



**Specification for Ropivacaine Hydrochloride, USP,
bioCERTIFIED(TM) (RO902)**

Item Number	RO902
Item	Ropivacaine Hydrochloride, USP, bioCERTIFIED(TM)
CAS Number	132112-35-7
Molecular Formula	C ₁₇ H ₂₆ N ₂ O•HCl•H ₂ O
Molecular Weight	328.89
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.5	101.0 %
pH OF A 10 mg/mL SOLUTION @ 25°C	4.5	6.0
WATER DETERMINATION	5.0	6.0 %
COLOR:		
@405nm		0.030
@436nm		0.025
CLARITY		TO PASS TEST
ORGANIC IMPURITIES (PROCEDURE 1):		
BUPIVACAINE		0.2 %
ANY OTHER INDIVIDUAL IMPURITY		0.1 %
TOTAL IMPURITIES		0.5 %
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT		10 ³ cfu/g
TOTAL COMBINED YEASTS AND MOLDS COUNT		10 ² cfu/g
BACTERIAL ENDOTOXINS		60 EU/mg
IDENTIFICATION		TO PASS TEST
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		TO PASS TEST

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