

Certificate of Analysis

Product Name	Diphenhydramine Hydrochloride	Batch No.:	RY180315
Quantity:	500KG	CAS NO.	147-24-0
Manufacture Date:	2018.03.15	Expiry Date:	2023.03.14
Item	Specification	Result	
Appearance	White or almost white crystalline powder	Conforms	
Identification	By UV, the ratio of the absorbance measured at the max at 258nm to the measured at the max, at 264nm is 1.2 to 1.4	Conforms	
	By IR as per BP2016	Conforms	
Solubility	Very soluble in water ,freely soluble in ethanol	Conforms	
Melting Point	168~172°C	170°C	
Chloride test	It gives reaction of chloride	Conforms	
Acidity or alkalinity	As per BP-2016	Conforms	
Appearance of solution	Clear and not more intensely colored than reference solution BY6	Clear and colorless	
Loss on drying	≤0.5%	0.20%	
Sulphated ash	≤0.1%	0.05%	
Related substance	Impurity A : ≤0.5%	Conforms	
	Impurity B : ≤0.3%	Conforms	
	Impurity C : ≤0.3%	Conforms	
	Impurity D : ≤0.3%	Conforms	
	Impurity E : ≤0.3%	Conforms	
	Any other unspecified impurity: ≤0.3%	0.070%	
	Total impurities: ≤1.0%	0.104%	
Assay (on the dried basis)	99.0%~101.0%	99.64%	
Total aerobic microbial count	≤1000cfu/gm	Conforms	
Total yeast&mold count	≤100cfu/gm	Conforms	
Residual solvents	ISO Propyl alcohol-2000ppm	N.D.	
	Mono Chloro Benzene 300ppm	888 ppm	
Standard: it conforms to BP2016 standard.			

Tested by: Cherry

Checked by: Alice

Approved by: Mich

