

CERTIFICATE OF ANALYSIS

Product Name	Bisoprolol Fumarate	Batch NO.	RY190321
Production date	2019.03.21	Expired Date	2021.03.20
CAS NO.	104344-23-2	Standard	EP9.0 standard
Tests	Limits	Test results	
Appearance	White to almost white Powder	White powder	
Identification	IR spectrum corresponds to that of Bisoprolol Fumarate CRS	Conforms	
Related substances(HPLC)	Impurity G $\leq 0.5\%$	$< 0.05\%$	
	Impurity A $\leq 0.3\%$	$< 0.05\%$	
	Impurity E $\leq 0.2\%$	$< 0.05\%$	
	The single impurity $\leq 0.10\%$	$< 0.05\%$	
	Total impurities $\leq 0.5\%$	$< 0.05\%$	
Water (K.F)	$\leq 0.5\%$	0.08%	
Sulfated ash	$\leq 0.1\%$	0.06%	
Assay (on anhydrous basis)	99.0%~101.0%	99.6%	
Residual solvents(GC)	2-propanol $\leq 5000\text{ppm}$	108ppm	
	Epichlorohydrin $\leq 100\text{ppm}$	6ppm	
	Dichloromethane $\leq 600\text{ppm}$	4ppm	
Conclusion: This batch meets EP9.6 standard.			

Tested by: Esther

Checked by: Alice

Approved by: Mich

