

## Jinan Hongfangde Pharmatech Co., Ltd. Tel: 86-531-88870908 Fax:86-531-88870908

Email: sdhfdchem@163.com Website: www.hfdchem.com

## CERTIFICATE OF ANALYSIS

| Product name | Gadopentetic acid |             |            |
|--------------|-------------------|-------------|------------|
| Batch No.    | 20190211          | Expiry date | 2021-02-10 |
| Report Date  | 2019-02-21        | Quantity    | 525kg      |

| Inspection Items                                | Accepted Standard   | Results                  |  |  |
|---|---|--------------------------|--|--|
| Appearance                                      | White or off-white crystalline powder,odorless,hygroscopic.   | White crystalline powder |  |  |
| Solubility                                      | Freely soluble in water, practically insoluble in alcohol and acetone.  | Complies                 |  |  |
| Identification                                  | The main peak retention time of test solution should comply with working standard   | Complies                 |  |  |
| Clarity and colour solution                     | Clarity and colorless, if colored, compare with NO.1 yellow standard colorimetric solution, no deeper. If turbid, compare with No. 1 turbidity standard solution, not deeper. | Complies                 |  |  |
| Loss on drying                                  | Not more than 6.0%  | 2.9%                     |  |  |
| Free DTPA                                       | Not more than 0.05%   | Not found                |  |  |
| pН  | 1.0~2.0   | 1.49                     |  |  |
| Related substance                               | Not more than 1.0%  | 0.18%                    |  |  |
| Assay   | 98.0~102.0%   | 99.89%                   |  |  |
| Conclusion: Complies to the enterprise standard |   |                          |  |  |

Analyst :lixin Checker:shilijuan Supervisor :maohongjun