



# Certificate of analysis

Productname: **Nevirapine**

Cas number: 129618-40-2

Molecular Formula: C<sub>15</sub>H<sub>14</sub>N<sub>4</sub>O

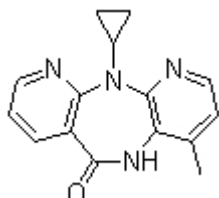
Molecular Weight: 266.30

Date of production: May. 16, 2014

Batch no: 20140516

Exp Date: May. 15, 2016

Chemical structure:



Items	Specifications	Results
<b>Appearance</b>	White to off-White ,odorless to nearly odorless crystalline powder	White crystalline powder
<b>Identification</b>	IR ,HPLC	Conforms
<b>Water</b>	≤0.2%	0.03%
<b>Residue on ignition</b>	≤0.1%	0.04%
<b>Heavy metals</b>	≤0.001%	Conforms
<b>Solubility</b>	Practically insoluble in water(0.001g in 100ml and over)	Conforms
	Slightly soluble in alcohol(0.1g in 100ml)	Conforms
	Slightly soluble in methanol(0.1g in 100ml)	Conforms
<b>Residual solvents</b>	Alcohol: ≤5000ppm Ethyl acetate: ≤5000ppm Diglyme: ≤50ppm	116PPM 339PPM undetected
<b>Related substances</b>	Nevirapine related compound A: ≤0.2% Nevirapine related compound B: ≤ 0.2% Nevirapine impurity C: ≤0.2% Individual impurity: ≤ 0.1% Total impurities : ≤0.6%	Conforms 0.02% Conforms Conforms 0.03%
<b>Particle size</b>	90%: ≤50.0 μ m	≤40 μ m
<b>Assay</b>	98.0%~102.0% ( anhydrous and solvent-free)	99.0%

**Conclusion: It complies with the USP33 Standard.**

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F