

## UNITED BIOCEUTICALS PVT. LTD.

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

## CERTIFICATE OF ANALYSIS

Product Name: ALFADOFOX-250

Test SPC No.: UB/QC/STP3267

Generic Name: Methyldopa tablets IP 250 mg

Marketed by: American remedies Healthcare Pvt. Ltd.

 Mfg. Lic No.: 94/UA/2017

 Batch No.: T241093

 Batch Size: 1,60,000 Tabs
 Pack Size: 10 x 10's
 A. R. No.: FPT24251227

 Sample Quantity: 60 Tabs
 Mfg. Date: 07/2024
 Expiry Date: 06/2026

 Shelf Life: 24 Months
 Sampling Date: 20.08.2024
 Report Date: 21.08.2024

Test	Specification	Results
Description	Yellow colour, circular, biconvex, film coated tablets, break line on one side	Yellow colour, circular, biconvex, film coated tablets, break line on one side
Identification:	A. By IR B. By UV C. By Chemically D. By Chemically	Complies Complies Complies Complies
Average Weight	600.0 mg ± 3.0% (582.0 to 618.0 mg)	584.8 mg
Uniformity of Weight	Not more than two tablets deviate from ± 7.5% and none deviates from ± 15% of average weight	Complies
Disintegration Test	NMT 30 Minutes	5:34 Minutes
Optical Rotation	-0.98º to -1.09º	-0.990
Dissolution Test	NLT 85%	92.90% to 98.30%
Assay: Each film coated tablet contains:		92.90% to 96.30%
Methyldopa IP Eq. to Anhydrous Methyldopa 250mg	237.50 mg to 262.50 mg 95.00% to 105.00%	248.18 mg 99.27%

2/100/2019

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

521/08/ban

Analysed by: Date: Checked by: Date:

Approved by:

Date: