



**Specification for Labetalol Hydrochloride, USP,
bioCERTIFIED (TM) (LA901)**

Item Number	LA901
Item	Labetalol Hydrochloride, USP, bioCERTIFIED (TM)
CAS Number	32780-64-6
Molecular Formula	C ₁₉ H ₂₄ N ₂ O ₃ •HCl
Molecular Weight	364.87
MDL Number	
Synonyms	5-[1-Hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl]salicylamide Hydrochloride

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	97.5	101.0 %
DIASTEREOISOMER A CONTENT	45.0	55.0 %
pH OF A 1 IN 100 SOLUTION	4.0	5.0
CHROMATOGRAPHIC PURITY	TO PASS TEST	
LOSS ON DRYING		1.0 %
RESIDUE OF IGNITION		0.1 %
ELEMENTAL IMPURITIES		AS REPORTED
TOTAL AEROBIC COUNT		10 ³ cfu/g
TOTAL MOLDS AND YEASTS		10 ² cfu/g
ENDOTOXIN		1.2 EU/mg
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS		AS REPORTED

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