



**Specification for Cyclopentolate Hydrochloride, USP,
bioCERTIFIED (TM) (CY900)**

Item Number	CY900
Item	Cyclopentolate Hydrochloride, USP, bioCERTIFIED (TM)
CAS Number	5870-29-1
Molecular Formula	C ₁₇ H ₂₅ NO ₃ •HCl
Molecular Weight	327.85
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0%
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (HPLC)	TO PASS TEST	
IDENTIFICATION (CHLORIDE)	TO PASS TEST	
pH	4.5	5.5
RESIDUE ON IGNITION		0.05 %
ELEMENTAL IMPURITIES		AS REPORTED
ORGANIC IMPURITIES:		
INDIVIDUAL IMPURITY		1.0 %
TOTAL IMPURITIES		2.0 %
LOSS ON DRYING		0.5 %
BACTERIAL ENDOTOXINS		0.05 EU/mg
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT	10 ³ CFU/g	
TOTAL YEAST AND MOLD COUNT	10 ² CFU/g	
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

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