

## Specification for Diphenhydramine Hydrochloride, USP (DI160)

Item Number	DI160
Item	Diphenhydramine Hydrochloride, USP
CAS Number	147-24-0
Molecular Formula	C <sub>17</sub> H <sub>21</sub> NO•HCl
Molecular Weight	291.82
MDL Number	
Synonyms	Benzhydramine Hydrochloride ; Benadryl

Test	Specification	
	Min	Max
ASSAY	98.0	102.0 %
ACIDITY OR ALKALINITY		0.5 ml 0.01N NAOH TO CHANGE COLOR TO YELLOW
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES		
DIPHENHYDRAMINE RELATED COMPOUND A		0.5 %
4-METHYLDIPHEN HYDRAMINE		0.3 %
4-BROMODIPHENHYDRAMINE		0.3 %
BENZHYDROL		0.3 %
BENZOPHENONE		0.3 %
ANY OTHER UNSPECIFIED IMPURITY		0.1 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B) as ID B (HPLC)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION C (Chloride)	POSITIVE FOR CHLORIDE	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

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