



四川青益纯医药科技有限公司
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CERTIFICATE OF ANALYSIS

Product Name	Quetiapine Fumarate	CAS No.	111974-72-2
Batch No.	P021160517A	Mfg. Date	Nov. 18, 2017
Quantity	200kg	Retest Date	Nov. 17, 2019
Packing	20kg/Drum	Report Date	Nov. 25, 2017
Specification	Ph.Eur		

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white powder	White powder
Solubility	Slightly soluble in water, in anhydrous ethanol and in methanol	Complies
Identification	IR: The IR spectrum of sample is identical with that of reference standard	Complies
Heavy Metals	≤ 10ppm	Complies
Loss on Drying	≤0.5%	<0.1%
Sulphated Ash	≤0.1%	<0.1%
Related Substances		
Impurity G	≤0.15%	Undetected
Impurity N	≤0.15%	Undetected
Impurity I	≤0.10%	<0.05%
DTC	≤0.10%	Undetected
Impurity B	≤0.10%	Undetected
Any Unspecified Impurity	≤0.10%	<0.05%
Total Impurities	≤0.5%	0.1%
Assay(Dried Basis)	Fumaric acid: 12.5%~13.8%	13.2%
	Quetiapine fumarate: 99.0%~101.0%	99.8%
Residual Solvents		
Methanol	≤3000ppm	43ppm
Ethanol	≤5000ppm	832ppm
Toluene	≤890ppm	Undetected
Conclusion	The product conforms to Ph.Eur.	
Remarks	N/A	

Analyst:

QC Manager:

QA: