



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|------------------------------------------|-----------------------------|----------------------------|
| Specification For Finished Product | Spec No.: SPE-BLN-FP-001-01 | Effective Date: 07/08/2021 |
| | Supersede: NA | Review Date: 06/08/2023 |
| | Material code: NA | Reference: In-house |
| Product Name: | Blonanserin | Page No.: 1 of 2 |



| Sr. No | Test | Specification |
|--------|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.0 | Description | White off-white crystalline powder |
| 2.0 | Solubility | Soluble in tetrahydrofuran and in methylene dichloride, partially insoluble in water. |
| 3.0 | Identification | |
| 3.1 | By IR | The Infra-red absorption spectrum of sample should be concordant with the reference spectrum of standard. |
| 3.2 | By HPLC | The retention time of the major peak of the test sample should match with that of Blonanserin standard in the test of related substances by HPLC. |
| 3.3 | By Melting Point | Between 117°C to 119° |
| 4.0 | Loss on drying (%w/w) | Not more than 1.0% |
| 5.0 | Sulphated ash (%w/w) | Not more than 0.1% |
| 6.0 | Related substances | |
| 6.1 | Single maximum unknown impurity | Not more than 0.30% |
| 6.2 | Total impurity | Not more than 1.0% |
| 7.0 | Assay (%w/w) (On dried basis) | Between 98.0% to 102.0% |
| 8.0 | Residual solvents (ppm) | |
| 8.1 | Dichloromethane | Not more than 600 ppm |
| 8.2 | Acetone | Not more than 5000 ppm |

| Prepared by (Sign & Date) | Review by (Sign & Date) | Approved by (Sign & Date) |
|---------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------|
|  07/08/2021 | N.D. Patel 07/08/2021 |  07/08/2021 |

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Remark:**History of revision:**

| Revision No | Effective Date | Details |
|-------------|----------------|-------------------------|
| 01 | 07/08/2021 | Remove Heavy Metal test |

| Prepared by (Sign & Date) | Review by (Sign & Date) | Approved by (Sign & Date) |
|---------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------------------------------------------------------------------------|
|  07/08/2021 | N. D. Patel 07/08/2021 |  07/08/2021 |