



## CERTIFICATE OF ANALYSIS

**Product Name:** Ora-Plus®

**Lot Number:** 3171061

**NDC Code:** N/A

**Size:** 473 mL

**Expiration Date:** 04/2025

**Manufacturing Date:** 05/2023

### TEST

### SPECIFICATION

### RESULT

|                                         |                                |                                                                   |
|-----------------------------------------|--------------------------------|-------------------------------------------------------------------|
| Total Aerobic Microbial Count           | NMT 100 CFU/mL                 | <10 CFU/mL (Beginning)<br><10 CFU/mL (Middle)<br><10 CFU/mL (End) |
| Absence of Escherichia coli             | Meets USP Requirements         | Meets USP Requirements                                            |
| Absence of Salmonella species           | Meets USP Requirements         | Meets USP Requirements                                            |
| Total Combined Molds and Yeasts count   | NMT 20 CFU/mL                  | <10 CFU/mL (Beginning)<br><10 CFU/mL (Middle)<br><10 CFU/mL (End) |
| Absence of Burkholderia cepacia complex | Meets USP Requirements         | Meets USP Requirements                                            |
| Description                             | White, somewhat viscous liquid | White, somewhat viscous liquid                                    |
| pH                                      | 4.0 – 4.5                      | 4.3                                                               |
| Specific Gravity                        | 1.002 – 1.022                  | 1.012                                                             |
| Viscosity                               | 1300 CP – 6700 CP              | 2400 CP                                                           |
| Residual Solvents Compliance            | Meets USP <467> Requirements   | Meets USP <467> Requirements                                      |
| Elemental Impurities Compliance         | Meets USP <232> Requirements   | Meets USP <232> Requirements                                      |

NMT = Not more than

Prepared

By/Date:

QA

Approved

By/Date:

Printed

Name:

Printed

Name:



3940 Quebec Ave N  
New Hope, MN 55427

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