Zhejiang Liaoyuan Pharmaceutical Co.,Ltd.
Zhejiang Provincial Chemical and Medical Raw Material
Base Linhai Zone, Duqiao Town, Linhai City,
Zhejiang Province, 317016, China

浙江燎原药业股份有限公司检验报告
ZHEJIANG LIAOYUAN PHARMACEUTICAL CO., LTD
CERTIFICATE OF ANALYSIS

检验单号 Cert. No.: F181529

Product Name 品名	Mirtazapine (hemihydrate) 米氮平(半水物)		
Batch No. 批号	A109(B)-1811014	Quantity 数量	50Kg
Mfg. Date 生产日期	2018/11/17	Pkg. Size 包装规格	25Kg/Drum
Retest Date 复验日期	2021/11/16	Grade 标准	USP40

Item 项目	Specification 规定	Result 分析结果
Character 性状	A white or almost white crystalline powder 白色或类白色结晶粉末	A almost white crystalline powder 类白色结晶粉末
Identification 鉴别	A)The IR absorption spectrum is accordant with the spectrum obtained with the reference standard 样品的红外吸收图谱与对照图谱相一致	Conforms 符合
	B) The RT of the major peak in the chromatogram of the sample corresponds to that of the reference standard, as obtained in the assay 含量测定项下，样品主峰的保留时间与对照品主峰的保留时间一致	Conforms 符合
Specific rotation 比旋度	-2.0° ~+2.0°	-0.20°
Water 水分	1.00%~3.5%	2.3%
Residue on ignition 灼烧残渣	≤0.10%	0.03%
Heavy metals 重金属	≤0.001%	Conforms 符合
Residual solvents 残留溶剂	Ethanol 乙醇≤5000ppm	87ppm
Related substances 有关物质	Impurity A 杂质 A≤0.10%	<0.03%
	Impurity B 杂质 B≤0.10%	<0.03%
	Impurity C 杂质 C≤0.10%	<0.03%
	Impurity D 杂质 D≤0.10%	<0.03%
	Impurity E 杂质 E≤0.10%	<0.03%
	Impurity F 杂质 F≤0.10%	<0.03%
	Individual impurity 单一杂质≤0.10%	<0.03%
	Total impurities 总杂质≤0.50%	<0.03%
Assay 含量	98.0~102.0%(anhydrous substance 以无水物计)	100.3%
Conclusion 结论:The product tested complies with the specification 符合规定		
Remarks 备注: Residual solvents 残留溶剂:N-Dmethylformamide N,N-二甲基甲酰胺≤880ppm ND		

QC Manager/Date: 2019.01.24
QC 经理/日期
☑ APPROVED 合格

Checked by/Date: 2019.01.20
复核人/日期
☐ REJECTED 不合格

Prepared by/Date: 2019.01.24
编制人/日期

Approved by QA/Date: 2019.01.24
QA 负责人/日期