

**AUROCHEM****PHARMACEUTICALS (INDIA) PVT. LTD.**

334, Gundecha Industrial Complex, 3rd Floor, Akurli Road,
Kandivli (East), Mumbai - 400 101. Tel. : 2885 8503 / 04/ 05 Fax : 2887 3236
E-mail : aurochem@mtnl.net.in & aurochem@vsnl.in Website : www.aurochemlabs.com

WORKING STANDARD REPORT

From : Q. C. Manager

AR Date : 18/12/2012

Retesting date : 18/12/2013

Manufacturer : DYMES PHARMACHEM LTD.

Item Name : **CLOPIDOGREL BISULFATE USP**MFG. DATE : Nov' 2012
EXP. DATE : Oct' 2016

Batch No : DCG-5B/00612

Qty : 1.0 g

Tests performed :

Evaluated against CLOPIDOGREL BISULFATE WS Batch No : CLOPI/1203-0017 On Date : 18/12/2012

Analysed as per USP

TEST	OBSERVATIONS	STANDARD
01. Description	White powder	White to off-white powder
02. Solubility	Freely soluble in water and in methanol; practically insoluble in ether.	Freely soluble in water and in methanol; practically insoluble in ether.
03. Identification		
A) Infrared absorption	The Infrared absorption spectrum of substance being examined is concordant with the IR spectrum obtained from Clopidogrel bisulphate working standard.	The Infrared absorption spectrum of substance being examined is concordant with the IR spectrum obtained from Clopidogrel bisulphate working standard.
B)	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay
C)	White precipitate is form	White precipitate should form
04. Loss of Drying	0.18%	Not more than 0.5%
05. Residue on Ignition	0.03%	Not more than 0.1%
06. Related compounds		
1) Related compound A	Less than 0.2%	Not more than 0.2%
2) Related compound B	Less than 0.3%	Not more than 0.3%
3) Related compound C	Less than 1.0%	Not more than 1.0%
4) Other Impurity	Less than 0.1%	Not more than 0.1%
5) Total Impurity	Less than 1.5 %	Not more than 1.5 %

**AUROCHEM****PHARMACEUTICALS (INDIA) PVT. LTD.**

334, Gundecha Industrial Complex, 3rd Floor, Akurli Road,
Kandivli (East), Mumbai - 400 101. Tel. : 2885 8503 / 04/ 05 Fax : 2887 3236
E-mail : aurochem@mtnl.net.in & aurochem@vsnl.in Website : www.aurochemlabs.com

WORKING STANDARD REPORT

From : Q. C. Manager

Page no: 2/2

AR Date : 18/12/2012

Retesting date : 18/12/2013

Manufacturer : DYMES PHARMACHEM LTD.

Item Name : **CLOPIDOGREL BISULFATE USP**

MFG. DATE : Nov' 2012

EXP. DATE : Oct' 2016

Batch No : DCG-5B/00612

Qty : 1.0 g

Tests performed :

Evaluated against CLOPIDOGREL BISULFATE WS Batch No : CLOPI/1203-0017 On Date : 18/12/2012

Analysed as per USP

TEST

OBSERVATIONS

STANDARD

07. Assay :

 $C_{16}H_{16}ClNO_2S \cdot H_2SO_4$

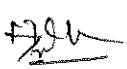
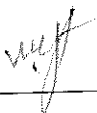
99.69% on as such basis

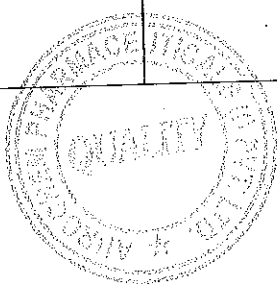
99.87% on dried basis.

97.0% to 101.5%
on dried basis.

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY, as per
USP 35. and can be used as working standard.

AUROCHEM PHARMACEUTICALS (I) PVT. LTD.

ANALYSED BY	CHECKED BY
	




Chandrakant Raut
Quality Control Manager