



JIANGXI SYNERGY PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

SYNERGY

CAS: 60142-96-3

version: 01

No.: D2007026

Product name	Gabapentin(E)		
According to	USP42	Batch No.	08-20200701D
Package	Fibre drum	Manufacturing date	2020.06.28
Package size	25KGS/drum	Report date	2020.07.11
Quantity	801.3KGS	Retest date	2022.06.27
Items	Specifications		Results
Appearance	A white to off white crystalline powder		White crystalline powder
Identification	A.IR spectrum should comply with the WS		Conform
	B.HPLC-RT should comply with the WS		Conform
pH	6.5-8.0		7.1
Water	Not more than 0.5%		0.1%
Residue on ignition	Not more than 0.1%		0.0%
Early Eluting Impurities	Impurity A: not more than 0.1%		<0.02%
	Impurity B: not more than 0.06%		<0.02%
	Impurity E: not more than 0.10%		<0.02%
	Impurity CDMA: not more than 0.10%		<0.02%
	Max individual impurity: not more than 0.10%		<0.02%
Late Eluting Impurities	Impurity D: not more than 0.10%		<0.02%
	Impurity CAI: not more than 0.05%		<0.02%
	Max individual impurity: not more than 0.10%		<0.02%
*Total impurity	Not more than 0.5%		<0.02%
Residual solvent	Ethyl acetate: Not more than 5000ppm		N.D
	Methylene chloride: Not more than 600ppm		N.D
	Ethanol: Not more than 5000ppm		80ppm
Assay(Calculated on the anhydrous basis)	98.0-102.0%		99.9%

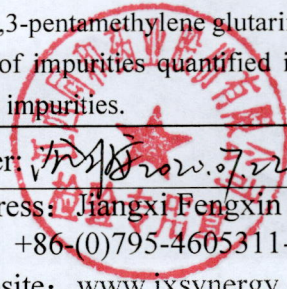
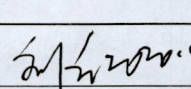
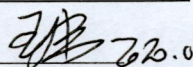
Conclusion: Complies with USP42.

Note:

CDMA: 1,1-cyclohexane diacetic acid mono amide

CAI: 3,3-pentamethylene glutarimide

*Sum of impurities quantified in limit of early eluting impurities and impurities quantified in limit of late eluting impurities.

Lister:  QC Supervisor:  QA Supervisor:  2020.07.22

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