



## Certificate of Analysis

**Product name:** **Tretinoin**  
**Number of analysis:** T0003727  
**Batch number / Weight:** **17H10-H02-00027 / 1g**  
**Producer / Producer Batch Number:** Chongqing Huapont Pharmaceutical Co., Ltd / TRER-20160408  
**Analysed according to:** **PH.EUR 8.8**

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|----------------------------------------------|---------|------|-----------------|
| Appearance             | Yellow or light orange, crystalline powder   | Conform |      |                 |
| Identification A       | Conform                                      | Conform |      | IR-spectrum     |
| Related substances     | Conform                                      | Conform |      | HPLC            |
| Impurity A             | $\leq 0,5$                                   | $<0,05$ | %    |                 |
| Unspecified impurities | $\leq 0,2$                                   | $<0,2$  | %    |                 |
| Total                  | $\leq 1,0$                                   | $<1,0$  | %    |                 |
| Heavy metals           | $\leq 20$                                    | Conform | ppm  |                 |
| Loss on drying         | $\leq 0,5$                                   | 0,1     | %    | 16h vacuo       |
| Sulfated ash           | $\leq 0,1$                                   | 0,1     | %    |                 |
| Assay Tretinoin        | 98,0 - 102,0                                 | 102,0   | %m/m | Dried           |
| Residual solvents      | CPMP/ICH/82 260/06                           | Conform |      | DP              |
| TSE/BSE-statement      | No contamination with TSE/BSE-risk materials | Conform |      | DP              |

Analysis performed by the authorized internal lab and lab Eurofins Parijs.

Release:  
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Pharmacist - QA Manager / QP

28/08/2017

Expiration: 13-04-2019

Conclusion: APPROVED

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