COSMOS LIMITED

Pharmaceutical manufacturers



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Certificate of Analysis (Research & Development)

Product Name	GLUCOWELL TABLETS 50mg		
Generic Name	VILDAGLIPTIN TABLETS 50mg	х г	
A.R. No.	E16D0025	Code	HTG 21
Batch No.	E60025	Receipt Date	14/04/2016
Pack Size	2 x 14 Tablets	Batch Size	5200 Tablets
Mfg. Date	Apr., 2016	Exp. Date	Mar., 2018
Qty. Sampled	1x100 Tabs	Analysis Date	14/04/2016
Date of Sampling	14/04/2016	Report Date	15/04/2016
Sample drawn by	Thomas Muasya	Page no.	1 of 2

S.No.	Test	Result	Specification
1'	Description	White, circular biconvex tablet embossed C on one side and breakline on the other side.	White, circular biconvex tablet embossed C on one side and breakline on the other side.
2	Identification		E O
a	By HPLC	The retention time of the major peak in the chromatogram obtained with the sample preparation in the assay corresponded to the retention time of Vildagliptin peak in the standard preparation.	The retention time of the major peak in the chromatogram obtained with the sample preparation in the assay corresponds to the retention time of Vildagliptin peak in the standard preparation.
3	Average weight	195.01mg	190.0 to 200.0mg
4	Uniformity of weight	Range:189.76 - 197.52mg, none >7.5%	180.0 to 210.0mg
5	Diameter	Min = 8 mm Max = 8.04 mm	7.8 to 8.2 mm
6 .	Thickness	Min = 3.68 mm Max = 3.74 mm	3.4 to 3.8 mm
7	Hardness	Min = 4 kg/cm 2 Max = 6 kg/cm 2	4.0 to 7.0 kg/cm2
8	Friability	0.13%w/w	Not more than 1.0%w/w
9	Disintegration Time	1min to 3min	NMT 15 minutes
. F	Analyzed by Che	Approved by 2016	Authorised by
Evans N	NO. III CANTON AND AND AND AND AND AND AND AND AND AN	Box 29726	21.11.22.11.21
}	R&D Analyst QC S	Supervisor Research & Development Hea	ad Pharmacist

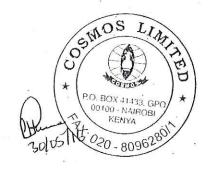


Certificate of Analysis (Research & Development)

Product Name	GLUCOWELL TABLETS 50mg	34	
Generic Name	VILDAGLIPTIN TABLETS 50mg		0 W W W W W W W W W W W W W W W W W W W
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Sample drawn by	Thomas Muasya	Page no.	2 of 2

S.No.	Test	Result	Specification
10	Dissolution		
a	VILDAGLIPTIN	Min: 99.44% Max: 105.31% Avg: 102.35%	NLT 80% of label claim
11	Assay	Found/Tab. Stated/Tab.	Limits
a. ,	VILDAGLIPTIN	49.59 mg 50 mg 99.17%	45.0 to 55.0 mg 90.0 to 110.0%

REMARKS: The sample complies with specifications.



Analyzed by	Checked by	Approved by 02 JUN A	Authorised by
le Szelmel.	OH.	A TEL: 978209 31 334	
Evans Mbati/Cornell Owuor	Mr. Patrick Ouma	Dhruv Mandali Box 29716 -	Dr Meshack Odenyo
R&D Analyst	QC Supervisor	Research & Development Head	Pharmacist