



Certificate of analysis

Product name: Apixaban

Cas number: 503612-47-3

Molecular Formula: $C_{25}H_{25}N_5O_4$

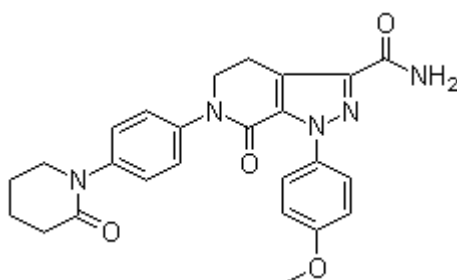
Molecular Weight: 459.50

Date of production: May. 07, 2018

Batch NO: 20180507

EXP DATE: May. 06, 2020

Chemical structure:



Items	Specifications	Results
Description	off-white powder to white powder	white powder
Identification	BY IR, HPLC & XRD	Conform
Residue on Ignition	$\leq 0.5\%$	0.20%
Water	$\leq 1.0\%$	0.23%
Residual Solvent	Methanol ≤ 3000 ppm	Conform
	Ethanol ≤ 5000 ppm	Conform
	Ethyl Acetate ≤ 5000 ppm	Conform
Related substances	Impurity A $\leq 0.1\%$	0.05%
	Any other impurity $\leq 0.1\%$	0.075%
	Total impurities $\leq 1.0\%$	0.32%
Particle size	D90 < 10 microns	Conform
Microbiological Examination	TAMC ≤ 1000 cfu/g	Conform
	TYMC ≤ 100 cfu/g	Conform
	Escherichia coli Absence in 1g	Conform
Assay	Not less than 98.0% and not more than 102.0% w/w	99.68%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang