## **SPECIFICATIONS**

| PRODUCT NAME                          |                     | CEFRADINE FOR INJECTION  |  |      |        |
|---------------------------------------|---------------------|--|--|------|--------|
| Structure                             |                     | $H_2N$ , $H_2O$ $H_2N$ $OH$ $OH$   |  |      |        |
| M. F.                                 |                     | C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>4</sub> S · H <sub>2</sub> O |  | M. W | 367.43 |
| No.                                   | ľ                   | ГЕМS   | SPECIFICATIONS   |      |        |
| 1                                     | Description         |  | White to off-white crystalline powder  |      |        |
| 2                                     | Identification      |  | Positive   |      |        |
| 3                                     | Solubility          |  | Complies with the test   |      |        |
| 4                                     | pН                  |  | 8.0 ~ 9.6  |      |        |
| 5                                     | Loss on drying      |  | NMT 5.0%   |      |        |
| 6                                     | Sterillity          |  | Sterile  |      |        |
| 7                                     | Bacterial endotoxin |  | NMT 0.20 USP EU/mg   |      |        |
| 8                                     | Cephalexin content  |  | NMT 5.0%   |      |        |
| 9                                     | Assay (HPLC)        |  | NLT 62.0% (as Cephradine, Anhydrous)   |      |        |
| 10                                    | Storage Condition   |  | Be kept in an airtight container, sealed so as to exclude protected from light and stored at temperature not exceeding $5^\circ\!$ |      |        |
| ♣ Specification : KP, USP, EP, JP, CP |                     |  |  |      |        |

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