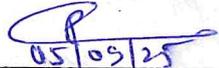
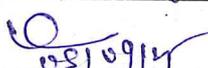
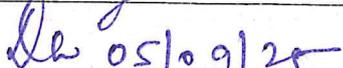


**BIOALTUS PHARMACEUTICAL PVT. LTD.,****DEPARTMENT: QUALITY CONTROL****CERTIFICATE OF ANALYSIS**

Product Name	DAPAFOX TRIO 500	Product code	701354
Batch No.	SIBP25516	Sample Quantity	02+04 Blister
Batch Size	1.0 Lacs	Date of Analysis	25/08/25
Mfg. Date	08/2025	Exp. Date:	07/2027
Specification No.	BP/FPS/D14-00	Date of Release	05/09/25
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP25/I05/0004
Sampling Date	25/08/25	STP. No.	BP/FPT/D14-00
Supplier Name	American Remedies Healthcare Pvt. Ltd.	Pack Size	10×10'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 ± 2.0 %	897.93 mg
4.	Uniformity of Weight	± 3.0 % of average weight.	Max: +2.64 % Min : -1.21 %
5.	Length	18.00 mm to 18.20 mm	18.15 mm
6.	Width	9.00 mm to 9.20 mm	9.11 mm
7.	Thickness	5.30 mm to 5.50 mm	5.38 mm
8.	Assay	Each film-coated bilayered tablet contains:	

Particulars	Prepared By	Checked By	Approved By
Name	Pushkar Raj	Vijay Kr. Singh	DURGESH KUMAR
Designation	Sr. officer - Q.C	Sr. Executive - Q.C	Manager - Q.C
Sign & Date	 05/09/25	 05/09/25	 05/09/25

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		Page No.	Page 2 of 2

	Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 10 mg	NLT 9.0 mg and NMT 11.0 mg NLT 90.0 % and NMT 110.0 %	9.89 mg 98.93 %		
	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 %	97.08 mg 97.08 %		
	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 %	505.09 mg 101.02 %		
9.	Dissolution	Limit	Avg.	Max.	Min.
	Metformin				
	1 st Hour	NMT 55 %	39.01 %	41.59 %	37.03 %
	3 rd Hour	NLT 50 %	72.66 %	75.07 %	70.00 %
	10 th Hour	NLT 80 %	99.97 %	101.19%	98.66 %

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/D14-00**.

Particulars	Prepared By	Checked By	Approved By
Name	Pushkar Raj	Vaman K. Singh	DURGESH KUMAR
Designation	Sr. Officer-Q.C	Sr. Executive-Q.C	Manager-Q.C
Sign & Date	 05/09/25	 05/09/25	 05/09/25