| AMUNA PHARMACEUTICALS LLP | | |
|---|---|---|
| **Specification For Finished Product** | **Spec No.:** SPE-PRI-FP-003-01 | **Effective Date :** 09/08/2021 |
| | **Supersedes :** NA | **Review Date :** 08/08/2023 |
| | **Material code :** NA | **Reference :** USP 43 |
| **Product Name :** Prilocaine Hydrochloride | | **Page No.:** 1 of 1 |

| Sr. No | Test | Specification |
|---|---|---|
| 1.0 | Appearance | White or almost white, crystalline powder |
| 2.0 | Identification | |
| 2.1 | By IR | The Infra-red absorption spectrum of sample should be concordant with the standard spectra. |
| 2.2 | Chloride Test | The Filtrate meets the requirements |
| 2.3 | By HPLC | The retention time of the major peak of the sample solution corresponds to that standard solution, as obtained in the Assay. |
| 3.0 | Loss on Drying (%w/w) | Not more than 0.3% |
| 4.0 | Residue on Ignition (%w/w) | Not more than 0.1% |
| 5.0 | Related Substances | |
| 5.1 | Prilocaine Related compound-A | Not more than 0.01% |
| 5.2 | Any Individual unspecified Impurities | Not more than 0.1% |
| 5.3 | Total Impurities | Not more than 0.2% |
| 6.0 | Assay on Dried Basis (%w/w) | Not less than 98.0% and Not more than 102.0% |
| 7.0 | Residual Solvents (in ppm) | |
| 7.1 | n-Hexane | Not more than 290 ppm |

**Remark:** NA

| History of revision : | | |
|---|---|---|
| Revision No | Effective Date | Details |
| 00 | 09/08/2021 | Original issue |

| Prepared by (Sign & Date) | Review by (Sign & Date) | Approved by (Sign & Date) |
|---|---|---|
| 09/08/2021 | N.D. Patel 09/08/2021 | 09/08/2021 |