

## Certificate of Analysis

**Product name:** Adrenalini tartras  
**Batch number / Weight:** 23I11-B18-232438 / 1 G  
**Analysed according to:** Ph.Eur.11.2  
**Number of analysis / Inspection Code** 23I11-B18 / INS-23-7471  
**Reference Code / No.:** V01483 / E80-22001

| Tests                           | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance                      | (Grey-)white, crystalline powder             | Conform |      |                 |
| Identification A                | -50 - -53,5                                  | -52,2   |      |                 |
| Identification B                | Conform                                      | Conform |      |                 |
| Identification C                | Conform                                      | Conform |      |                 |
| Appearance of solution          | <=ref. susp. II / <= BY5                     | Conform |      |                 |
| Related substances              | Conform                                      | Conform |      |                 |
| Impurity A                      | <=0,3  | 0,15    | %    |                 |
| Impurity B                      | <=0,2  | <0,05   | %    |                 |
| Impurity C                      | <=0,2  | <0,05   | %    |                 |
| Impurity D                      | <=0,1  | <0,05   | %    |                 |
| Impurity E                      | <=0,1  | <0,05   | %    |                 |
| Unspecified impurities          | <=0,10                                       | <0,05   | %    |                 |
| Total impurities                | <=0,6  | 0,15    | %    |                 |
| Loss on drying                  | <= 0,5                                       | 0,05    | %    |                 |
| Sulphated ash                   | <= 0,1                                       | 0,00    | %    |                 |
| Metallic residues               | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents               | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay Adrenaline hydrogen tartr | 98,5 - 101,0                                 | 99,62   | %m/m |                 |
| TSE/BSE-statement:              | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

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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 Fagron PL lab

Release:  
Dominika Soltysik  
Qualified Person

08-11-2023

Expiration: 16-10-2026

Conclusion: APPROVED

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