



Specification for Methylphenidate Hydrochloride (CII), USP (M1600)

Item Number	M1600
Item	Methylphenidate Hydrochloride (CII), USP
CAS Number	298-59-9
Molecular Formula	C ₁₄ H ₁₉ NO ₂ •HCl
Molecular Weight	269.77
MDL Number	
Synonyms	Methyl ?-Phenyl-2-piperidylacetate Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
LOSS ON DRYING		0.5 %
ORGANIC IMPURITIES (PROCEDURE 2):		
METHYLPHENIDATE RELATED COMPOUND A		0.2 %
PHENYLACETIC ACID		0.1 %
(+/-)-ERYTHRO-ISOMER		0.2 %
ETHYLPHENIDATE		0.1 %
BIS-METHYLPHENIDATE		0.1 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.1 %
TOTAL IMPURITIES		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES:		
PALLADIUM (Pd)	AS REPORTED	
PLATINUM (Pt)	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

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