



新昌县九信药业有限公司

Xinchang JiuXin Pharmaceutical Co.,Ltd

质量检测报告书 Certificate of analysis

报告单编号 (COA NO.) COA-QC-050045-06

检字号 (serial no.) 15037081

检品名称 product	盐酸左旋咪唑 levamisole hydrochloride	批号 batch no.	M-150366
包装 packaging size	25kg/桶 (drum)	数量 quantity	500kg
生产日期 MFG DATE	28/03/2015(d/m/y)	报告日期 reporting date	01/04/2015(d/m/y)
执行标准 according to	英国药典 2013 版 BP2013	失效日期 Expiry date	27/03/2019(d/m/y)

Tests	acceptance criteria	results
description	White or almost white crystalline powder	white crystalline powder
solubility	Freely soluble in water, soluble in ethanol, slightly soluble in methylene chloride	Conforms
specific optical rotation	-121°~ -128°	-124°
identification	(1) IR: conforms to the reference spectrum (2) specific optical rotation (3) chemical reaction: positive (4) chemical reaction: positive	Conforms
appearance of solution	Conforms	Conforms
PH	3.0~4.5	4.2
Related substances (HPLC)	Impurity A、B、C、D、E≤0.2%	Impurity D≤0.05%
	Any other impurity ≤0.1%	not detected
	Total impurities ≤0.30%	0.05%
loss on drying	≤0.5%	0.1%
sulphated ash	≤0.1%	0.03%
Heavy metals	≤20ppm	Conforms
assay	C11H12N2S·HCL:98.5%~101.0% (on dried basis)	99.9%

结论: 本品按英国药典 2013 版标准检验, 结果符合标准

Conclusion: conforms to BP2013

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan