



Specification for Buprenorphine Hydrochloride (CIII), USP (B1637)

Item Number	B1637
Item	Buprenorphine Hydrochloride (CIII), USP
CAS Number	53152-21-9
Molecular Formula	C ₂₉ H ₄₁ NO ₄ •HCl
Molecular Weight	504.10
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
Country of Origin (COO)		
Animal Origin (BSE/TSE)		
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
SPECIFIC ROTATION [a] _D	-92° to -98°	
ACIDITY OR ALKALINITY		0.2 ml
WATER DETERMINATION		1.0 %
ORGANIC IMPURITIES:		
ETHENOBUPRENORPHINE		0.10 %
BUPRENORPHINE RELATED COMPOUND A		0.20 %
BUPRENORPHINE 2,2'-DIMER		0.10 %
ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.65 %
ELEMENTAL IMPURITIES	AS REPORTED	
PALLADIUM (Pd)	AS REPORTED	
RESIDUE ON IGNITION		0.1 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

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