Clopidogrel Hydrogen Sulfate

PRODUCT DESCRIPTION
- Clopidogrel hydrogen sulfate EP
- CEP available / Written Confirmation / GMP
- Polymorph form 1 – CEP R0-CEP 2014-176-Rev 01
- Polymorph form 2 – CEP R0-CEP 2017-247-Rev 00

KEY CHARACTERISTICS
- Made by Praveen Laboratories P. Ltd.
- **Same salt as in the original** (Plavix®)
- Strict control of enantiomeric purity (impurity C), important for stability of finished dosage form
- **Innovative and cost effective route of synthesis** (low camphor sulfonic acid; cyclisation of 2-thienylethanol)
- Production capacity 40 t/y
- Useful for substitution of other salts like clopidogrel besylate
- **Easy switch to polymorph form 2 after patent expiry**
- **Exclusive distribution by Selectchemie AG**
- Flexibility in meeting customer requirements (PSD)

APPLICATIONS
- Prevention of atherothrombotic events in patients suffering from
  - myocardial infarction, ischaemic stroke or established peripheral arterial disease;
  - acute coronary syndrome, including patients with thrombolytic therapy or after stent placement following percutaneous coronary intervention
- Prevention of atherothrombotic and thromboembolic events, including stroke, in atrial fibrillation
- Long-term therapy with 75 mg clopidogrel per day (equivalent to 100 mg clopidogrel hydrogen sulfate)

MARKET SITUATION
- Clopidogrel annual sales worldwide still over 3.3 billion USD, with continued strong growth in volume of 4.4 % p.a. (IMS March 2018)
- **Patent expiry of polymorph form 2 in 2019**
MANUFACTURER

PRAVEEN LABORATORIES P. LTD.
720, Golden Point, Falsawadi, Ring Road, Surat-395003, Gujarat, India
• Established in 1996
• Specialist in chiral APIs and intermediates
• New state of the art plant, cGMP approved and operational since 2013
• Domestic sales and exports to regulated markets
• Certificates: Local GMP & WHO GMP, WC-0193, KFDA
• Audit history: WHO GMP, COFEPRIS, KFDA; several multinational customers
• Established routes of synthesis for Clopidogrel hydrogen sulfate polymorphs form 1 and form 2

COMPETITIVE EDGE
• CEP available (Oct. 2015)
• Stable polymorph form 1 even under stress conditions
• Cost effective synthesis of API
• Customized particle size distribution on request
• Exclusive distribution by Selectchemie AG with own warehouses in Europe, EU-import and release
• Easy switch to polymorph form 2 after patent expiry
PERSONAL NOTES/YOUR CONTACT

SELECTCHEMIE AG

- Established in 1969 in Zurich, Switzerland
- Premier supplier of high quality ingredients for the pharmaceutical and human nutrition industries
- Extensive global network with offices in 15 countries
- Just-in-time deliveries from our local warehouses in Basel, Zurich and Hamburg
- Certificates: ISO 9001 & 22000, GMP & GDP, FDA inspected in 2011, Bio-Inspecta
- EU-registered in Hamburg, Germany (BGV)