MEDS

Quality Control Laboratory

Assuring Quality of Medicines

MISSION FOR ESSENTIAL DRUGS & SUPPLIES

CERTIFICATE OF ANALYSIS

REGISTRATION NUMBER: RT/4277 **Request Date :** 30.07.2014 **Test Date**: 25.08.2014

NAME OF PRODUCT: SULPHAMETHOXAZOLE AND TRIMETHOPRIM TABLETS [COSATRIM-DS]

CLIENT:	**MANUFACTURER:**
USAID/ Kenya Pharma Project P.O Box 1325-00606, Nairobi. Kenya.	Cosmos Ltd P.O Box 41433-00100, Nairobi. Kenya

LABEL CLAIM: Each tablet contains; Sulphamethoxazole BP 800 mg, Trimethoprim BP 160 mg
Batch Number: 40291. Manufactured-06/2014, Expires- 05/2019

RESULTS OF ANALYSIS

Appearance: White capsule shaped uncoated tablet, scored on one side and embossed 'COSATRIM DS' on the other side, packed in a blister pack of 10's

TEST	METHOD	SPECIFICATIONS	RESULTS	REMARKS
Identification	USP36-NF31	Sulphamethoxazole and Trimethoprim	Sulphamethoxazole and Trimethoprim	**COMPLIES**
Friability	USP36-NF31	Not more than 1.0% weight loss	0.26% weight loss	**COMPLIES**
Dissolution	USP36-NF31	≥75% of the stated amounts is dissolved in dissolution medium in 60 minutes	Trimethoprim: Range 95.4% to 103.9% of stated amount Average =98.6% of stated amount Sulphamethoxazole: Range 95.6% to 103.4% of stated amount, Average =98.5% of stated amount	**COMPLIES**
Weight Variation	USP36-NF31	Maximum acceptance value for 10 units- not more than 15	Average mass per tablet =1061.2mg Trimethoprim: Range: 99.7% to 102.2% of label claim. Average =101.2%, Acceptance value =2.2 Sulphamethoxazole: Range: 101.8% to 104.3% of label claim. Average = 103.3%, Acceptance value =4.0	**COMPLIES**
Assay	USP36-NF31	93.0% to 107.0% of the stated amount	Trimethoprim:101.0% w/w Sulphamethoxazole: 103.1% w/w	**COMPLIES**

CONCLUSION: The sample supplied complies with USP36-NF31 (2013) monograph specifications with regards to identity, friability, dissolution, weight variation and assay test *

***Results given are specific to the indicated batch.**

Mission for Essential Drugs and Supplies MEDS

PREPARED BY: Peter Wang'ere		REVIEWED BY: Joseph Thuranira		APPROVED BY: Stephen Kigera	
Laboratory Analyst	Date: 4/09/2014	Laboratory Supervisor	Date: 4/9/2014	Quality Assurance Manager	Date: 04/09/2014

A Joint Service of the Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK)
P.O BOX 78040, VIWANDANI 00507
NAIROBI, KENYA
Website: www.meds.or.ke
TEL: (+254) 20-3920000, 0734-600310, 0722-202106, 0726-937222
WIRELESS: 0202124453, 0202532216, 0202460022, 02032214
E-mail: sahibu@africaonline.co.ke, lab@meds.or.ke