



# UNITED BIOCEUTICALS PVT. LTD.

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

## CERTIFICATE OF ANALYSIS

|   |                           |                                    |
|---|---------------------------|------------------------------------|
| Product Name: <b>WARFOX-1</b>                       |                           | Test SPC No.: <b>UB/QC/STP3423</b> |
| Generic Name: Warfarin Sodium tablets IP 1 mg       |                           |                                    |
| Marketed by: American remedies Healthcare Pvt. Ltd. |                           |                                    |
| Mfg. Lic No.: 94/UA/2017                            |                           | <b>Batch No.: T241236</b>          |
| Batch Size: 1,10,000 Tabs                           | Pack Size: 20 x 10's      | A. R. No.: FPT24251178             |
| Sample Quantity: 60 Tabs                            | Mfg. Date: 08/2024        | Expiry Date: 07/2026               |
| Shelf Life: 24 Months                               | Sampling Date: 13.08.2024 | Report Date: 14.08.2024            |

| Test  | Specification   | Results  |
|---|---|--|
| <b>Description</b>  | White to off white, circular, biconvex, uncoated tablets.   | Off white, circular, biconvex, uncoated tablets. |
| <b>Identification</b>   | By IR<br>By Melting point about 159°  | Complies<br>Complies                             |
| <b>Average Weight</b>   | 170.0 mg $\pm$ 3.0% (164.9 to 175.1 mg)   | 170.6 mg   |
| <b>Uniformity of Weight</b>   | Not more than two tablets deviates from $\pm$ 7.5% and none deviates from $\pm$ 15% of Average Weight | Complies   |
| <b>Disintegration Test</b>  | NMT 15 Minutes  | 4:23 Minutes                                     |
| <b>Friability Test</b>  | NMT 1.0%  | 0.19%  |
| <b>Uniformity of content</b>  | 85.0% to 115.0%   | 97.30% to 100.25%                                |
| <b>Dissolution Test</b>   | NLT 75%   | 94.14% to 99.95%                                 |
| <b>Related Substances</b>   | Meets the test  | Complies   |
| <b>Assay:</b> Each uncoated tablet contains:<br>Warfarin Sodium Clathrate IP Eq. to (Anhydrous)<br>Warfarin Sodium 1 mg | 0.925 mg to 1.075 mg<br>92.50% to 107.50%   | 0.9918 mg<br>99.18%                              |

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

Analysed by:  
Date:

Checked by:  
Date:

Approved by:  
Date:

*14/08/2024*

*14/08/2024*

*14/08/2024*