



**Specification for Phenylephrine Hydrochloride, USP,  
bioCERTIFIED (TM) (PH901)**

Item Number	PH901
Item	Phenylephrine Hydrochloride, USP, bioCERTIFIED (TM)
CAS Number	61-76-7
Molecular Formula	C <sub>9</sub> H <sub>13</sub> NO <sub>2</sub> •HCl
Molecular Weight	203.67
MDL Number	
Synonyms	(1R)-1-(3-Hydroxyphenyl)-2-methylaminoethanol Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (CHLORIDE)	TO PASS TEST	
IDENTIFICATION (HPLC)	TO PASS TEST	
SPECIFIC ROTATION @25 C	-43° to -47°	
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.2 %
SULFATE		0.20 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:	ACCEPTANCE CRITERIA	
NORPHENYLEPHRINE		0.10 %
PHENYLEPHRINE RELATED COMPOUND C		0.1 %
PHENYLEPHRINE RELATED COMPOUND D		0.10 %
PHENYLEPHRINE RELATED COMPOUND E		0.1 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.2 %
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		10 <sup>3</sup> CFU/g
TOTAL MOLDS AND YEASTS COUNT (TMYC)		10 <sup>2</sup> CFU/g
ENDOTOXIN BY LAL		25 EU/mg
IDENTIFICATION	TO PASS TEST	
APPEARANCE		
RETEST DATE		
MANUFACTURE DATE		

Test	Specification	
	Min	Max
RESIDUAL SOLVENTS	TO PASS TEST	

***Spectrum Chemical Mfg Corp***

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