

BIOALTUS PHARMACEUTICAL PVT. LTD.,

DEPARTMENT: QUALITY CONTROL

CERTIFICATE OF ANALYSIS

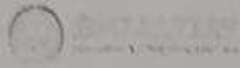
Product Name	DAPAFIX TRIO 500	Product code	701354
Batch No.	SIBP26477	Sample Quantity	02+02 Blister
Batch Size	100000 Nos	Date of Analysis	03/08/26
Mfg. Date	07/2026	Exp. Date:	06/2028
Specification No.	BP/FPS/D14-01	Date of Release	03/09/26
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP26/H27/0001
Sampling Date	03/08/26	STP. No.	BP/FPT/D14-01
Supplier Name	American Remedies Healthcare Pvt. Ltd.	Pack Size	1x10'S
		Page No.	Page 1 of 2

Sl. No.	Tests	Specification	Results
1.	Description	Capsule shaped, biconvex, bilayer tablet where Dapagliflozin and Sitagliptin Phosphate layer is light pink colour and Metformin layer is white to off white colour having plain on both side.	Capsule shaped, biconvex, bilayer tablet where Dapagliflozin and Sitagliptin Phosphate layer is light pink colour and Metformin layer is off white colour having plain on both side.
2.	Identification For, Sitagliptin and Dapagliflozin (By HPLC)	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	Complies
	Metformin HCl (By UV)	The absorbance of sample solution matches with absorbance of standard solution, obtained in the assay.	Complies
3.	Average weight	913.0 mg $\pm$ 3.0 %	903.28 mg
4.	Uniformity of Weight	$\pm$ 5.0 % of average weight.	Max: +0.97 % Min: -0.81 %
5.	Length	18.00 mm to 18.20 mm	18.15 mm
6.	Width	9.00 mm to 9.20 mm	9.16 mm
7.	Thickness	5.30 mm to 5.50 mm	5.47 mm
8.	Assay	Each film-coated bilayered tablet contains:	

Particulars	Prepared By	Checked By	Approved By
Name	RIPUNJAY KUMAR SINHA	Vaun Km. Singh	DURGESH KUMAR
Designation	OFFICER	Sr. Executive - Q.C.	Manager - Q.C.
Sign & Date	Ripunjay 03/09/26	03/09/26	03/09/26

FORMAT NO. - F03-03/QCC 004

03/09/26

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	Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 10 mg	NLT 9.0 mg and NMT 11.0 mg NLT 90.0 % and NMT 110.0 %	10.10 mg 101.0 %		
	Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 100 mg	NLT 90.0 mg and NMT 110.0 mg NLT 90.0 % and NMT 110.0 %	97.46 mg 97.5 %		
	Metformin HCl IP: 500 mg (as extended release form)	NLT 450.0 mg and NMT 550.0 mg NLT 90.0 % and NMT 110.0 %	493.73 mg 98.8 %		
9.	Dissolution	Limit	Avg.	Max.	Min.
	Metformin				
	1 st Hour	NLT 20 % to NMT 40 %	37.9 %	38.7 %	37.3 %
	3 rd Hour	NLT 40 % to NMT 70 %	62.6 %	63.7 %	61.8 %
	10 th Hour	NLT 70 %	87.4 %	88.6 %	86.3 %

Remarks: The above sample ~~complies~~ **does not comply** to the prescribed standards of quality in respect of the above Tests as per Finished Product Specification No: BP/FPS/D14-01.

Particulars	Prepared By	Checked By	Approved By
Name	RIPUNJAY KUMAR SINGH	Naman Kr. Singh	DURGESH KUMAR
Designation	OFFICER	Sr. Executive-Q.C.	Manager-QC
Sign & Date	<u>Ripunjay</u> 07/09/26	<u>[Signature]</u> 09/09/26	<u>[Signature]</u> 03/09/26