

## Certificate of Analysis

**Product name:** Heparinum natricum  
**Batch number / Weight:** 24K06-B11-006064 / 1 g  
**Producer / Producer Batch Number:** Changzhou Qianhong Bio-Pharma. Co.,Ltd. / 18240623038  
**Analyzed according to:** Ph. Eur. 11.7  
**Number of Analysis / Certificate no.:** 24K06-B11 / QO0010905

|                                                 | Requirement                                  | Result  | Unit  | Standard remark |
|-------------------------------------------------|----------------------------------------------|---------|-------|-----------------|
| Appearance                                      | (Almost) white hygroscopic powder            | Conform |       |                 |
| Identification                                  | A, B, C, D, E                                | Conform |       |                 |
| Appearance of solution                          | Clear / <=ref. colour 5                      | Conform |       |                 |
| pH                                              | 5,5 - 8,0                                    | 6,59    |       |                 |
| Nucleotidic impurities                          | A (260nm) <= 0,15                            | 0,075   |       |                 |
| Protein                                         | <=0,5                                        | 0,11    | %     |                 |
| Related substances                              | Conform                                      | Conform |       |                 |
| Sum of dermatan sulfate and chondroitin sulfate | <=2,0                                        | 0,40    | %     |                 |
| Any other impurity                              | <=0,02                                       | <0,02   | %     |                 |
| Nitrogen                                        | 1,5 - 2,5                                    | 1,79    | %     |                 |
| Sodium                                          | 10,5 - 13,5                                  | 11,7    | %     |                 |
| Loss on drying                                  | <=8,0                                        | 0,01    | %     |                 |
| Bacterial endotoxins                            | <=0,01                                       | <0,01   | IU/IU |                 |
| Assay                                           | >=180                                        | 212     | IU/mg |                 |
| Metallic residues                               | CHMP/ICH/353369/2013                         | Conform |       | DP              |
| Residual solvents                               | CPMP/ICH/82 260/06                           | Conform |       | DP              |
| TSE/BSE-statement:                              | No contamination with TSE/BSE-risk materials | Conform |       | DP              |

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

**Release:**

11-5-2025  
 Dominika Sotysik  
 Qualified Person

**Expiration:** 22-6-2027

**Conclusion:** APPROVED

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