SINOWAY INDUSTRIAL CO.,LTD.

16/F.,HUICHENG COMM.COMPLEX, 839 XIAHE RD.,XIAMEN,CHINA
TEL: 0086-592-5854962 POSTCODE: 361004
FAX: 0086-592-5854960 E-MAIL: shi@china-sinoway.com

检验报告书 COA

品名 Product Name	富马酸伏诺拉生 Vonoprazan Fumarate	检验规格 Test specification	C098A
批号 Batch Number	C098A230801	包装规格 Packaging specification	C098A
生产日期 Manufacturing Date	2023.07.20	批量 Batch Size	25kg
复验期 Retest Date	2025.07.19	报告日期 Report Date	2023.08.31
检验依据 Test Reference	Enterprise Standard		

检验项目 Test Items	**质量标准 Criteria**	**检验结果 Result**	**检验结论 Conclusion**
性状 Characters			
外观 Appearance	本品应为白色或类白色结晶性粉末。 White or almost white crystalline powder.	为白色结晶性粉末。 White crystalline powder.	符合规定 Conforms
溶解性 Solubility	本品在二甲基亚砜中溶解，在水和甲醇中微溶，在乙醇中极微溶解，在乙腈中几乎不溶。 Soluble in dimethyl sulfoxide, slightly soluble in water and methanol, very slightly soluble in ethanol, and almost insoluble in acetonitrile.	本品在二甲基亚砜中溶解，在水和甲醇中微溶，在乙醇中极微溶解，在乙腈中几乎不溶。Soluble in dimethyl sulfoxide, slightly soluble in water and methanol, very slightly soluble in ethanol, and almost insoluble in acetonitrile.	符合规定 Conforms
鉴别 Identification			
红外鉴别 IR Identification	本品的红外光吸收图谱应与对照品的图谱一致。IR absorption spectrum should be in accordance with the reference standard.	本品的红外光吸收图谱与对照品的图谱一致。IR absorption spectrum is in accordance with the reference standard.	符合规定 Conforms
HPLC 鉴别 HPL C Identification	在含量测定项下记录的色谱图中，供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time of the main peak of the test solution should be consistent with that of the reference solution, as obtained in the assay.	在含量测定项下记录的色谱图中，供试品溶液主峰的保留时间与对照品溶液主峰的保留时间一致 The retention time of the main peak of the test solution is consistent with that of the reference solution, as obtained in the assay.	符合规定 Conforms
检查 Test			
酸度 Acidity	3.2~4.2	3.8	符合规定 Conforms
水分 Water	≤0.5%	0.1%	符合规定 Conforms
炽灼残渣 Residue on ignition	≤0.1%	0.05%	符合规定 Conforms
重金属 Heavy metals	≤10ppm	＜10ppm	符合规定 Conforms
有关物质 HPLC Related Substances HPLC			
杂质 API-ZZ1 Impurity API-ZZ1	≤0.20%	未检出 Not detected	符合规定 Conforms
杂质 API-ZZ2 Impurity API-ZZ2	≤0.10%	未检出 Not detected	符合规定 Conforms
杂质 API-ZZ3 Impurity API-ZZ3	≤0.20%	0.081%	符合规定 Conforms
杂质 API-ZZ5	≤0.20%	0.025%	符合规定

检验项目 Test Items	质量标准 Criteria	检验结果 Result	检验结论 Conclusion
Impurity API-ZZ5			Conforms
杂质 API-ZZ7 Impurity API-ZZ7	≤0.10%	未检出 Not detected	符合规定 Conforms
杂质 API-ZZ8 Impurity API-ZZ8	≤0.10%	未检出 Not detected	符合规定 Conforms
杂质 API-ZZ9 Impurity API-ZZ9	≤0.20%	0.034%	符合规定 Conforms
杂质 M1-ZZ2 Impurity M1-ZZ2	≤0.20%	未检出 Not detected	符合规定 Conforms
未知杂质 Unspecified Impurities	≤0.10%	0.028%	符合规定 Conforms
总杂质 Total Impurities	≤1.0%	0.3%	符合规定 Conforms
富马酸 Fumarate	23.5%~26.5%	25.1%	符合规定 Conforms
残留溶剂 Residual Solvents			
甲醇 Methanol	≤3000ppm	未检出 Not detected	符合规定 Conforms
乙醇 Ethanol	≤5000ppm	114ppm	符合规定 Conforms
乙酸乙酯 Ethyl acetate	≤5000ppm	28ppm	符合规定 Conforms
乙腈 Acetonitrile	≤410ppm	未检出 Not detected	符合规定 Conforms
N,N-二甲基乙酰胺 N, N-dimethylacetamide	≤1090ppm	33ppm	符合规定 Conforms
微生物限度检查 Microbiological Limit			
需氧菌总数 Total Aerobic Microbial Count	≤10^3cfu/g	＜20cfu/g	符合规定 Conforms
霉菌及酵母菌总数 Total Yeasts &Moulds Count	≤10^2cfu/g	＜20cfu/g	符合规定 Conforms
大肠埃希菌 Escherichia coli	应不得检出/g Not detected/g	未检出/g Not detected/g	符合规定 Conforms
含量 Assay	98.0%～102.0%	100.0%	符合规定 Conforms

结论：本品符合规定。
Conclusion: The test results conform to Enterprise Standard.

以下为空白
Below is blan

SINOWAY INDUSTRIAL CO., LTD.