OFIPHARMA

# Certificate of analysis

| | | | |
|---|---|---|---|
| **Product:** | **CLOPIDOGREL HYDROGEN SULFATE (FORM II)** | | |
| **Batch number:** | **2507033.1877** | **Manuf. Batch number:** | **CM20380325** |
| **Manufacturing date:** | Mar-2025 | **Expiry date:** | Feb-2030 |
| **Quality:** | EP 01/2017:2531 corrected 10.0 | | |

| Test | Requirement | Result | Unit | Standard remark | Control by |
|---|---|---|---|---|---|
| **Characters** | | | | | |
| Appearance | White or almost white powder | Complies | | | AC Man |
| Solubility | Freely soluble in methanol, practically insoluble in cyclohexane | Complies | | | AC Man |
| | | | | | |
| **Identification** | | | | | |
| Specific optical rotation | +54.0 – +58.0 | +56.7 | ° | On anhydrous basis | AC Man |
| Infrared absorption | The infrared absorption spectrum of the sample shall be concordant with that of Clopidogrel Hydrogen Sulfate standard infrared absorption spectrum | Complies | | | AC Man |
| HPLC | The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained from Enantiometric purity by HPLC | Complies | | | AC Man |
| Sulfate | It responds to the test for sulfates | Complies | | | AC Man |
| | | | | | |
| **Test** | | | | | |
| Appearance of solution | Solution should be clear and colour is not more than reference solution Y6 | Complies | | | AC Man |
| Water content | ≤ 0.50 | 0.12 | % w/w | KFR | AC Man |
| Sulfated ash | ≤ 0.10 | 0.05 | % w/w | | AC Man |
| Polymorhic identification | The PXRD pattern of the sample should exhibit, the presence of peak at 2-theta values of Clopidogrel hydrogen sulfate Ph.Eur, (Form-II) are at about 12.9°, 18.5° and 21.6° ±0.2° 2-theta | Complies | | PXRD, In House | AC Man |
| Para Formaldehyde content | ≤ 5 | Not applicable | ppm | HPLC; In House | AC Man |
| | | | | | |
| **Related substances** | | | | **HPLC** | |
| Impurity A | ≤ 0.15 | 0.01 | % | | AC Man |
| Impurity B | ≤ 0.15 | BDL | % | LOD=0.004% | AC Man |
| Highest individual Unspecified impurity | ≤ 0.10 | 0.05 | % | | AC Man |
| Total impurities | ≤ 0.50 | 0.16 | % | | AC Man |
| | | | | | |
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| Test | Requirement | Result | Unit | Standard remark | Control by |
|---|---|---|---|---|---|
| **Enantiomeric purity** | | | | **HPLC** | |
| Impurity C | ≤ 0.15 | 0.06 | % | | AC Man |
| | | | | | |
| **Assay** | | | | | |
| Potentiometry | 99.0 – 101.0 | 99.8 | % w/w | On anhydrous basis | AC Man |
| HPLC | 99.0 – 101.0 | N/A | % w/w | On anhydrous basis; In house | AC Man |
| | | | | | |
| **Residual solvents** | | | | **GC; In house** | |
| Methanol | ≤ 3000 | 81 | ppm | | AC Man |
| Acetone | ≤ 5000 | 865 | ppm | | AC Man |
| Dichloromethane | ≤ 600 | BDL | ppm | LOD=16.99 ppm | AC Man |
| Cyclohexane | ≤ 3880 | BQL | ppm | LOQ=6.26 ppm | AC Man |
| Toluene | ≤ 890 | BQL | ppm | LOQ=3.18 ppm | AC Man |
| | | | | | |
| **Mesityl oxide** | | | | **GC; In house** | |
| Content | ≤ 200 | BQL | ppm | LOQ=44.22 ppm | AC Man |

Storage condition: Store protected from light and at controlled room temperature between 20°C and 25°C (excursions allowed between 15°C and 30°C)

| Other data | Requirement | Result | Standard remark |
|---|---|---|---|
| TSE/BSE-statement | No contamination with TSE/BSE-risk materials | Conform | Data producer |
| Metallic Residues | Conform CHMP/ICH/353369/2013 | Conform | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | Data producer |
| Nitrosamine statement | (EMA/369136/2020) | Conform | Data producer |
| CEP | Available on request \| R1-CEP 2015-331 - Rev 00 | Conform | Data producer |

Manufacturer: MSN Organics Private Limited (IN)

Production, expiry/retest date conform primary packaging. I hereby confirm that the above mentioned results are in compliance with the referred Pharmacopoeia and are authentic and accurate.

Conclusion: Approved

**Quality Assurance**

21 JUL 2025

D. Pals, MSc