

# ExaminingReport

|                        |                                                                                                                                                                                                                                                                                                |                      |                     |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------|
| Sample Name            | H24                                                                                                                                                                                                                                                                                            | Sample Number        | 25B11113-9          |
| Sample size            | 1 unit                                                                                                                                                                                                                                                                                         | Sample Source        | End product         |
| Examination date       | 2026.03.05                                                                                                                                                                                                                                                                                     | Sample Status        | Freeze-dried powder |
| Storage Conditions     | 2-8℃                                                                                                                                                                                                                                                                                           | Inspection Personnel | QL                  |
| Facility information   | HPLC, ELISA microplate reader, pH meter, etc.                                                                                                                                                                                                                                                  |                      |                     |
| Inspecting item        | Protein concentration, purity testing, pH value, appearance inspection                                                                                                                                                                                                                         |                      |                     |
| Inspection standard    | Refer to the ICH "Technical Requirements for the Registration of Human Use Pharmaceuticals"                                                                                                                                                                                                    |                      |                     |
| Inspect the conclusion | <div>Key parameters such as protein concentration and purity all met the expected requirements.</div> <div>Conclusion: The quality of this batch of protein samples meets the standards.</div> <div></div> |                      |                     |
| Remarks                | All instruments and equipment used during the testing process have been calibrated, and the detection methods have been validated.                                                                                                                                                             |                      |                     |

| Order number | Inspecting item                   | Result            | Standard Requirements | Conclusion  |
|--------------|-----------------------------------|-------------------|-----------------------|-------------|
| 1            | Protein concentration measurement | 8.46mg/ml         | ≥ 8 mg/ml             | Qualified   |
|              | Bioactivity                       | 25.4IU/ml         | ≥ 2.4 IU/ml           | Qualified   |
| 2            | Purity Testing                    | 97.93%            | ≥96%                  | Qualified   |
| 3            | PH price                          | 7.0               | PH7.0                 | Qualified   |
| 4            | Surface                           | White fine powder | White fine powder     | Accord with |
| 5            |                                   |                   |                       |             |

Test Items and Methods:

- 1. Protein concentration determination: Determined using Agilent high-performance liquid chromatography (HPLC).
- 2. Purity determination: Analyzed using Agilent high-performance liquid chromatography (HPLC).
- 3. Other: such as pH value, appearance, etc.

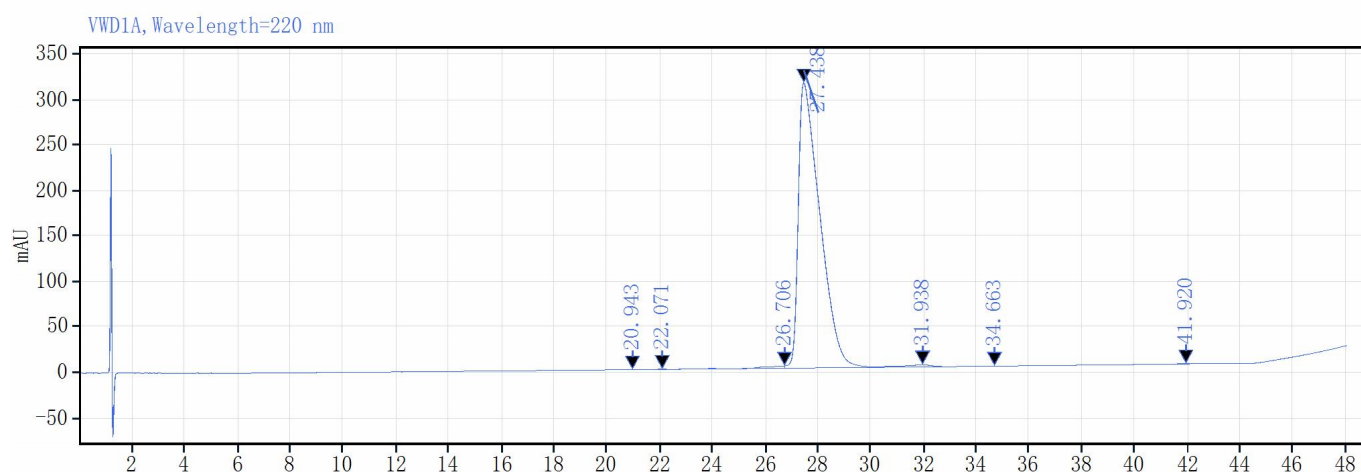
# Single Injection Report



Agilent Technologies

**data file :** 2026-03-05 10-53-13+08-00-01.dx  
**Sequence Name:** HPLC1290-2026-03-05 10-53-02+08-00  
**Sample Name:** H24 25B11113-9  
**instrument :** HPLC1290  
**Injection volume:** 3.000  
**acquisition method :** GH  
**processing method :** GC\_LC  
 Area Percentage\_DefaultMethod.pmx  
**Manual modification:** Manual Integration

**project name :** Agilent 1290 Infinity  
**handlers :** system  
**Injection date:** 2026-03-05 10:53:58+08:00  
**position :** 60  
**type :** sample  
**Sample Content:** 0.00



**signal :** VWD1A, Wavelength=220 nm

| retention time | type | peak width [min] | peak area | altitude | peak area % | name |
|----------------|------|------------------|-----------|----------|-------------|------|
| 20.943         | MM m | 0.74             | 4.74      | 0.11     | 0.03        |      |
| 22.071         | MM m | 0.41             | 8.37      | 0.24     | 0.05        |      |
| 26.706         | MM m | 0.96             | 149.52    | 2.58     | 0.83        |      |
| 27.438         | MM m | 0.84             | 17744.31  | 314.01   | 97.93       |      |
| 31.938         | MM m | 1.05             | 192.57    | 2.37     | 1.06        |      |
| 34.663         | MM m | 0.60             | 8.32      | 0.23     | 0.05        |      |
| 41.920         | MM m | 0.45             | 11.82     | 0.31     | 0.07        |      |
|                |      | sum              | 18119.65  |          |             |      |