



## TYPICAL CERTIFICATE OF ANALYSIS

|                                                                                                                    |                                             |                                                                                  |                                                 |
|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------|
| Product : Quinine Dihydrochloride BP                                                                               |                                             |                                                                                  | Page 1 of 1                                     |
| Reference : British Pharmacopoeia-2024                                                                             |                                             |                                                                                  |                                                 |
| Manufactured By : Nicotine Vault                                                                                   |                                             | Product code : QDHCL                                                             |                                                 |
| Self Life (Retest Date) : 3 years                                                                                  |                                             |                                                                                  |                                                 |
|                                                                                                                    |                                             |                                                                                  |                                                 |
| SR.NO                                                                                                              | TESTS                                       | SPECIFICATION                                                                    | RESULTS                                         |
| 1                                                                                                                  | Appearance                                  | A white or almost white powder                                                   | A white powder                                  |
| 2                                                                                                                  | Solubility                                  | Very soluble in water; soluble In ethanol (96%)                                  | Very soluble in water; Soluble in ethanol (96%) |
| 3                                                                                                                  | Identification A,B &C.                      | A) By TLC<br>B) Acidity Test.<br>C) Yields reaction a characteristic of Chloride | Complies<br>Complies<br>Complies                |
| 4                                                                                                                  | pH                                          | 2.0 to 3.0                                                                       | 2.80                                            |
| 5                                                                                                                  | Specific Optical Rotation                   | -223.0° to -229.0°                                                               | -225.31°                                        |
| 6                                                                                                                  | Other cinchona alkaloids by HPLC            |                                                                                  |                                                 |
| 6.1                                                                                                                | Dihydroquinine                              | Not more than 10.0%                                                              | 4.60%                                           |
| 6.2                                                                                                                | Any related substance Eluted before quinine | Not more than 5.0%                                                               | 0.29%                                           |
| 6.3                                                                                                                | Any other related substance                 | Not more than 2.5%                                                               | 0.01%                                           |
| 7                                                                                                                  | Loss on drying                              | NMT 3.0 %                                                                        | 1.18%                                           |
| 8                                                                                                                  | Sulphated Ash                               | Not more than 0.10%                                                              | 0.05%                                           |
| 9                                                                                                                  | Sulphates                                   | ≤0.12%                                                                           | Complies                                        |
| 10                                                                                                                 | Barium                                      | The solution remains clear for at least 15 minutes                               | Complies                                        |
| 12                                                                                                                 | Assay (on dry basis)                        | 99.0% to 101.0%                                                                  | 99.91%                                          |
| REMARK : As opinion of under signed product is <u>Complies/ does not Comply</u> as per prescribe Standard BP-2024. |                                             |                                                                                  |                                                 |