

Certificate of Analysis

Product Name	Candesartan Cilexetil	Mfg. Date	2019.06.02
Batch No.	PBG2019060205	Testing Date	2019.06.03
Batch Quantity	55kg	Exp. Date	2021.06.01

Items	Specifications	Results
Appearance	A white or almost white powder	White powder
Identification-IR	Complies with the reference spectrum	Complies
Identification- UV	Maximal absorptions at 254nm, minimum absorption at 242nm	Complies
Water	≤ 0.3%	0.19%
Residual solvents		
Methanol	≤ 3000ppm	Not found
Ethanol	≤ 5000ppm	Not found
Ethyl ether	≤ 5000ppm	68ppm
Acetone	≤ 5000ppm	482ppm
Ethyl acetate	≤ 5000ppm	Not found
Dichloromethane	≤ 600ppm	Not found
Dimethylformamide	≤ 880ppm	Not found
Related substances		
Impurity A	≤ 0.15%	< 0.05%
Impurity B	≤ 0.3%	< 0.05%
Impurity F	≤ 0.2%	< 0.05%
Impurity G	≤ 0.2%	< 0.05%
Impurity H	≤ 0.15%	Not found
Other individual impurity	≤ 0.10%	0.04%
Total impurities	≤ 0.6%	0.21%
Sulfated ash	≤ 0.1%	0.06%
Heavy metals	≤ 10ppm	<10ppm
Assay (Dried substance)	99.0~101.0%	99.8%
Conclusion:	The product complies with EP 9.0	



Corrector:

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Analyst:

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