

## Certificate of Analysis

Certificate No.: 9758

Product: Genestran 75mcg/ml inj 50ml RO      Manufacturing date: 27-06-19  
Product-No.: 00100317      Expiry date: 28-02-22  
Batch-No.: 6450519  
Split: 0  
Quantity: 200 Unit(s)

| Parameter                                   | Specification                                                       | Result         |
|---------------------------------------------|---------------------------------------------------------------------|----------------|
| Appearance                                  | Clear, odorless and colorless solution, free from particular matter | complies       |
| pH-Value                                    | 5,5 ... 6,5                                                         | 5,8            |
| Relative Density                            | 1,005 ... 1,015                                                     | 1,009          |
| Identity (+)-Cloprostenol-Natrium           | positive                                                            | Corresponds to |
| Identity Chlorocresol                       | positive                                                            | Corresponds to |
| Assay (+)-Cloprostenol                      | 71,2 ... 78,8                                                       | 75,9 µg/ml     |
| Assay Chlorocresol                          | 0,9 ... 1,1 mg/ml                                                   | 1,0 mg/ml      |
| 3-Chlorophenol                              | Max. 1,0 %                                                          | 0,0 %          |
| 15S-(+)-Cloprostenol                        | Max. 1,0 %                                                          | 0,0 %          |
| Unkown impurity of(+)-Cloprostenol, single  | Max. 1,0 %                                                          | < 1,0 %        |
| Unkown impurities of(+)-Cloprostenol, total | Max. 1,0 %                                                          | < 1,0 %        |
| Unkown impurity of Chlorocresol, single     | Max. 0,1 %                                                          | < 0,1 %        |
| Unkown impurities of Chlorocresol, total    | Max. 0,5 %                                                          | < 0,5 %        |
| Sterility                                   | sterile                                                             | Corresponds to |
| Extractable volume 50ml                     | Min. 50 ml                                                          | > 50 ml        |
| System-Suitability                          | corresponds to                                                      | Corresponds to |

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|-----------|---------------|--------|
|-----------|---------------|--------|

The finished product has been tested in accordance with the testing instruction and is of the required quality.

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

- ☒ no deviations/irregularities have been observed.  
☐ the following deviations/irregularities have been observed:

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

- ☐ for dispatch  
☒ for the market

Comments:

Date, Signature Qualified Person