



Certificate of analysis

Product name: Adapalene

Cas number: 106685-40-9

Molecular Formula: $C_{28}H_{28}O_3$

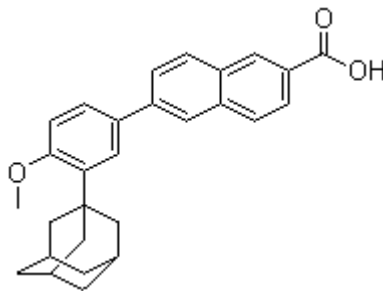
Molecular Weight: 412.52

Date of production: Sep. 22, 2017

Batch No: 20170922

Date of Expiry: Sep, 21st, 2019

Chemical structure:



Items	Specifications	Results
Appearance	White or almost white powder	Conform
Solubility	Practically insoluble in water, sparingly soluble in tetrahydrofuran, practically insoluble in ethanol (96 percent)	Conform
Appearance of solution	The solution is clear and not more intensely coloured than reference solution BY6	Conform
Identification	By HPLC	Conform
Loss on drying	$\leq 0.5\%$	0.20%
Sulfated ash	$\leq 0.1\%$	0.05%
Heavy metals	$\leq 20\text{ppm}$	Conform
Residual solvent	Triethylamine $\leq 80\text{ppm}$	undetected
Related substances	Impurity A: $\leq 0.3\%$ Impurity D: $\leq 0.2\%$ Impurity C: $\leq 0.15\%$ Disregard limit: $\leq 0.05\%$ Unspecified impurities: $\leq 0.1\%$ Total Impurities: $\leq 0.5\%$	Conform Conform Conform Conform 0.27%
Assay (dried substance)	98.0 per cent to 102.0 per cent	99.73%

Conclusion: It complies with the EP7.0 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F