



QAF-462

Issued Date: 13-04-2010

QUALITY ASSURANCE Raw Material Quality Report

Date: 03-02-2014

Issue Status: 02

C13-2

Item Name:	Clopidogrel Bisulphate USP		
Manufacturer:	Ind-Swift Labs Limited, India.		
L/C . No. (If any):	Ledger No / Page No:	04/14	
Batch No.	7010814013	Lot No.	
Mfg. Date:	01-14	Exp. Date:	12-17
Quantity Received:	10X25 kg	Received on:	03-02-2014
Sampled by:	Anees	Sampled on:	03-02-2014
Date of Test:	03-02-2014	Date of Retest:	03-02-2015
Quantity of Sample:	20 gm	Q.C. No.	34813/R14

TEST	SPECIFICATION	RESULTS / REMARKS	
PHYSICAL CHECKS			
Physical Form & Colour	White to off-white Crystalline Powder	As/Sp	Complies
Solubility:	Freely soluble in Methanol, slightly soluble in Water and insoluble in chloroform.	As/Sp	Complies
Loss on Drying	NMT 0.5%	0.25 %	Complies
Residue on Ignition	NMT 0.1%	0.06 %	Complies
Bulk Density:	Between 665—0.7500gm/ml	0.700 g/ml	Complies
Tapped Density:	Between 0.731---0.810gm/ml	0.760 g/ml	Complies
Sieve # 100	Should be more than 75% pass	80.0 % passed	Complies
CHEMICAL TEST			
Identification:			
by IR spectrum	Should comply the standard spectrum	As/Sp	Complies
by Sulphates Test	A white ppt. should produce	As/Sp	Complies
Assay			
Clopidogrel Bisulphate	Between 97.0 % to 101.5% on dried basis.	97.55%(as is) 97.79%(OAB)	Complies

Overall Remarks:

OK

Quality Control Officer
Date

03-02-14

AM Quality Control
Date

28 OCT 2014

Manager Quality Control
Date

3/2/14