



# Certificate of analysis

**Product name:** Alirocumab  
**Batch No.** 201801  
**Manufacture Date** 2018/03/25  
**Expire Date** 2021/03/24  
**Storage condition** Sealed and stored at  $-70\pm 15$  °C

| Test items                        | Quality standard  | Results     |
|-----------------------------------|---|-------------|
| 1. Concentration                  | $150.0\pm 15.0$ mg/ml   | 151.3 mg/ml |
| 2. pH value                       | Corresponds to reference standard   | Pass        |
| 3. Purity                         |   |             |
| 3.1 Non-reduced CE-SDS            | Main peak NLT 90.0%   | 98.3%       |
| 3.2 SEC-HPLC                      | Main peak NLT 95.0%   | 99.2%       |
| 4. Isoelectric Point              | Corresponds to reference standard   | Pass        |
| 5. Bacterial Endotoxins Test      | <15 EU/ml   | 1 EU/ml     |
| 6. Residual Proteins of Host Cell | $\leq 100$ ng/mg  | 1 ng/mg     |
| 7. Exogenous Residual DNA         | $\leq 100$ pg/mg  | <1 pg/mg    |
| 8. Residual protein A             | $\leq 100$ ng/mg  | <1 ng/mg    |
| 9. Biological Activity            | Compared with standard, the range of biological activity is from 80% to 125%. | 101%        |
| 10. Osmolality                    | Corresponds to reference standard   | Pass        |
| 11. Peptide mapping               | Corresponds to reference standard   | Pass        |
| 12. N-terminal sequence           | Corresponds to reference standard   | Pass        |

Reported by/Date  
Zhang Ziling  
2018/04/12

Approved by/Date  
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2018/04/12

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