

## P.J.Healthcare

## PRODUCT: Ciprofloxacin 40% Granules/Powder (TASTE MASKING GRANULES/POWDER)

## **COMPOSITION:**

Each 100 gm Contains: Ciprofloxacin hydrochloride Eq. to Ciprofloxacin 40 gm Excipients Q.S

## **SPECIFICATIONS:**

| S. No. | TEST   | SPECIFICATION  |
|--------|--|--|
| 1      | Characters   | Customized coloured free flowing granular powder, which after reconstitution gives coloured & flavoured suspension.  |
| 2      | Identification   | The retention time obtained in the chromatogram for sample preparation must concordant to the standard preparation in assay test of ciprofloxacin HCI.                                     |
| 3      | pH (15% w/v suspension in purified water)                                    | Between 8.0 to 11.0  |
| 4      | Taste  | Bitterless & flavoured pleasant taste suspension after reconstitution with diluents (Purified water)   |
| 5      | Bulk density   | Between 0.6 to 0.8 g/ml  |
| 6      | Sieve Test   | 100% material should pass through 20 mesh (850 micron), & not less than 90 % material pass through 25 mesh (710 micron), and more than 90% material should retain on 45 mesh (355 micron). |
| 7      | Dissolution  | Not less than 75% of Ciprofloxacin<br>(625 mg Granules/900 ml 0.01M Hcl<br>at 100 RPM for 60 minutes by dissolution apparatus of USP<br>type2 Paddle).                                     |
| 8      | Assay: Each 100gm<br>Ciprofloxacin hydrochloride<br>Eq. to Ciprofloxacin40gm | 36 gm to 44 gm<br>(90.0% to 110.0%)  |

NOTE: Customized specification & flavour will be available on request.

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