

AKUMS DRUGS & PHARMACEUTICALS LTD.At : Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur, Haridwar - 249403 Uttarakhand,
INDIA**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	DAPASmart GM 2/1000		
Generic Name :	Dapagliflozin, Glimepiride & Metformin Hydrochloride (Extended Release) Tablets		
Mfg. Lic. No. :	4/UA/LL/2014	Market:	DOMESTIC
Batch No. :	PLA2BM01	A. R. No.:	F20240703117
Mfg. Date :	Jun. 2024	Pack Size:	1x10 Tabs
Expiry date:	May. 2026	Pack Type:	Alu-Alu Blister (Sale)
Batch Size :	100000 Tabs	Sampled On:	03/07/24
Product Code :	40067839	Sample Quantity:	100 Tabs
Specification No, Ver No.:	STS/FP/40067839-00	Sampled By:	HARSHIT JOSHI
Ref. STP No. , Ver No.:	STP/FP/1865	Analyzed By:	MOHIT KUMAR
Manufactured For :	Healing Pharma	Date of Analysis:	04/07/24
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	18/07/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Pink coloured, oval shaped, biconvex, both side plain bilayered film coated tablets. 10 tablets packed in an alu-alu blister of printed aluminium foil and base aluminium foil.	Pink coloured, oval shaped, biconvex, both side plain bilayered film coated tablets. 10 tablets packed in an alu-alu blister of printed aluminium foil and base aluminium foil.
2	Identification (By HPLC)	As below	As below

	Prepared By QC	Reviewed By QC	Approved By QC
Date	19/07/24	19/07/24	19/07/24
Name	ROBIN KUMAR	MUKESH PRIYA	RAJESHWAR SINGH
Designation	ASST. OPERATOR	SR. EXECUTIVE	DY. MANAGER

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QA REVIEWED

Name : SHRI NIVAS ; Date : 19/07/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Dapagliflozin and Glimepiride	In the assay, the major peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with standard solution.	Complies
b.	Metformin hydrochloride	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with standard solution.	Complies
3	Dimension	As below	As below

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Manufactured For :	Healing Pharma	Date of Analysis:	04/07/24
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	18/07/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Length	21.4 mm $\pm$ 0.2 mm. (21.2 mm to 21.6 mm)	Min. 21.40 mm Max. 21.43 mm
b.	Width	10.4 mm $\pm$ 0.2 mm. (10.2 mm to 10.6 mm)	Min. 10.38 mm Max. 10.42 mm
c.	Thickness	7.8 mm $\pm$ 0.4 mm. (7.4 mm to 8.2 mm)	Min. 7.91 mm Max. 7.97 mm
4	Average weight	1515.0 mg $\pm$ 5.0%	1509.90 mg
5	Uniformity of weight	Not more than two of individual weight deviate from the average weight by more than 5% and none deviates by more than 10%.	-1.1% to +0.9%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
6	Uniformity of content (By HPLC)	As below	As below

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Dapagliflozin	The preparation complies with the test if each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 per cent of the average content. If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits	95.12% to 108.39%

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Manufactured For :	Healing Pharma	Date of Analysis:	04/07/24
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	18/07/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		of 75 to 125 per cent, repeat the determination using another 20 dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content.	

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
b.	Glimepiride	The preparation complies with the test if each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 per cent of the average content. If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits	95.43% to 105.34%

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Manufactured For :	Healing Pharma	Date of Analysis:	04/07/24
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	18/07/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		of 75 to 125 per cent, repeat the determination using another 20 dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content.	
7	Dissolution	As below	As below

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
a.	Dapagliflozin	Level S1 (No. of tablets tested 6 units): Each unit is not less than 70 % (Q) which is equivalent to 75 % of the labelled amount is released. Level S2 (No. of tablets tested 6 units): Average of 12 units (S1 + S2) is equal to or greater than 70 % and no unit is less than 55 % (Q – 15 %). Level S3 (No. of tablets tested 12 units): Average of 24 units (S1 + S2 + S3) is equal to or greater than 70 %	88.77%, 76.10%, 94.39%, 91.00%, 87.80%, 94.28%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		not more than 2 units are less than 55 % (Q – 15 %) and no unit is less than 45 % (Q – 25 %).	

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
b.	Glimepiride	Level S1 (No. of tablets tested 6 units): Each unit is not less than 70 % (Q) which is equivalent to 75 % of the labelled amount is released. Level S2 (No. of tablets tested 6 units): Average of 12 units (S1 + S2) is equal to or greater than 70 % and no unit is less than 55 % (Q – 15 %). Level S3 (No. of tablets tested 12 units): Average of 24 units (S1 + S2 + S3) is equal to or greater than 70 %	93.59%, 99.62%, 87.06%, 86.14%, 89.98%, 95.16%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
c.	Metformin hydrochloride	Level L1 (No. of tablets tested 6 units): No individual value lies outside each of the stated ranges and no individual value is less than the stated amount at the final test time. Level L2 (No. of tablets tested 6 units): The average value of the 12 units (L1 + L2) lies within each of the stated ranges and is not less than the stated amount at the final test time, none is more than 10 per cent of labelled content outside each of the	As below

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INDIA**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	DAPASmart GM 2/1000		
Generic Name :	Dapagliflozin, Glimepiride & Metformin Hydrochloride (Extended Release) Tablets		
Mfg. Lic. No. :	4/UA/LL/2014	Market:	DOMESTIC
Batch No. :	PLA2BM01	A. R. No.:	F20240703117
Mfg. Date :	Jun. 2024	Pack Size:	1x10 Tabs
Expiry date:	May. 2026	Pack Type:	Alu-Alu Blister (Sale)
Batch Size :	100000 Tabs	Sampled On:	03/07/24
Product Code :	40067839	Sample Quantity:	100 Tabs
Specification No, Ver No.:	STS/FP/40067839-00	Sampled By:	HARSHIT JOSHI
Ref. STP No. , Ver No.:	STP/FP/1865	Analyzed By:	MOHIT KUMAR
Manufactured For :	Healing Pharma	Date of Analysis:	04/07/24
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	18/07/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		stated ranges, and none is more than 10 per cent of labelled amount below the stated amount at the final test time. Level L3 (No. of tablets tested 12 units): The average value of the 24 units (L 1 + L2 + L3) lies within each of the stated ranges, and is not less than the stated amount at the final test time, not more than 2 of the 24 units are more than 10 per cent of labelled content outside each of the stated	

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Name	ROBIN KUMAR	MUKESH PRIYA	RAJESHWAR SINGH
Designation	ASST. OPERATOR	SR. EXECUTIVE	DY. MANAGER

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		ranges, not more than 2 of the 24 units are more than 10 per cent of labelled content below the stated amount at the final test time, and none of the units is more than 20 per cent of labelled content outside each of the stated ranges or more than 20 per cent of labelled content below the stated amount at the final test time	
c.1.	After 1 hour	25% to 50%	42.31%, 38.71%, 39.58%, 37.72%, 40.57%, 39.45%
c.2.	After 3 hours	45% to 75%	63.70%, 61.80%, 60.57%, 61.30%, 63.69%, 63.67%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
c.3.	After 10 hours	Not less than 80%	91.87%, 95.79%, 98.64%, 97.64%, 98.31%, 97.79%
8	Related Substances (By HPLC)	As below	As below
a.	Dapagliflozin	As below	As below
a.1.	Single Maximum unknown impurity	Not more than 0.5%	Below Disregard Limit
a.2.	Total Impurities	Not more than 2.0%	Below Disregard Limit
b.	Glimepiride	As below	As below
b.1.	Glimepiride Impurity B	Not more than 2.5%	Not Detected

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
b.2.	Glimepiride Impurity C	Not more than 0.5%	Not Detected
b.3.	Single Maximum Unknown Impurity	Not more than 0.5%	0.24 %
b.4.	Total impurities (Total Known Impurities + Total Unknown Impurities)	Not more than 3.5 %	0.83 %
c.	Metformin Hydrochloride	As below	As below
c.1.	Any Individual Impurity	Not more than 0.1 %	0.01 %

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
c.2.	Total Impurities	Not more than 0.6 %		0.01 %
9	Assay - Each film coated bilayered tablet contains:	Shelf Life Limit	Release Limit	
a.	Dapagliflozin Propanediol USP eq. to Dapagliflozin - 10 mg	NLT 9.00mg to NMT 11.00mg (NLT 90.00% to NMT110.00% of label claimed)	NLT 9.50mg to NMT 11.00mg (NLT 95.00% to NMT110.00% of label claimed)	9.54mg 95.40%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
b.	Metformin Hydrochloride IP (as extended-release form) - 1000 mg	NLT 900.00mg to NMT 1100.00mg (NLT 90.00% to NMT110.00% of label claimed)	NLT 950.00mg to NMT 1100.00mg (NLT 95.00% to NMT110.00% of label claimed)	952.12mg 95.21%
c.	Glimepiride IP - 2 mg	NLT 1.800mg to NMT 2.200mg (NLT 90.00% to NMT110.00% of label claimed)	NLT 1.900mg to NMT 2.200mg (NLT 95.00% to NMT110.00% of label claimed)	1.960mg 98.00%

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CONCLUSION : The Finished Product complies as per IH Specifications.

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