NE

		PRIMIDONE
Batch No.	PMD2023005	Manufacture Date
Total Quantity	503.00KG	Report Date
Commercial Quantity	500.00KG	Re-test Date
Inspection No.	2302000011	
	-	-

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Batch No.	PMD2023005	Manufac
Total Quantity	503.00KG	Report D
Commercial Quantity	500.00KG	Re-test I
Inspection No.	2302000011	
TEST	SPECIFICATIONS	

Duton 140.	111111111111111111111111111111111111111
Total Quantity	503.00KG
Commercial Quantity	500.00KG
Inspection No.	2302000011
TEST	SPECIFICA
	(USP
Characteristics	white crystalline, Powde
Identification	A. IR
	R The retention time of t

Loss on drying

Assay

Residue on ignition

(Calculated on the dried basis)

500.00KG	Re-tes
2302000011	
SPECIFICA	TIONS
(USP)	
white crystalline, Powder	, odourless. S
A. IR	
B.The retention time of the	he major peak
corresponds to that of the	standard solu
primidone related compo phenobarbital ≤0.1%	und $A^a \leq 0.1^c$
	SPECIFICA (USP) white crystalline, Powder A. IR B.The retention time of the corresponds to that of the primidone related compo

0
(USP)
white crystalline, Powder, odourless. Slightly bit
A. IR
B.The retention time of the major peak in the sar
corresponds to that of the standard solution, as of
primidone related compound Aª ≤0.1%
phenoherbital < 0.1%

primidone related compound C^b≤0.1% 2-Cyano-2-phenylbutyramide ≤0.1% 2-phenylbutyric acid ≤0.1% phenylpropyl- primidone^c≤0.3% Any unspecified impurity ≤0.1%

≤0.5%

≤0.2%

98.0~102.0%

Total impurities ≤0.5%

Complies itter taste Complies Complies imple solution btained in the assay

N.D.
N.D.
0.02%
0.03%
0.10%
0.06%

99.48%

N.D.

N.D.

N.D.

<LOD,LOD=5×10⁻⁸g/ml