



# UNITED BIOCEUTICALS PVT. LTD.

Plot No. 33C, Industrial Park-IV, Begumpur, Haridwar-249402, (Uttarakhand)

## CERTIFICATE OF ANALYSIS

Product Name: <b>ALFADOFX-250</b>		Test SPC No.: <b>UB/QC/STP3267</b>
Generic Name: Methyldopa Tablets IP 250 mg		
Marketed by: American remedies Healthcare Pvt. Ltd.		
Mfg. Lic No.: 94/UA/2017		<b>Batch No.: T242709</b>
Batch Size: 2,04,000 Tabs	Pack Size: 10 x 10's	A. R. No.: FPT25260191
Sample Quantity: 60 Tabs	Mfg. Date: 12/2024	Expiry Date: 11/2026
Shelf Life: 24 Months	Sampling Date: 16/01/2025	Report Date: 17/01/2025

Test	Specification	Results
<b>Description</b>	Yellow colour, circular, biconvex, film coated tablets, break line on one side.	Yellow colour, circular, biconvex, film coated tablets, break line on one side.
<b>Identification:</b>	A. By IR B. By UV C. By Chemically D. By Chemically	Complies Complies Complies Complies
<b>Average Weight</b>	600.0 mg $\pm$ 5.0% (570.0 to 630.0 mg)	591.6 mg
<b>Uniformity of Weight</b>	Not more than two tablets deviate from $\pm$ 7.5% and none deviates from $\pm$ 15% of average weight	Complies
<b>Disintegration Test</b>	NMT 30 Minutes	6:20 Minutes
<b>Optical Rotation</b>	-0.98 <sup>o</sup> to -1.09 <sup>o</sup>	-0.99 <sup>o</sup>
<b>Dissolution Test</b>	NLT 85%	91.74% to 95.15%
<b>Assay:</b> Each film coated tablet contains: Methyldopa IP Eq. to Anhydrous Methyldopa 250mg	237.50 mg to 262.50 mg 95.00% to 105.00%	247.24 mg 98.90%

**OPINION:** The sample **Complies/Does not Complies** as per Standard specification.

Prepared By		Reviewed By		Approved By	
Name	Rupesh Sharma	Name	Praveesh Kumar	Name	Suresh Kumar
Designation	QC Officer	Designation	QC Executive	Designation	Manager Q.C
Date	17/01/2025	Date	17/01/2025	Date	17/01/2025