



Jinan Hongfangde Pharmatech Co., Ltd.
Tel:86-531-88870908 Fax:86-531-88870908
sdhfdchem@163.com
www.hfdpharma.com

CERTIFICATE OF ANALYSIS

Product name	Sertaconazole Nitrate		
Batch No.	19080301	CAS	99592-32-2
Report Date	2019-08-20	Expiry date	2021-08-02

Item	Specification	Result
Appearance	White or almost white powder	White crystalline powder
Melting point	163. 0~167. 0℃	164. 1~165. 6℃
Identification	(1) should be (+) reaction	(+)
	(2) have maximum absorption at 261nm 、 293nm and 303nm wavelength	Conform
	(3) By IR, Matching with working standard	Conform
Related substance	Complies with the standard	Conform
Loss on drying	Not more than 0.5%	0.06%
Residue on ignition	Not more than 0.2%	0.04%
Heavy metals	Not more than 20ppm	Conform
Assay	Not less than 98.5% (C ₂₀ H ₁₅ C ₁₃ N ₂ O ₅ · HNO ₃)	99. 54%
【microorganism】		
total bacterial count	≤100/g	Conform
Fungus total count	≤100/g	Conform
Staphylococcus aureus Rosenbach	absent	not detected
P.Aeruginosa	absent	not detected
Conclusion: Complies with enterprise standard.		

Analyst :shilijuan

Checker: maohongjun

Supervisor :wangsulan