



## Certificate of Analysis

Product Name	Gabapentin	Standard	EP9.0
Batch No.	VANZ-20190523	Batch Quantity	200kg
Manufacture Date	2019.05.06	Report Date	2019.07.04
Expiry Date	2023.05.05	Packing	25kg/drum

Items	Specifications	Results
Appearance	White or off-white crystalline powder	White crystalline powder
Identification	Sparingly soluble in water, slightly soluble in ethanol (96 percent), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides	Conform
Identification	IR: complies with spectrum of WS.	Conform
Water	Not more than 0.3%	0.2%
Appearance of solution	The solution is clear and colourless	Conform
PH	6.5-7.5	7.2
Sulfated ash	Not more than 0.1 %	0.1%
Heavy metals	Not more than 20ppm	Less than 20ppm
Limit of chloride	Not more than 100ppm	Less than 100ppm
Related substance	Impurity A: not more than 0.15%	<0.03%
	Impurity B: not more than 0.10%	<0.03%
	Impurity CDMA: not more than 0.10%	<0.03%
	Max individual unknown impurity: not more than 0.10%	<0.03%
	Impurity D: not more than 0.05%	<0.02%
	Impurity CAI: not more than 0.05%	<0.02%
	Max individual unknown impurity: not more than 0.05%	<0.02%



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Total impurity(A and B )	Not more than 0.5%	0.04%
Residual solvent	Methanol: not more than 3000ppm	99ppm
	Isopropanol: not more than 5000 ppm	86ppm
	Methylene chloride: not more than 600ppm	N.D
	Toluene: not more than 890ppm	N.D
	Benzene: not more than 2ppm	N.D
Particle size distribution	D10:/	3.5um
	D50:/	26.1 um
	D90:/	112.2um
Assay(Calculated on the anhydrous basis)	97.5-102.0%	100.3%
Conclusion	The above Product conforms to EP9.0	

Tested by: Wang Xiaohang  
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Checked by: Du Ke  
Issued by: Lei Xiaogang

