

## Certificate of Analysis

**Productname:** Latanoprostum (Latanoprost)  
**Number of analysis/Inspection Code:** 1 / KEUR-197948B  
**Batchnumber:** 23F08-F01-384991  
**Reference code / No.:** 4095 / ND1234  
**Analysed according to:** USPNF 23/1

| Tests                      | Requirement                                  | Result       | Unit | Standard remark            |
|----------------------------|----------------------------------------------|--------------|------|----------------------------|
| Appearance                 | Colourless to slightly yellow oil            | Conform      |      |                            |
| Identification A           | Conform                                      | Conform      |      | IR-spectrum                |
| Identification B           | Conform                                      | Conform      |      | Assay                      |
| Residue on ignition        | <=0,50                                       | 0,00         |      |                            |
| Organic impurities         | Conform                                      | Conform      |      | HPLC                       |
| Orlistat rel.subst.C       | <=0,15                                       | Not detected | %    |                            |
| Isopr.diph.phph.pentanoate | <=0,1                                        | <0,05        | %    |                            |
| Latanoprost rel subst. B   | <=0,5                                        | <0,05        | %    |                            |
| Latanoprost rel subst. A   | <=3,5                                        | 0,1          | %    |                            |
| Any other impurity         | <=0,1                                        | <0,05        | %    |                            |
| Total impurities           | <=0,5                                        | 0,1          | %    |                            |
| Latanoprost rel subst. E   | <=0,2                                        | 0,0          | %    | HPLC                       |
| Specific optical rotation  | +31 - +38                                    | +34          | °    |                            |
| Water (Karl Fischer)       | <=2,0                                        | 0,2          | %    |                            |
| Metallic residues          | CHMP/ICH/353369/2013                         | Conform      |      | Data producer              |
| Residual solvents          | CHMP/ICH/82260/2006                          | Conform      |      | Data producer              |
| Assay Latanoprost          | 94,0 - 102,0                                 | 99,2         | %    | Anhydrous and solvent-free |
| TSE/BSE-statement:         | No contamination with TSE/BSE-risk materials | Conform      |      | Data producer              |

Analysis performed by the authorized laboratory Proxylabs.

**Manufacturer / Country** : Newchem Spa - SMS (Pavia) / IT  
**CEP** : Not available

Release:  
 Anthony Amoureux  
 Qualified Person

08/09/23

Expiration: 30-04-26

Conclusion: APPROVED

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