

## CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Name and dosage form of product: **MISOPROSTOL TABLETS 200 MCG**  
**LIVPROSTOL-200**1.1 Active ingredient (s)<sup>2</sup> and amount (s) per unit dose<sup>3</sup>: Composition:

Active ingredient

Each uncoated tablet contains:

Misoprostol USP.....200 mg

Excipients.....q.s.

1.2 Is this product licensed to be placed on the market for use in the exporting country<sup>5</sup>? YES

1.3 Is this product actually on the market in the exporting country? YES

If the answer to 1.2 is yes, continue with section 2A and If the answer to 1.2 is no, omit section 2B<sup>6</sup>.

2.0

|        |  |        |  |
|--------|--|--------|--|
| 2A.1.0 | Number of product license <sup>7</sup> and Date of Issue:<br><b>G/25A/4782-A DATE : 16/10/2020</b>   | 2B.1.0 | Application for certificate<br>(Name and Address) : NA   |
| 2A.2.0 | Product License holder :<br><b>M/s. Livealth Biopharma Pvt. Ltd.,<br/>102/B, New Anand Kiran Appt. ,<br/>Manisha Crossing Old Padra Road,<br/>Vadodara- 390007</b> | 2B.2.0 | Status of applicant : NA   |
| 2A.3.0 | Status of product-license Holder <sup>8</sup> : MANUFACTURER   | 2B.2.1 | For categories b and c the name and address of<br>the manufacturer producing the dosage from<br>area <sup>9</sup> : N.A. |
| 2A.3.1 | For categories b and c the name and address of the<br>manufacturer producing the dosage form: N.A.   | 2B.3.0 | Why is marketing authorization lacking?<br>: N.A.  |
| 2A.4.0 | In an officially approved summery basis<br>Appended? <sup>10</sup> :No   | 2B.4.0 | Remark : <sup>13</sup><br>N.A.   |
| 2A.5.0 | Is the attached, officially approved product Information<br>complete and consonant<br>With the license? <sup>11</sup> : NOT PROVIDED                               |        |  |
| 2A.6.0 | Applicant for certificate if different from License<br>holder <sup>12</sup> : N.A  |        |  |

3.0 Does the certifying authority arrange for periodic inspection of the manufacturing plant?  
in which the dosage form is produced?

: Yes

3.1 Periodicity of routine inspections (years)

: One year

3.2 Has the manufacture of this type of dosage form been inspected?

: Yes

4.0 Does the information submitted by the applicant satisfy the certifying authority on all?

Aspects of the manufacture of the product? <sup>16</sup>

: N.A

**This Certificate is valid up to two Years from the date of issue.**

Address of certifying authority:

Food &amp; Drug Control Administration, Block No. 8,

1<sup>st</sup> Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar,

Gujarat, India.

Telephone No.: 91-79-23220176

Fax No.: 91-79-23220170

Name of Authorized Person: **Mr. H. L. RAVAT**

Signature:

Stamp &amp; Date: Joint Commissioner

Food &amp; Drug Control Administration

Gujarat State, India.

14 SEP 2023