

**Pure & Cure Healthcare Pvt. Ltd.**

Plot No. 26A-30, Sector-8A, I.I.E., SIDCUL, Ranipur  
Haridwar-249403, Uttarakhand, INDIA.

**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

|                                   |                                  |                                  |                        |
|-----------------------------------|----------------------------------|----------------------------------|------------------------|
| <b>Product Name :</b>             | VERTIHIST-16                     |                                  |                        |
| <b>Generic Name :</b>             | Betahistine Tablets IP           |                                  |                        |
| <b>Mfg. Lic. No. :</b>            | 31/UA/2013                       | <b>Market:</b>                   | DOMESTIC               |
| <b>Batch No. :</b>                | PA2BE09                          | <b>A. R. No.:</b>                | F20240626163           |
| <b>Mfg. Date :</b>                | Jun. 2024                        | <b>Pack Size:</b>                | 1x15 Tabs              |
| <b>Expiry date:</b>               | May. 2026                        | <b>Pack Type:</b>                | Alu-Alu Blister (Sale) |
| <b>Batch Size :</b>               | 300000 Tabs                      | <b>Sampled On:</b>               | 26/06/24               |
| <b>Product Code :</b>             | 40050069                         | <b>Sample Quantity:</b>          | 135 Tabs               |
| <b>Specification No, Ver No.:</b> | STS/FP/40050069-02               | <b>Sampled By:</b>               | VIKAS TYAGI            |
| <b>Ref. STP No. , Ver No.:</b>    | STP/FP/0038-02                   | <b>Analyzed By:</b>              | HARKISHAN              |
| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

| S.No. | TEST        | ACCEPTANCE CRITERIA                                                                                                                                                                | RESULTS                                                                                                                                                               |
|-------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1     | Description | White to off white coloured, round, biconvex, both side plain uncoated tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil and printed base aluminium foil. | White coloured, round, biconvex, both side plain uncoated tablets. 15 tablets packed in an alu-alu blister of printed aluminium foil and printed base aluminium foil. |

|                    | Prepared By QC | Reviewed By QC | Approved By QC |
|--------------------|----------------|----------------|----------------|
| <b>Date</b>        | 30/06/24       | 30/06/24       | 30/06/24       |
| <b>Name</b>        | NITIN BHATT    | SHRAVAN        | PRASHANT TYAGI |
| <b>Designation</b> | ASST. OPERATOR | ASST. MANAGER  | ASST. MANAGER  |

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Name : NITIN KUMAR ; Date : 30/06/2024

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| <b>Batch No. :</b>                | PA2BE09                          | <b>A. R. No.:</b>                | F20240626163           |
| <b>Mfg. Date :</b>                | Jun. 2024                        | <b>Pack Size:</b>                | 1x15 Tabs              |
| <b>Expiry date:</b>               | May. 2026                        | <b>Pack Type:</b>                | Alu-Alu Blister (Sale) |
| <b>Batch Size :</b>               | 300000 Tabs                      | <b>Sampled On:</b>               | 26/06/24               |
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| <b>Ref. STP No. , Ver No.:</b>    | STP/FP/0038-02                   | <b>Analyzed By:</b>              | HARKISHAN              |
| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

| S.No. | TEST           | ACCEPTANCE CRITERIA                                                                                                                                                                                                                                                                                                                                                                                    | RESULTS  |
|-------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 2     | Identification | (A) By IR: The IR spectrum of the test preparation should concordant to that of the reference preparation of Betahistine Hydrochloride reference standard or working standard.<br><br>(B) By HPLC: In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution of Betahistine Hydrochloride. | Complies |
| 3     | Dimension      | As below                                                                                                                                                                                                                                                                                                                                                                                               | As below |

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| <b>Batch Size :</b>               | 300000 Tabs                      | <b>Sampled On:</b>               | 26/06/24               |
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| <b>Ref. STP No. , Ver No.:</b>    | STP/FP/0038-02                   | <b>Analyzed By:</b>              | HARKISHAN              |
| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

| S.No. | TEST                 | ACCEPTANCE CRITERIA                                                                                                          | RESULTS                       |
|-------|----------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| a.    | Diameter             | 8.0 mm $\pm$ 0.2 mm (7.8 mm to 8.2 mm )                                                                                      | Min. 8.05 mm Max. 8.09 mm     |
| b.    | Thickness            | 3.6 mm $\pm$ 0.3 mm ( 3.3 mm to 3.9 mm )                                                                                     | Min. 3.51 mm Max. 3.62 mm     |
| 4     | Average weight       | 171.0 mg $\pm$ 7.5%                                                                                                          | 168.97 mg                     |
| 5     | Uniformity of weight | Not more than two of individual weight deviate from the average weight by more than 7.5% and none deviates by more than 15%. | -2.1% to +1.7%                |
| 6     | Disintegration Time  | Not more than 15 minutes                                                                                                     | Passes (25 Seconds)           |
| 7     | Hardness             | Not less than 30 Newton                                                                                                      | Min. 36 Newton Max. 41 Newton |
| 8     | Friability           | Not more than 1.0% w/w                                                                                                       | 0.12 %w/w                     |

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| <b>Name</b>        | NITIN BHATT    | SHRAVAN        | PRASHANT TYAGI |
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| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

| S.No. | TEST        | ACCEPTANCE CRITERIA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | RESULTS                                                 |
|-------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| 9     | Dissolution | <b>Level S1 (No. of tablets Tested 6 units):</b> Each unit is not less than 80 % (Q) which is equivalent to 85 % of the labelled amount is released.<br><br><b>Level S2 (No. of tablets tested 6 units):</b> Average of 12 units (S1 + S2) is equal to or greater than 80 % and no unit is less than 65 % (Q – 15 %).<br><br><b>Level S3 (No. of tablets tested 12 units):</b> Average of 24 units (S1 + S2 + S3) is equal to or greater than 80 % not more than 2 units are less than 65 % (Q – 15 %) and No unit is less than | 105.01%, 104.61%, 105.82%,<br>104.61%, 105.82%, 106.63% |

|                    |                       |                       |                       |
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| <b>Name</b>        | NITIN BHATT           | SHRAVAN               | PRASHANT TYAGI        |
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| <b>Expiry date:</b>               | May. 2026                        | <b>Pack Type:</b>                | Alu-Alu Blister (Sale) |
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| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

| S.No. | TEST | ACCEPTANCE CRITERIA | RESULTS |
|-------|------|---------------------|---------|
|       |      | 55 % (Q – 25 %).    |         |

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| S.No. | TEST                  | ACCEPTANCE CRITERIA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | RESULTS           |
|-------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| 10    | Uniformity of content | <p>The preparation complies with the test if each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 to 125 per cent of the average content.</p> <p>If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits of 75 to 125 per cent, repeat the determination using another 20</p> | 98.76% to 102.56% |

|                    |                       |                       |                       |
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| S.No. | TEST                         | ACCEPTANCE CRITERIA                                                                                                                                                                                                                                                           | RESULTS      |
|-------|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|       |                              | dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content. |              |
| 11    | Related Substance            | As below                                                                                                                                                                                                                                                                      | As below     |
| a.    | Betahistine Impurity C       | Not more than 2.0%                                                                                                                                                                                                                                                            | Not Detected |
| b.    | Betahistine Impurity A       | Not more than 0.2%                                                                                                                                                                                                                                                            | Not Detected |
| c.    | Any other secondary impurity | Not more than 0.2%                                                                                                                                                                                                                                                            | Not Detected |

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| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
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| S.No. | TEST                                     | ACCEPTANCE CRITERIA                                                                    |                                                                                        | RESULTS           |
|-------|------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------|
| d.    | Sum of all the secondary impurities      | Not more than 2.0%                                                                     |                                                                                        | Not Detected      |
| 12    | Assay - Each uncoated tablet contains:   | Shelf Life Limit                                                                       | Release Limit                                                                          |                   |
|       | Betahistine Hydrochloride IP - 16 mg/Tab | NLT 15.20mg/Tab to NMT 16.80mg/Tab<br><br>(NLT 95.00% to NMT 105.00% of label claimed) | NLT 15.52mg/Tab to NMT 16.80mg/Tab<br><br>(NLT 97.00% to NMT 105.00% of label claimed) | 15.84mg<br>99.00% |

**CONCLUSION :** The Finished Product complies as per IP Specifications.

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| <b>Batch Size :</b>               | 300000 Tabs                      | <b>Sampled On:</b>               | 26/06/24               |
| <b>Product Code :</b>             | 40050069                         | <b>Sample Quantity:</b>          | 135 Tabs               |
| <b>Specification No, Ver No.:</b> | STS/FP/40050069-02               | <b>Sampled By:</b>               | VIKAS TYAGI            |
| <b>Ref. STP No. , Ver No.:</b>    | STP/FP/0038-02                   | <b>Analyzed By:</b>              | HARKISHAN              |
| <b>Manufactured For :</b>         | Healing Pharma India Pvt. Ltd.   | <b>Date of Analysis:</b>         | 27/06/24               |
| <b>Manufactured By :</b>          | Pure & Cure Healthcare Pvt. Ltd. | <b>Analysis Completion Date:</b> | 30/06/24               |

|                    | <b>Prepared By QC</b> | <b>Reviewed By QC</b> | <b>Approved By QC</b> |
|--------------------|-----------------------|-----------------------|-----------------------|
| <b>Date</b>        | 30/06/24              | 30/06/24              | 30/06/24              |
| <b>Name</b>        | NITIN BHATT           | SHRAVAN               | PRASHANT TYAGI        |
| <b>Designation</b> | ASST. OPERATOR        | ASST. MANAGER         | ASST. MANAGER         |

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : NITIN KUMAR ; Date : 30/06/2024