

扑米酮

PRIMIDONE

Batch No.	PMD2023005	Manufacture Date	Feb.6,2023
Total Quantity	503.00KG	Report Date	Feb.15,2023
Commercial Quantity	500.00KG	Re-test Date	Feb.5,2026
Inspection No.	2302000011		

TEST	SPECIFICATIONS (USP)	RESULTS
Characteristics	white crystalline, Powder, odourless. Slightly bitter taste	Complies
Identification	A. IR	Complies
	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%	N.D.
	phenobarbital ≤0.1%	<LOD,LOD=5×10 ⁻⁸ g/ml
	primidone related compound C ^b ≤0.1%	N.D.
	2-Cyano-2-phenylbutyramide ≤0.1%	N.D.
	2-phenylbutyric acid ≤0.1%	N.D.
	phenylpropyl- primidone ^c ≤0.3%	N.D.
	Any unspecified impurity≤0.1%	0.02%
	Total impurities ≤0.5%	0.03%
Loss on drying	≤0.5%	0.10%
Residue on ignition	≤0.2%	0.06%
Assay	98.0~102.0%	99.48%
(Calculated on the dried basis)		