

200400013P 精华制药集团南通有限公司检验报告

NANTONG JINGHUA PHARMACEUTICAL CO. LTD.
CERTIFICATE OF ANALYSIS

No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong,

Nantong Jiangsu China, 226407

Tel: 86-513-85609405/85609406

扑米酮

PRIMIDONE

Batch No.	PMD2019056M	Manufacture Date	Sep. 7, 2019
Total Quantity	501.98KG	Report Date	Dec. 24, 2019
Commercial Quantity	500.00KG	Re-test Date	Sep. 6, 2022
Inspection No.	190200143		

TEST	SPECIFICATIONS (USP)	RESULTS
Characteristics	white crystalline, Powder, odourless. Slightly bitter taste	Complies
Solubility	slightly soluble in alcohol; very slightly soluble in water and in most organic solvents.	Complies
Identification	A. IR B. The retention time of the major peak in the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies
Organic Impurities	primidone related compound A ^a ≤ 0.1% phenobarbital ≤ 0.1% primidone related compound C ^b ≤ 0.1% 2-Cyano-2-phenylbutyramide ≤ 0.1% 2-phenylbutyric acid ≤ 0.1% phenylpropyl- primidone ^c ≤ 0.30% Any unspecified impurity ≤ 0.1% Total impurities ≤ 0.5%	N.D. < LOD, LOD = 5 × 10 ⁻³ g/ml N.D. N.D. N.D. N.D. 0.02% 0.02%
Loss on drying	≤ 0.5%	0.10%
Residue on ignition	≤ 0.2%	0.08%
Assay	98.0~102.0%	99.41%
(Calculated on the dried basis)		
Particle size	D(0.9) < 100 μm	33.8 μm
(Malvern Masterizer)	D(1.0) < 450 μm	96.1 μm
Residual solvents	Methanol ≤ 0.3% Ethanol ≤ 0.5%	N.D. N.D.
Melting range	279-284 °C	281.0-283.0 °C
Bulk Volume		

Conclusion The product meets the requirements of USP42 and customer's requirements

Analyst 王莹 李莹 李莹 李莹 Supervisor 李莹 Chief of Laboratory 李莹
Dec. 24, 2019 QA Release Date Dec. 24, 2019



MASTERSIZER



Result Analysis Report

Sample Name:
PMD2019056M

SOP Name:
pmd surface

Measured:
2019年12月23日 10:16:24

Sample Source & type:
南通精华制药

Measured by:
石磊星

Analysed:
2019年12月23日 10:16:26

Sample bulk lot ref:
123-ABC

Result Source:
Measurement

Particle Name:
pmd

Accessory Name:
Scirocco 2000

Analysis model:
General purpose

Sensitivity:
Normal

Particle RI:
1.520

Absorption:
0.1

Size range:
0.020 to 2000.000 μm

Obscuration:
2.32 %

Dispersant Name:

Dispersant RI:
1.000

Weighted Residual:
0.124 %

Result Emulation:
Off

Concentration:
0.0003 %Vol

Span :
2.679

Uniformity:
0.833

Result units:
Volume

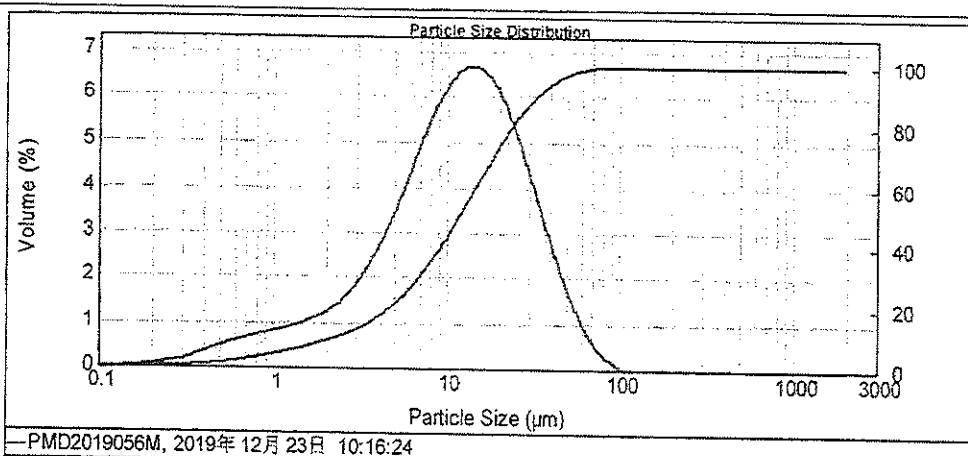
Specific Surface Area:
1.02 m^2/g

Surface Weighted Mean D[3,2]:
4.609 μm

Vol. Weighted Mean D[4,3]:
15.561 μm

d(0.9) : 33.753 μm

D(1.00) : 95.11 μm



Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %	Size (μm)	Vol Under %
0.010	0.00	0.105	0.00	1.096	4.85	11.482	49.07	120.226	100.00
0.011	0.00	0.120	0.00	1.258	5.64	13.183	55.00	136.038	100.00
0.013	0.00	0.138	0.00	1.445	6.49	15.138	61.02	156.489	100.00
0.015	0.00	0.156	0.01	1.660	7.40	17.379	66.96	181.970	100.00
0.017	0.00	0.182	0.04	1.905	8.41	19.953	72.57	208.530	100.00
0.020	0.00	0.209	0.09	2.188	9.52	22.909	78.00	239.893	100.00
0.023	0.00	0.240	0.17	2.512	10.80	26.303	82.83	275.423	100.00
0.026	0.00	0.275	0.28	2.884	12.27	30.200	87.07	316.228	100.00
0.030	0.00	0.316	0.43	3.311	13.99	34.674	90.64	363.078	100.00
0.035	0.00	0.363	0.64	3.802	16.04	39.811	93.55	416.869	100.00
0.040	0.00	0.417	0.92	4.365	18.47	45.709	95.80	478.630	100.00
0.046	0.00	0.479	1.29	5.012	21.35	52.481	97.46	549.541	100.00
0.052	0.00	0.550	1.73	5.754	24.73	60.256	98.61	630.557	100.00
0.060	0.00	0.631	2.23	6.607	28.54	69.183	99.34	724.436	100.00
0.069	0.00	0.724	2.80	7.586	33.06	79.433	99.76	831.754	100.00
0.079	0.00	0.832	3.43	8.710	37.96	91.201	99.95	954.963	100.00
0.091	0.00	0.955	4.12	10.002	43.35	104.713	100.00	1095.478	100.00

Operator notes:

Malvern Instruments Ltd.
Malvern, UK

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Mastersizer 2000 Ver. 6.50
Serial Number : MAL1039341

File name: 1 (Recovered)
Record Number: 119
2019-12-23 10:16:26