GULF PHARMACEUTICAL INDUSTRIES
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United Arab Emirates.

Julphar
Quality Control Department

شركة الخليج للصناعات الدوائية
رأس الخيمة - ص.ب: ٩٩٧
تلفون: ٢٤٦١٤٦١ ٩٧١٧+ فاكس: ٢٤٦٢٤٦٢ ٩٧١٧+
الإمارات العربية المتحدة

WRS
G2-7

5

Certificate of Analysis
Secondary Reference Standard

Name: Glimepiride
Material No: 10000353

Batch No: 0000032573/II
Insp. Lot No: 10000032008

Test	Specification	Result
Description	White to almost white powder, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method.	Conform
Water content	NMT 0.50%	0.33%
Limit of cis-isomer (related compound A)	NMT 0.80%	0.01%
Related compounds	Related compound B: NMT 0.40%	0.073%
	Related compound C: NMT 0.10%	0.00%
	Related compound D: NMT 0.20%	0.00%
	Any unspecified individual impurity: NMT 0.10%	0.00%
	Total impurities excluding related compound B: NMT 0.50%	0.00%
Assay	NLT 98.0% and NMT 102.0%, calculated on the anhydrous basis.	99.59% (as is basis) 99.92% (on anhydrous basis)

Standardization date: 09/05/2015

Standardized by: Anas

Exp. date: 05/2016

Weight per vial: 500mg

Standardized against: Glimepiride USP Reference Standard (Lot No: G0K135)

Checked by: Pensee Mohamed, B. S. Pharm
Quality Control Assistant Manager

QUALITY CONTROL LABORATORY
RECEIVED
10 NOV 2015
TEL: 27...
FAX: 2718073
P.O. Box 20726 - 00202, NAIROBI

Head of Quality Control Department
Sheikha Khamis

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Quality Control Department

Certificate of Analysis

Code No	:1213SA0102779 / 121379	**M.F.G.Date**	: 07.2015
Product Name	:GLYPRIDE 1MG TABLETS	**Expiry Date**	: 07.2017
		Batch Size	: 1,000,000.000 NO
Batch Number	: 0008		

Test	Specifications	Results	UOM
Description	Light pink, mottled, dumbbell shaped, flat face beveled edge tablets.	Conform	
Dimension, Length	10.0 mm ± 0.5 mm	10.1500	mm
Dimension, Width	5.0 mm ± 0.5 mm	5.0600	mm
Marking	Face one: Breakline, embossed ' G I 1 ' Face two: Breakline , Plain	Conform	
Uniformity of weight	140 mg/tablet Limit : Average weight ± 7.5% NMT 2 of the individual weight deviate from the average weight by more than 7.5% and none deviates by more than 15%.	140.9100	mg/tab
Water content	NMT 7.5%	4.9600	%
Friability	NMT 1.0%	0.3700	%
Identification Color (Iron Oxide)	Passes the test	Conform	
Identification, Glimepiride	The retention time of the major peak in the chromatogram of the assay p reparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	Conform	
Dissolution , Glimepiride	NLT 80.0%(Q) of the L.A of Glimepiride is dissolved in 15 minutes.	94.980	%
Assay Glimepiride	1.0 mg/tab Limit: NLT 90.0% and NMT 110.0% of the L.A of Glimepiride.	103.1500	%
Related substances, Overall Total impurities	NMT 3.5%	0.0000	%
Related substances, Total impurities	NMT 1.0% (Total impurities excluding glimepiride related compound B)	0.0000	%
Glimepiride related compound B	NMT 2.5%	0.0000	%
Related substances, any Other individual impurity	NMT 0.5%	0.0000	%
Uniformity of Dosage Units	Av (n=10) ≤ 15, if not then Av (n=30) ≤ 15 and 30/30 = 0.75M to 1.25M	1.6	
Microbial limit, TAMC	NMT 1000 cfu/g	Conform	
Microbial limit, TYMC	NMT 100 cfu/g	Conform	

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Evaluation: The product compiles to in-house specifications and release for shipment

Checked By:

23.08.15

Approved By:

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Quality Control Department

Certificate of Analysis

صناعة الخليج للصناعات الدوائية
ص.ب ٩٩٧ - رأس الخيمة
تلفون: ٢٤٦١٤٦١ +٩٧١٧ فاكس: ٢٤٦٢٤٦٢ +٩٧١٧
الإمارات العربية المتحدة

Code No	:1213SA0102779 / 121379	M.F.G.Date	: 07.2015
Product Name	:GLYPRIDE 1MG TABLETS	Expiry Date	: 07.2017
		Batch Size	: 1,000,000.000 NO
Batch Number	: 0008		

Test	Specifications	Results	UOM
Microbial Limit, Test for Pathogens	Absence of Escherichia coli	Absent	

Evaluation: The product compiles to in-house specifications and release for shipment

Checked By: 23-03-15

Approved By: 23/3/15

QUALITY CONTROL Julphar DEPARTMENT

NATIONAL QUALITY CONTROL LABORATORY
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10 NOV 2015
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Quality Control Department

Certificate of Analysis

Code No	:1213OM0202780 / 121380	M.F.G.Date	: 04.2015
Product Name	: GLYPRIDE 2MG TAB[3X10BL]OM-SGH	Expiry Date	: 04.2017
		Batch Size	: 1,000,000.000 NO
Batch Number	: 0025		

Test	Specifications	Results	UOM
Description	Olive green, mottled, dumbbell shaped, flat face beveled edge tablets	Conform	
Dimension, Length	Length, 10.0 mm ± 0.5 mm	9.8300	mm
Dimension, Width	Width, 5.0 mm ± 0.5 mm	4.9900	mm
Marking	Face one: Breakline, embossed 'G / 2' ; Face two: Breakline, plain	Conform	
Uniformity of weight	140mg/tablet Limit: Average weight ± 7.5% NMT 2 of the individual weight deviate from the average weight by more than 7.5% and none deviates by more than 15%.	144.0400	mg/tab
Water content	NMT 7.5%	4.1500	%
Friability	NMT 1.0%	0.0180	%
Identification Color (FD&C Blue No.2)	Passes the test	Conform	
Identification Color (Iron Oxide)	Passes the test	Conform	
Identification, Glimepiride	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained in the assay.	Conform	
Dissolution Glimepiride	NLT 80.0%(Q) of the L.A of Glimepiride is dissolved in 15 minutes.	91.5000	%
Assay Glimepiride	2.0 mg/tablet Limit: NLT 90.0% and NMT 110.0% of the L.A of Glimepiride.	102.2000	%
Related substances A	Glimepiride related compound B :- NMT 2.5%	0.0000	%
Related substance B	Any other individual impurity:- NMT 0.5%	0.000	%
Related substance C	Total impurities excluding Glimepiride related compound B : - NMT 1.0%	0.0000	%
Related substance D	Overall total impurities :- NMT 3.5%	0.0000	%
Uniformity of Dosage Units	Av(n= 10)< = 15 , if not , then Av(n= 30)< = 15 and 30/30 = 0.75M to 1.25M	3.1	pf
Microbial limit, TAMC	NMT 1000 Cfu/g	Conform	

Evaluation: The product compiles to in-house specifications and release for shipment

10 NOV 2015

Checked By:

Approved By:

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شركة الخليج للصناعات الدوائية
ص.ب: ٩٩٧ رأس الخيمة
تلفون: ٢٤٦١٤٦١-٠٧١٧+ فاكس: ٢٤٦٢٤٦٢-٠٧١٧+
الإمارات العربية المتحدة

Certificate of Analysis

Code No :1213OM0202780 / 121380
Product Name : GLYPRIDE 2MG TAB[3X10BL]OM-SGH
Batch Number : 0025

M.F.G.Date : 04.2015
Expiry Date : 04.2017
Batch Size : 1,000,000.000 NO

Test	Specifications	Results	UOM
Microbial limit, TYMC	NMT 100 cfu/g	Conform	
Test for pathogen	Absence of Escherichia Coli	Absent	

Evaluation: The product compiles to in-house specifications and release for shipment

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10 NOV 2015
P.O. BOX 30202, NAIROBI

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Approved By:
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DEPARTMENT

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شركة الخليج للصناعات الدوائية
رأس الخيمة، ص.ب: ٩٩٧
تلفون: ٢٤٦١٤٦١ ٧١٧+، فاكس: ٢٤٦٢٤٦٢ ٧١٧+
الإمارات العربية المتحدة

Certificate of Analysis

Code No :1213IQ0102781 / 121381
Product Name :Glypride 3 mg Tablets

Batch Number : 0015

M.F.G.Date : 06.2015
Expiry Date : 06.2017
Batch Size : 1,000,000.000 NO

Test	Specifications	Results	UOM
Description	Light yellow, mottled, dumbbell shaped, flat face beveled edge tablets .	Conform	
Dimension, Length	Length,10.0 mm ± 0.5 mm	10.1500	mm
Dimension, Width	Width,5.0 mm ± 0.5 mm	5.1000	mm
Marking	Face one: Breakline, embossed ' G I 3 Face two: Breakline, plain	Conform	
Uniformity of weight	140 mg/tablet Limit : Average weight ± 7.5% NMT 2 of the individual we ight deviate from the average weight by more than 7.5% and none deviat es by more than 15%	142.2100	mg/tab
Water content	NMT 7.5%	4.1300	%
Identification Color (Iron Oxide)	Passes the test	Conform	
Identification, Glimepiride	The retention time of the major peak in the chromatogram ofthe assay p reparation corresponds to that of the standard preparation as obtained in the assay.	Conform	
Friability	NMT 1.0%	0.2400	%
Dissolution Glimepiride	NLT 80.0%(Q) of the L.A of Glimepiride is dissolved in 15 minutes.	97.1100	%
Assay Glimepiride	3.0 mg/tablet Limit: NLT 90.0% and NMT 110.0% of the L.A of Glimepiride	101.2300	%
Related substances 1	Glimepiride related compound B NMT 2.5%	Conform	
Related substances 2	Any other individual impurity: NMT 0.5%	0.0000	%
Related substances 3	Total impurities excluding Glimepiride related compound B NMT 1.0%	Conform	
Related substances 4	Overall total impurities compound B NMT 3.5%	Conform	
Uniformity of Dosage Units	Av (n= 10)< = 15, if not, then Av (n= 30)< = 15 and 30/30 = 0.75 M to 1.25 M	4.6	
Microbial limit, TAMC	NMT 1000 cfu/g	Conform	
Microbial limit, TYMC	NMT 100 cfu/g	Conform	
Microbial Limit, Test for Pathogens	Absence of Escherichia Coli	Absent	

Evaluation: The product compiles to in-house specifications and release for shipment

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10 NOV 2015
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Checked By:
24-08-15

Approved By: