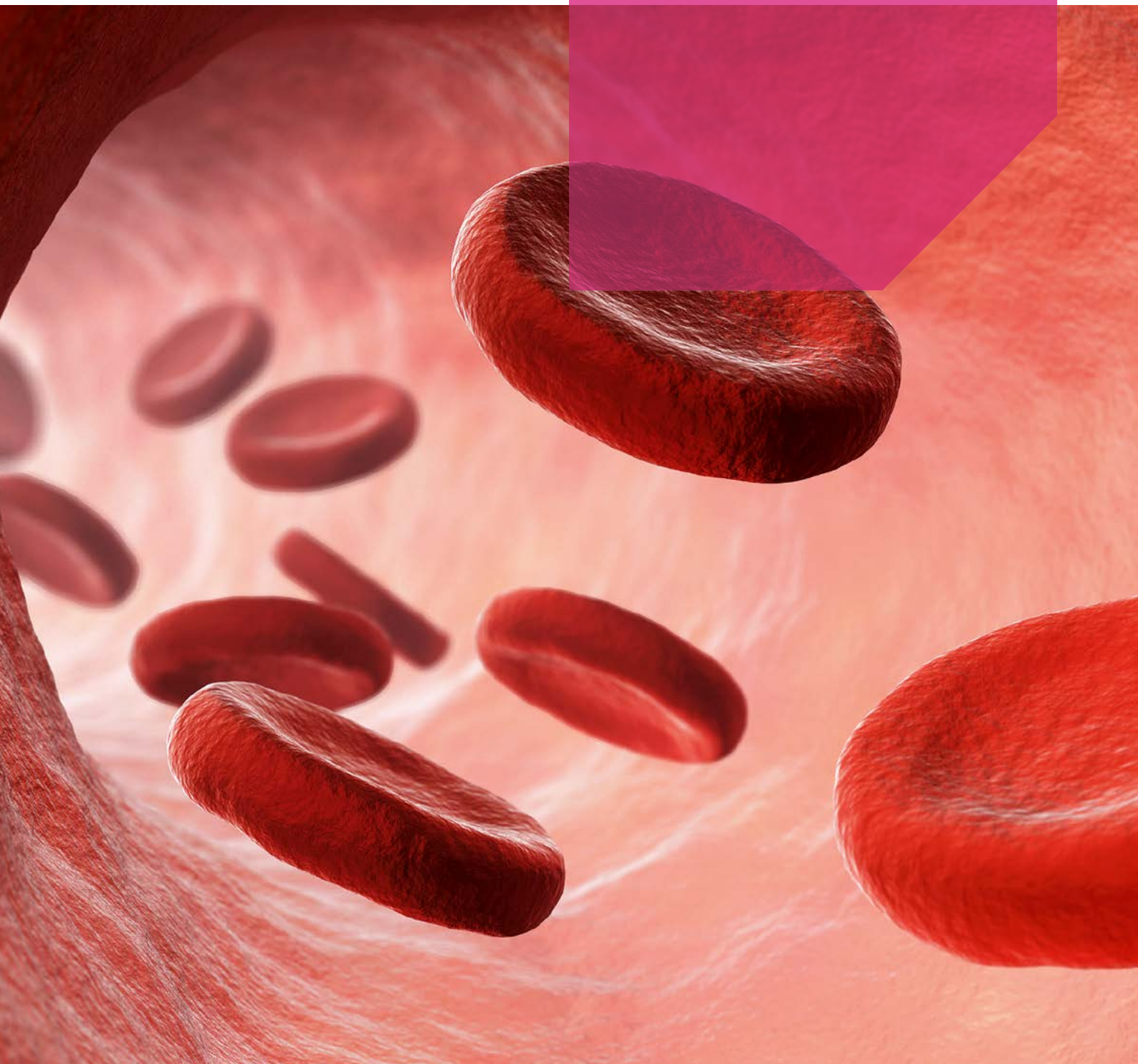




Selectchemie

# CLOPIDOGREL HYDROGEN SULFATE



CEP GRADE

# 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**



# Praveen Labora- tories



## **PRAVEEN LABORATORIES P. LTD.**

**720, Golden Point, Falsawadi, Ring Road, Surat-395003, Gujarat, India**

**MANUFACTURER**

- 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

## **AUTHORISED DISTRIBUTOR**

### **Selectchemie AG Switzerland**

Etzelstrasse 42

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Fax +41 44 487 96 90

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www.selectchemie.ch



## **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)

### **Pharma**

**ACTIVE PHARMACEUTICAL  
INGREDIENTS**

**INTERMEDIATES**

**PHARMACEUTICAL  
EXCIPIENTS**

### **Nutrition**

**FOOD INGREDIENTS**

**HEALTH INGREDIENTS**

### **New Business Develop- ment Pharma**

**MARKET EVALUATION**

**PRODUCT DEVELOPMENT**

**SUPPLY CHAIN MANAGEMENT**

**PROJECT MANAGEMENT**

**DOSSIER PROJECTS**

### **Services beyond Sourcing**

**COMMERCIAL SUPPORT**

**SCIENTIFIC SUPPORT**

**MATERIAL SAFETY DATA  
SHEET SERVICES**

**REGULATORY SUPPORT**

**APPLICATION LAB (FOOD)**

**YOUR CHOICE FOR QUALITY ALL OVER THE WORLD**