C13-1 C13-1

AUROCHEM
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QUALITY CONTROL LABORATORY RECEIVED 06 AUG 2013

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 2) Related compound B 3) Related compound C 4) Other Impurity 5) Total Impurity	 Less than 0.2% Less than 0.3% Less than 1.0% Less than 0.1% Less than 1.5 %	 Not more than 0.2% Not more than 0.3% Not more than 1.0% Not more than 0.1% Not more than 1.5 %

QUALITY CONTROL

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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.
Chandrakant Rout
Quality Control Manager

ANALYSED BY	CHECKED BY

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