



UNITED BIOCEUTICALS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

Product Name: METHOTREX-2.5	Test SPC No.: UB/QC/STP1569
Generic Name: Methotrexate tablets IP 2.5 mg	
Marketed by: Healing Pharma	
Mfg. Lic No.: 94/UA/2017	Batch No.: T241043
Batch Size: 3,03,000 Tabs	Pack Size: 10 x 10's
Sample Quantity: 60 Tabs	Mfg. Date: 07/2024
Shelf Life : 24 Months	Expiry Date: 06/2026
Sampling Date: 22.08.2024	Report Date: 23.08.2024

Test	Specification	Results
Description	Pale yellow colour, circular, biconvex, uncoated tablets	Pale yellow colour, circular, biconvex, uncoated tablets
Identification	By UV	Complies
Average Weight	170.0 mg $\pm$ 3.0% (164.9 to 175.1 mg)	170.6 mg
Uniformity of Weight	Not more than two tablets deviate from $\pm$ 7.5% and none deviates from $\pm$ 15% of average weight	Complies
Disintegration Test	NMT 15 Minutes	5:14 Minutes
Friability Test	NMT 1.0%	0.20%
Related substance	any peak corresponding to Methotrexate impurity C NMT 3.0% any peak corresponding to Methotrexate impurity B NMT 0.5% any peak corresponding to Methotrexate impurity E NMT 0.3% The area of any other secondary peak NMT 0.2% The sum of the area of any other secondary peak NMT 1.0%	Not Detected Not Detected Not Detected Not Detected Not Detected
Dissolution Test	NLT 80%	92.16% to 97.44%
Assay: Each uncoated tablet contains: Methotrexate IP 2.5 mg	2.25 mg to 2.75 mg 90.00% to 110.00%	2.489 mg 99.55%

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

Analysed by: 
Date: 23/08/2024

Checked by: 
Date: 23/08/2024

Approved by: 
Date: 23/08/2024