

CERTIFICATE OF ANALYSIS

Product Name	Meclofenoxate hydrochloride	Batch NO.	RY190405
Production date	2019.04.05	Expired Date	2021.04.04
CAS NO.	3685-84-5	Standard	JP standard
Tests	Limits	Test results	
Appearance	White crystals or crystalline powder	White crystalline powder	
PH	3.5~4.5	4.03	
Identification	Iron(III) chloride TS	Conforms	
	Reinecke salt TS	Conforms	
	UV	Conforms	
	Qualitative test for chloride	Conforms	
Melting point	139~143℃	139.8~142.1℃	
Charity and color of solution	Clear and colorless	Pass	
Sulfate	≤0.048%	Pass	
Heavy metals	≤20ppm	Pass	
Arsenic	≤2ppm	Pass	
Organic acids	≤0.54ml	0.12ml	
Water	≤0.5%	0.20%	
Residue on ignition	≤0.1%	0.03%	
Residual organic solvents	ethanol≤0.5%	None	
	isopropanol≤0.5%	None	
	methylbenzene≤0.089%	None	
Related substances	Single unknown impurity ≤0.5%	0.01%	
	Total impurities ≤1.0%	0.02%	
Count of bacteria	Bacillus<1000Enteries/1g	Conforms	
	Mildew<100Enteries/1g	Conforms	

	Microzyme < 100 Enteries/1g	Conforms
Assay (calculated on the anhydrous basis )	≥ 98%	99.1%
Color absorbance test	UV absorbance at 410nm ≤ 0.05	0.004
Bacterial endotoxins	≤ 0.35 EU/mg	Pass
Conclusion: It conforms JP standard.		

Tested by: Esther

Checked by: Alice

Approved by: Mich

