

Item Number	N1231
Item	Naloxone Hydrochloride, Dihydrate, USP
CAS Number	51481-60-8
Molecular Formula	C ₁₉ H ₂₁ NO ₄ •HCl•2H ₂ O
Molecular Weight	399.87
MDL Number	
Synonyms	17-Allyl-6-deoxy-7,8-dihydro-14-hydroxy-6-oxo-17-normorphine Hydrochloride

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS)	98.0	102.0 %
SPECIFIC ROTATION [α] _D	-170° to -181°	
CONTENT OF CHLORIDE	9.54	9.94 %
LIMIT OF NALOXONE RELATED COMPOUND D		0.010 %
ORGANIC IMPURITIES:		
10?-HYDROXYNALOXONE		0.15 %
NOROXYMORPHONE		0.15 %
10?-HYDROXYNALOXONE		0.15 %
2,2'-BISNALOXONE		0.15 %
3-O-ALLYLNALOXONE		0.15 %
ANY UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.8 %
LOSS ON DRYING		11.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

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