

JIANGXI SYNERGY PHARMACEUTICAL CO., LTD.

OF ANALYSIS **CERTIFICATE**

CAS: 60142-96-3 version: 01 No.: D2007026

| CAS. 00142-90-3 | VCISI | 110 D2007020 | |
|--|--|--------------------|--------------------------|
| 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 |
| pН | 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% |
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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.

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