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Certificate of Analysis

Product Name:	Diphenhydramine Hydrochloride	
Chemical Name:	2-(Diphenylmethoxy)- <i>N,N</i> -dimethylethylamine hydrochloride	
CAS No.:	147-24-0	
Molecular Formula:	C ₁₇ H ₂₁ NO·HCl	
Molecular Weight:	291.82	
Batch No.:	DH-202307201	
Quantity:	1002.46kg	
Production Date:	June 27, 2023	
Analysis Date:	July 04, 2023	
Retest Date:	June 26, 2027	
Packaging Size:	25kg/fiber drum	
Packaging and Storage:	Preserve in tight, light-resistant containers. Store at room temperature.	
Method of Analysis:	USP2023	
NDC No.:	68166-001-01	
TEST ITEMS CHARACTER	SPECIFICATION	TEST RESULTS
Appearance	White crystalline powder	Complies
IDENTIFICATION		
A. IR	Conform to the requirements	Complies
B. HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
C. Chloride	Conform to the requirements	Complies
ASSAY		
Assay	98.0%–102.0% on the dried basis	100.3%
IMPURITIES		
Residue on ignition	NMT 0.1%	0.04%
Organic impurities	Diphenhydramine related compound A: NMT 0.5%	0.1%
	4-Methyldiphenhydramine: NMT 0.3%	Not detected
	4-Bromodiphenhydramine: NMT 0.3%	Not detected
	Benzhydrol: NMT 0.3%	Not detected
	Benzophenone: NMT 0.3%	Not detected
	Any other unspecified impurity: NMT 0.10%	Not detected
	Total impurities: NMT 1.0%	0.1%
Residual solvents	Ethanol: NMT 0.5%	0.03%
	Toluene: NMT 0.089%	0.001%
SPECIFIC TESTS		
Acidity or alkalinity	NMT 0.5 mL of 0.01N sodium hydroxide is required to change the color of the solution to yellow.	Complies
Loss on drying	NMT 0.5%	0.08%
Conclusion:	All of the results conform to USP2023 specs.	

