



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240385

| | |
|-------------------|--|
| Product: | DUTASTERIDE |
| Lot: | 240385 |
| Expiry date: | 13/01/2029 |
| Reference: | Cumple PhEur11.3 |
| Synonyms: | |
| Formula: | C ₂₇ H ₃₀ F ₆ N ₂ O ₂ |
| Molecular weight: | 528,5 g/mol |

| Assay | Result | Specification | # |
|--|---------------|-------------------|---|
| | < 380 ppm | <= 380 ppm | # |
| Impurity C | ND | <= 0,2 % | |
| Impurity E | < 0,05 % | <= 0,3 % | |
| Impurity F | < 0,05 % | <= 0,4 % | |
| Impurity G | < 0,05 % | <= 0,3 % | |
| Impurity H | < 0,05 % | <= 0,3 % | |
| Impurity I | < 0,05 % | <= 0,5 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Not specif. impurities with retention time > dutasteride | < 0,05 % | <= 0,10 % | |
| Total impurities (sum test A + B) | < 0,05 % | <= 1,5 % | |
| Residual solvent: Methanol | < 3000 ppm | <= 3000 ppm | # |
| Residual solvent: Acetonitrile | < 410 ppm | <= 410 ppm | # |
| Residual solvent: methylene chloride | < 600 ppm | <= 600 ppm | # |
| Residual solvent: Ethanol | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Pyridine | < 200 ppm | <= 200 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Identification | Conform (A,B) | Test PhEur (A,B) | |
| Organoleptic properties | Conform | PhEur | |
| Specific rotation | +35,7 | (+33,0) - (+39,0) | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Water | < 0,01 % | <= 0,2 % | |
| Sulphated ashes | 0,00 % | <= 0,1 % | |
| Assay | 99,6 % | 97,0 - 102,0 % | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity A | < 0,05 % | <= 0,2 % | |
| Impurity B | < 0,05 % | <= 0,15 % | |

Organoleptic characteristics: White or pale yellow powder. Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol.

Conservation:

Date of analysis: 21/02/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: DT240101

| Product | Name | Capacity | Batch |
|---------|-------------|----------|------------|
| 1111038 | DUTASTERIDA | 1 g | 240385-D-1 |
| 1111038 | DUTASTERIDA | 1 g | 240385-D-2 |
| 1111040 | DUTASTERIDA | 10 g | 240385-F-1 |
| 1111040 | DUTASTERIDA | 10 g | 240385-F-2 |
| 1111041 | DUTASTERIDA | 50 g | 240385-I-1 |
| 1111041 | DUTASTERIDA | 50 g | 240385-I-2 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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