



## CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized  
Quantity : 10kg  
Mfg. date: 2020.08.06  
CEP No.: R1-CEP 2013-238-Rev 00

Batch No. : EU-FTD200801M  
Specification: EP10  
Retest date: 2025.08.05

| Item                      | Specifications                           | Results                                                   |
|---------------------------|------------------------------------------|-----------------------------------------------------------|
| Description               | White or almost white crystalline powder | Almost white crystalline powder                           |
| Identification            | IR: Comparison: finasteride CRS.         | Sample spectrum is similar to that of reference standard. |
| Specific optical rotation | +12.0° ~ +14.0° (On dried substance)     | +12.5°                                                    |
| Loss on drying            | ≤ 0.5 %                                  | 0.10%                                                     |
| Related substances        | Impurity A ≤ 0.3%                        | 0.02%                                                     |
|                           | Impurity C ≤ 0.3%                        | 0.13%                                                     |
|                           | Any other unknown impurity ≤ 0.10 %      | 0.04%                                                     |
|                           | Total impurities ≤ 0.5%                  | 0.23%                                                     |
| Residual Solvents         | Methanol ≤ 3000ppm                       | Not detected                                              |
|                           | Ethanol ≤ 5000ppm                        | 515ppm                                                    |
|                           | Methylene chloride ≤ 600ppm              | Not detected                                              |
|                           | Isopropyl acetate ≤ 5000 ppm             | Not detected                                              |
|                           | Toluene ≤ 890ppm                         | Not detected                                              |
| Pd                        | ≤ 10ppm                                  | Not detected                                              |
| Assay                     | 98.0 ~ 102.0 % (On dried substance)      | 101.3%                                                    |
| Particle Size             | 100% < 20μm                              | Conform                                                   |

**Conclusion: Complies with the requirements of EP10**

Q.C. director:

QP:

Date:

2020.11.13

Date:

2020.11.13



## CERTIFICATE OF ANALYSIS

**Product :** Finasteride Micronized  
**Quantity :** 10kg  
**Mfg. date:** 2020.08.08  
**CEP No.:** R1-CEP 2013-238-Rev 00

**Batch No. :** EU-FTD200802M  
**Specification:** EP10  
**Retest date:** 2025.08.07

| Item                      | Specifications                           | Results                                                   |
|---------------------------|------------------------------------------|-----------------------------------------------------------|
| Description               | White or almost white crystalline powder | Almost white crystalline powder                           |
| Identification            | IR: Comparison: finasteride CRS.         | Sample spectrum is similar to that of reference standard. |
| Specific optical rotation | +12.0° ~ +14.0° (On dried substance)     | +12.5°                                                    |
| Loss on drying            | ≤ 0.5 %                                  | 0.02%                                                     |
| Related substances        | Impurity A ≤ 0.3%                        | 0.02%                                                     |
|                           | Impurity C ≤ 0.3%                        | 0.12%                                                     |
|                           | Any other unknown impurity ≤ 0.10 %      | 0.04%                                                     |
|                           | Total impurities ≤ 0.5%                  | 0.22%                                                     |
| Residual Solvents         | Methanol ≤ 3000ppm                       | Not detected                                              |
|                           | Ethanol ≤ 5000ppm                        | 562ppm                                                    |
|                           | Methylene chloride ≤ 600ppm              | Not detected                                              |
|                           | Isopropyl acetate ≤ 5000 ppm             | Not detected                                              |
|                           | Toluene ≤ 890ppm                         | Not detected                                              |
| Pd                        | ≤ 10ppm                                  | Not detected                                              |
| Assay                     | 98.0 ~ 102.0 % (On dried substance)      | 101.1%                                                    |
| Particle Size             | 100% < 20μm                              | Conform                                                   |

**Conclusion: Complies with the requirements of EP10**

**Q.C. director:**

**QP:**

**Date:**

2020.11.03

**Date:**

2020.11.03