Lot: 9220617

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CERTIFICATE OF ANALYSIS

Product Name	Tadalafil		
Batch No.	D5071-17-001	Batch Size	174.96kg
Batch Type	Commercial	Report Date	2017-3-6
Retest Date	2019-12	Storage Condition	Preserved in a well-closed container
Manufacture Date	2017-1-17	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)		+78.7°
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		86ppm
**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: Huangxianhua (QC manager) Issued Date: 2017.03.08

Signature: Qiuxingi (QA manager) Issued Date: 2017.03.08