

CERTIFICATE OF ANALYSIS

Product	Deflazacort	Manufacturing Date	2018.01.27
Batch No.	180108	Report Date	2018.01.29
Criteria	Enterprise Standard	Retest Date	2023.01.27
Item	Specification	Test result	
Description	White off white micronized power	White off white micronized power	
Solubility	Pratically insoluble in water, freely soluble in aceticacyd and methilene chloride,sparingly soluble in acetone and metanol	Conforms	
Sulphated Ash	≤0.1%	0.02%	
Melting Point	255°C – 256°C	255°C– 256°C	
Loss On Drying	≤0.5%	0.03%	
Water	≤0.5%	Conforms	
Identification	UV,HPLC,IR	Positive	
Residual solvents	Methanol < 1000 ppm	Conforms	
	Acetone < 1500 ppm	Conforms	
	Tetrahydrofurano < 500 ppm	Conforms	
	Heptano < 3000 ppm	Conforms	
Total Microbial Count	Not more than 1000 ufc/g	Conforms	
Mold and yeast:	Not more than 100 ufc/g	Conforms	
Specific Optical Rotation	+58° – +62°	+61.2°	
Heavy Metal	< 10 ppm	None	
Related substances compound	Total Impurity <1.0%	0.43%	
	Unknow <0.1%	0.07%	
	Single <0.1%	0.09%	
Average Particle size	100%<100 microns 90%<10 microns	Conforms	
Assay	98.0%-102.0%	100.1%	
Quantity:	14KGS		
Conclusion:	The above product conforms to Enterprise Standard		

Q.A. Manager:



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检验中心粒度分析报告

测试信息

样品名称: 180108【平均】
分散剂: 十二烷基硫酸钠
测量范围: $1\mu\text{m}$ ~ $300\mu\text{m}$
软件版本: 8.0.5

送样单位: 中南
分散介质: 水
样品浓度: 2.0

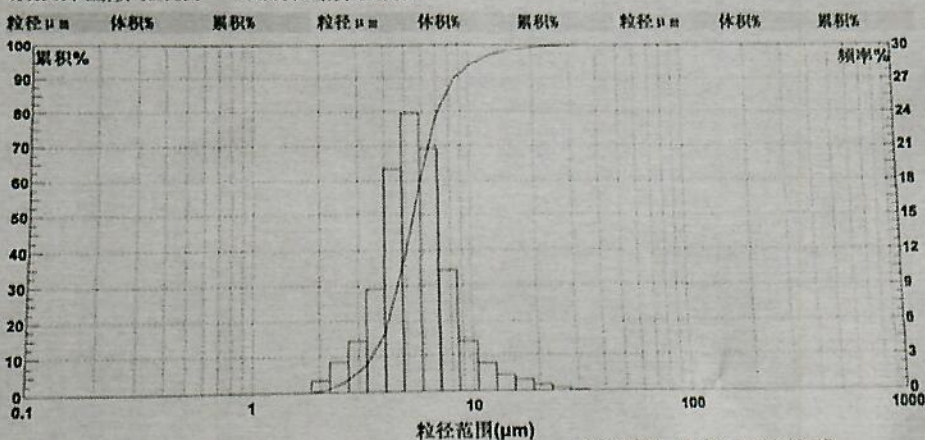
送样时间: 18.02.06
超声时间: 240s
分析模式: 自定义粒粒

分析结果

D10=3.46 μm D50=5.46 μm D90=8.59 μm
D99=18.25 μm D5=2.90 μm D2=2.41 μm
D1=2.22 μm D100=33.54 μm D80=7.11 μm
D70=6.51 μm D60=5.90 μm D40=5.02 μm
D30=4.58 μm D20=4.14 μm D.6=2.06 μm
<30.00 μm 累积=99.95% <10.00 μm 累积=93.44%
<20.00 μm 累积=99.30% <50.00 μm 累积=100.00%
<100.00 μm 累积=100.00% <90.00 μm 累积=100.00%
<5.00 μm 累积=39.44% <2.00 μm 累积=0.43%
<1.00 μm 累积=0.00% <120.00 μm 累积=100.00%
<150.00 μm 累积=100.00% <70.00 μm 累积=100.00%

分析结果

S/V=11721.86 cm^2/cm^3 Dav=5.98 μm
D[4,3]=0.00 μm D[3,2]=0.00 μm



检测人:

检测时间: 2018-2-6 10:38:45

DEFLAZACORT
BATCH NO.:180108