

SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

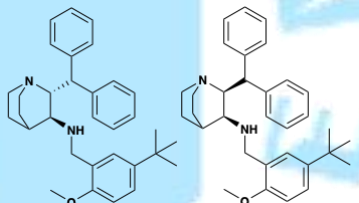
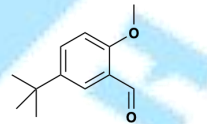
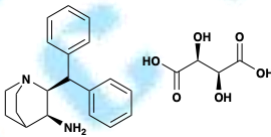
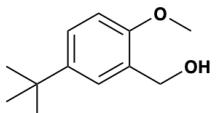
Product name	Maropitant Citrate (Cas 359875-09-5)		
Batch No.	20210301	Mfg. date	2021.03.15
Rep. Date	2021.03.24	Exp. date	2024.03.14
Packaging	1kg/bag	Batch Size	6.5kg
Test Items	Standards: Enterprise		Results
Appearance	White to almost white powder		White power
Identification	IR: It should be corresponds to the standard.		conforms
	Identification of citrate: Addition of pyridine-acetic anhydride(3:1) produces a yellow color, turning to red or amaranth.		conforms
Appearance of solution	Soluble in methanol, the solution is clear and colorless.		conforms
Residue on ignition	≤ 0.1%		0.05%
pH	4.0~4.5		4.5
Heavy metals	≤20ppm		<20ppm
Citric acid	27.7-28.9%		28.1%
Related Substances	Impurity A≤0.50%		Not detected
	Impurity B≤0.50%		Not detected
	Impurity C≤0.50%		Not detected
	Impurity D≤0.50%		Not detected
	Specified impurity(RRT=0.90)≤0.5%		0.22%
	Individual unspecified impurity≤0.20%		0.05%
Total impurities≤2.0%		0.34%	
Enantiomer	≤0.5%		Not detected
Water	2.5%~4.0%		2.6%
Residual Solvents 1	Methanol≤3000ppm		189ppm
	2-Butanil≤5000ppm		<4ppm
	Ethyl acetate≤5000ppm		<1.2ppm
	Tetrahydrofuran≤720ppm		<0.7ppm
	2-Propanol≤5000ppm		<0.6ppm
	Acetone≤5000ppm		<0.1ppm
	n-Heptane≤5000ppm		341ppm
	Toluene≤890ppm		<0.3ppm
	Tert-Butylmethyl ether≤5000ppm		393ppm
	Tert-butanol≤161.5ppm		<1ppm
	triethylamine≤5000ppm		<15ppm
	Acetonitrile≤410ppm		<0.7ppm

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Residual Solvents 2	N,N-Dimethylformamide≤880ppm		<1ppm
Residual Solvents 3	Dichloromethane≤600ppm		<0.9ppm
Assay	98.5~101.5%(on the anhydrous basis)		99.5%
Conclusion	It meets the requirements of Enterprise Standards.		
Storage	In an air tight container, protected from light and moisture.		
Prepared by: LI	Reviewed by: WEI	Released by: Zhang	

Information of impurity

	Name	Structure
Impurity A	(2R,3S)-(2-Benzhydryl-1-aza-bicyclo[2.2.2]oct-3-yl)-(5-tert-butyl-2-methoxy-benzyl)-amine (2S,3S)-(2-Benzhydryl-1-aza-bicyclo[2.2.2]oct-3-yl)-(5-tert-butyl-2-methoxy-benzyl)-amine	
Impurity B	5-tert-butyl-2-methoxybenzaldehyde	
Impurity C	(2S,3S)-(2-Benzhydryl-1-aza-bicyclo[2.2.2]oct-3-yl)-amine D-tartaric acid	
Impurity D	5-tert-butyl-2-methoxybenzyl alcohol	

END OF REPORT