

Certification of Analysis for Hydroxypropyl-beta-cyclodextrin

CAS No.:128446-35-5

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| Batch No. | HP20221005P | Packing | 10kg/bag |
| Manufacturing date | 2022.10.05 | Quantity | 1260kg |
| Sampling Time | 2022.10.12 | Report Date | 2022.10.28 |
| Sample From | Warehouse | Expiry Date | 2024.10.04 |
| Test Standard | USP 43-NF38 | | |
| Items | Standard | Results | |
| Appearance | White or almost white ,amorphous or crystalline powder.Freely soluble in water and in propylene glycol | Conforms | |
| Identification | IR: Same absorption bands as USP Hydroxypropyl Betadex RS | Conforms | |
| | Clarity of solution : Positive | Conforms | |
| Molar Substitution | 0.40~1.50 | 0.7 | |
| Betadex | ≤1.5% | 0.4% | |
| Propylene Glycol | ≤2.5% | 0.1% | |
| Any other single impurity | ≤0.25% | Not detected | |
| Total impurities excluding betadex and Propylene Glycol | ≤1.0% | Not detected | |
| Propylene Oxide | ≤1ppm | 0.01ppm | |
| Clarity of solution | 1.0g/2ml water solution is clear and transparent | Conforms | |
| Loss on drying | ≤10.0% | 4.2% | |
| Conductivity | ≤200Us/cm | 77 Us/cm | |
| The total combined moulds and yeasts count | ≤100cfu/g | <10cfu/g | |
| The total combined moulds and yeasts count | ≤1000cfu/g | <10 cfu/g | |



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|--|-------------------|---------|
| The total aerobic microbial count | ≤ 1000 cfu/g | 10cfu/g |
| The total combined moulds and yeasts count | ≤ 100 cfu/g | 10cfu/g |
| Conclusion: According to enterprise standard | | |



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