	2018-10-17
Retest Date	2021-12	Storage Condition	Preserved in a well-closed container
Manufacture Date	2017-1-20	Manufacturing Site	Chuannan, Duqiao, Linhai, Zhejiang 317016, China
Reference	CEP(R0-CEP 2013-189-Rev 02)		
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)	+80.0°	
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(LOD:0.014%)	
	Unspecified impurities≤ 0.10%	N.D(LOD:0.015%)	
Related substances (HPLC)	Unspecified impurities≤ 0.10%	<LOD(LOD:0.02%)	
	Total impurities≤ 0.3%	<LOD	
Residual Solvents Test 1 (GC)	Methanol≤ 3000 ppm	104ppm	
**Genotoxic impurity (GC-MS)	Methyl chloroacetate≤37.5ppm	-----	
Conclusion	Complies with CEP(R0-CEP 2013-189-Rev 02)		

* 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: Fangfengze (QC manager)

Issued Date: 2018.10.17

Signature: Lijiang (QA manager)

Issued Date: 2018.10.18

Q/ZHH QC-075-2