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湖北帝柏化工有限公司
HUBEI DIBO CHEMICAL INDUSTRY CO., LTD.

检 验 报 告
Certificate Of Analysis

Rosuvastatin Calium

BATCH NO.	180501	MANUFACTURING DATE	2018.05.07
BATCH SIZE	10kg	TEST DATE	2018.05.10
QUANTITY	500g	EXPIRY DATE	2020.05

TEST	SPECIFICATION	RESULT
Appearance	White to almost white powder	White powder
Identification	(1) UV	Conforms
	(2) IR	Conforms
	(3) Reaction of calcium	Conforms
	(4)HPLC	Conforms
Specific Rotation	+16°~+20°	+17°
Water Content	Not More Than 5.0%	1.9%
Calcium Content	3.5%~4.5%	4.0%
Heavy Metals	Not More Than 10ppm	<10ppm
Related Substance		
Rosuvastatin Lactone	Not More Than 0.15%	<0.02%
Oxidation Rosuvastatin	Not More Than 0.15%	0.08%
Rosuvastatin amide	Not More Than 0.15%	0.03%
Rosuvastatin isomer	Not More Than 0.15%	0.04%
Diastereo isomer	Not More Than 0.15%	0.03%
Enantiomer	Not More Than 0.15%	<0.02%
Any other unknown impurity	Not More Than 0.10%	0.06%
Total Impurities	Not More Than 1.0%	0.35%
Assay	98.5% to 102.0%(Calculated on the anhydrous basis)	99.2%
Residual Solvent		
Methanol	Not More Than 3000 ppm	161ppm
Methylene Chloride	Not More Than 600 ppm	<16ppm
Methyl Tertiary Butyl Ether	Not More Than 5000 ppm	<3ppm
Ethyl Acetate	Not More Than 5000 ppm	<4ppm
Tetrahydrofuran	Not More Than 720 ppm	<3ppm
Toluene	Not More Than 890 ppm	<6ppm

Conclusion: The results conform to enterprise standard.

湖北帝柏化工有限公司 质检专用章

Quality audit:Chen Inspector: Li Xiao Analyst:Wang ZhiXue