

WRS G23-2

WRS
G23-2**BETA
HEALTHCARE**beta healthcare international ltd
an aspen group companymogadishu road off lunga lunga road industrial area nairobi kenya
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tel +254 20 6530106 fax +254 20 556 198 info@betashelys.com
www.aspenpharma.com www.betacare.co.ke www.shelysafrica.com**CERTIFICATE OF ANALYSIS**

STANDARD NAME GLYCOMIN TABLETS	PRE-PURCHASE SAMPLE..... CONSUMER COMPLAINT SAMPLE ANY OTHER...FOR EXPORT.....	SUPPLIER BETA HEALTHCARE INT LTD MANUFACTURER BETA HEALTHCARE INT LTD
QUANTITY SUBMITTED.....100 tablets.....	SUBMITTED BY:.....PRODUCTION..... DATE:25/1/2017.....	
BATCH/LOT NO.....1611079	RECEIVED BY:... Odhiambo DATE:....25/1/2017.....	

DOM: DEC 2016**DOE: DEC 2019****ANALYTICAL TESTS.****QUALITY CONTROL REPORT.**SPECIFICATIONSCOMPLIANCE

1. Description

A white, flat, oval, bevelled edge
tablet, bisected on both sides.

Complies

2. Average weight

0.1520 g to 0.1680g

159.7mg

3. Hardness

6.0 – 18.0kP.

15.5Kp

4. Moisture Content

Not more than 10 % w/w

8.0%w/w

5. Disintegration

Not More Than 15 Minutes.

9.0Minutes

6. Friability

Not More than 1.0%.

0.17%

7. Assay: Content of Glibenclamide

95-105%

97.34

8. Dissolution

NLT 80%.

90.43%

9. Microbiological Test

Total viable Aerobic count.

(i) Total aerobic microbial count(TAMC)

NMT 10³CFU/g

Less than 10cfu/g

(ii) Total Yeast /Mould combined(TYMC)

NMT 10²cfu/g

Less than 10cfu/g

(iii) *Escherichia coli*:

Absent.

Absent

REMARKS.

COMPLIES

Signature.....

Ibrahim.M.Lezeni

Senior QC Analyst

Date...12.9.2017

Signature:.....

Mr.Clifton O.Odhiambo

Manager-QC

Date 12/09/2017

Signature:.....

Dr.Nkolsaen Ramaita

Manager-QA

Date...12.09.2017

