

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 21A0170/02

Lot No. : A-210089

Quantity. : 42.45 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder	Conforms	
Identification	Test A.- IR, Test B.- HPLC - Assay and Test C.- Chloride identification.	Conforms	
pH	3.5 - 5.5	5.2	
Loss on Drying	NMT 0.5%	Less than 0.05 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Chromatographic purity. Impurity MXT-200	NMT 0.10%	0.00 %	Not detected
Chromatographic purity. Impurity MXT-300.	NMT 0.10%	0.00 %	Not detected
Chromatographic purity. Any other individual impurity	NMT 0.10%	0.00 %	Not detected
Chromatographic purity. Total impurities	NMT 1.5%	0.00 %	Not detected
Assay	98.0 - 102.0% (on dry basis)	100.7 %	
2,6-Dimethylphenol	NMT 0.1%	Conforms	Not detected

Manufacturing date: February 9, 2021

Retest date: February 9, 2024

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