

河南天方科技有限公司
Henan Topfond Sci-Tech Co.,Ltd.
检验报告单
Certificate of Analysis

品名/Name: 辛伐他汀/Simvastatin

检验号/Analysis NO.: 2024140061

批号/Batch NO.: 240204002

数量/Quantity: 10.00Kg

生产日期/Date of Manufacture: 02/02/2024

报告日期/Date of Report: 06/06/2024

检验标准/Test Standards: USP46

复验期/Retest Date: 01/02/2027

Items/检验项目	Standards/标准	Results/检验结果	Conclusions/结论
[性状] Characters	白色至类白色粉末 White to off-white powder	白色粉末 White powder	符合规定 Conform
[溶解度] Solubility	易溶于三氯甲烷、甲醇和乙醇；微溶于丙二醇；极微溶于正己烷；几乎不溶于水。 Freely soluble in chloroform, in methanol, and in alcohol; sparingly soluble in propylene glycol; very slightly soluble in hexane; practically insoluble in water	符合规定 Conform	符合规定 Conform
[比旋度](干燥品计) Specific optical rotation(dried substance)	+285° ~ +298°	+289	符合规定 Conform
[鉴别] Identification	A. 红外吸收应符合规定 A. IR: Conforming	红外吸收符合规定 IR: Conforming	符合规定 Conform
	B. 含量检测项目下，供试品溶液主峰保留时间应与对照品溶液主峰保留时间一致。 B. The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay	符合规定 Conform	符合规定 Conform
[色谱纯度] Chromatographic purity	辛伐他汀羟酸 Simvastatin hydroxy acid: ≤0.4%	0.07%	符合规定 Conform
	表洛伐他汀和洛伐他汀 Epilovastatin and Lovastatin: ≤1.0%	0.26%	符合规定 Conform
	亚甲基辛伐他汀 Methylene Simvastatin: ≤0.4%	0.04%	符合规定 Conform
	乙酰辛伐他汀 Acetyl Simvastatin: ≤0.4%	Undetectable	符合规定 Conform
	无水辛伐他汀 Anhydro Simvastatin: ≤0.4%	0.13	符合规定 Conform
	辛伐他汀二聚体 Simvastatin Dimer: ≤0.4%	0.02%	符合规定 Conform
	其他任一单个杂质 Any other individual impurity: ≤0.10%	0.06%	符合规定 Conform
	除洛伐他汀和表洛伐他汀之外所有杂质总和 Total impurities other than lovastatin and epilovastatin: ≤1.0%	0.37%	符合规定 Conform

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[干燥失重] Loss on drying	$\leq 0.5\%$	0.05%	符合规定 Conform
[炽灼残渣] Residue on ignition	$\leq 0.1\%$	0.05%	符合规定 Conform
[重金属] Heavy metals	$\leq 0.002\%$	<0.002%	符合规定 Conform
[含量](干燥品计) Assay(dried substance)	98.0%~102.0%	98.7%	符合规定 Conform
[残留溶剂] Residual solvents	甲醇 Methanol: $\leq 3000\text{ppm}$	Undetected	符合规定 Conform
	乙醇 Ethanol: $\leq 5000\text{ppm}$	393ppm	符合规定 Conform
	二氯甲烷 Dichloromethane: $\leq 600\text{ppm}$	Undetected	符合规定 Conform
	甲基叔丁基醚 Methyl tert-butyl ether: $\leq 5000\text{ppm}$	Undetected	符合规定 Conform
	乙酸乙酯 Ethyl acetate: $\leq 5000\text{ppm}$	Undetected	符合规定 Conform
	四氢呋喃 Tetrahydrofuran: $\leq 720\text{ppm}$	Undetected	符合规定 Conform
	环己烷 Cyclohexane: $\leq 3880\text{ppm}$	Undetected	符合规定 Conform
	吡啶 Pyridine: $\leq 200\text{ppm}$	Undetected	符合规定 Conform
	N,N-二甲基甲酰胺 N,N-Dimethylformamide: $\leq 880\text{ppm}$	Undetected	符合规定 Conform

结论: 本品按辛伐他汀美国药典USP46版标准检验, 结果符合规定

Conclusion: This is to certify that we, the undersigned, have performed tests on the very batch of the substance according to Corresponding procedures and found that this batch of simvastatin meets the requirement of the monograph of Simvastatin in USP46

负责人/Assessed by

杨柯

检验者/Tested by

尚伟杰 胡景轩

复核者/Checked by

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*Packaging form: The inner layer is low density polyethylene (LDPE) bag and the outer layer is Full paper bucket. Packing size: 1*15kg/drum.

*Storage condition: Protected from light, store in an airtight container.