

Unipharm Pharmaceutical Industry Co., Ltd 山东优阜药业科技有限公司

Certificate of Analysis

| Product | HYDROXYETHYL STARCH 130/0.4 | | |
|---------------------------|-----------------------------|--|------------|
| Batch No. | 2F200301 | Approval Date | 04/10/2020 |
| Mfg. Date | 03/2020 | Exp. Date | 02/2023 |
| Tests | Results | Specifications | |
| Character | Complies | Should comply | |
| Identification | Complies | Chemistry reaction, should be positive reaction | |
| | Complies | By IR absorption, to match with the working standard | |
| рН | 5.6 | 4.5-7.0 | |
| Appearance of solution | Complies | Should comply | |
| Absorbance | 0.022 | Max.0.025 at 400nm | |
| Loss on drying | 2.8% | ≤15.0% | |
| Heavy metals | <10ppm | ≤10ppm | |
| Sodium chloride | 0.03% | ≤0.1% | |
| Ethylene glycol | 0.0024% | Not more than 0.004% | |
| Ethylene oxide | 0% | Not more than 0.0001% | |
| 2-Chloroethanol | 0% | Not more than 0.0005% | |
| Mw | 124 300 | 110 500~149 500 | |
| Mw10%min | 21573 | ≥15 000 | |
| Mw10%max | 373545 | ≤380 000 | |
| Molar Substitution | 0.41 | 0.368~0.432 | |
| C2/C6 ratio | 8.5 | 7.2~10.8 | |
| Microbial contamination | Complies | TAMC not more than 100CFU/g | |
| Bacterial endotoxins | Complies | ≤2.5IU/g | |
| Conclusion: Conforms to H | EP 8.0 standard. | | |

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