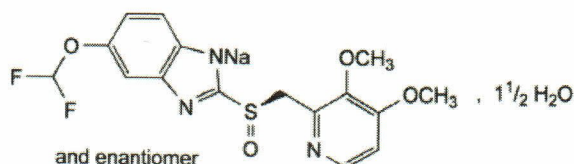


Batch no 20260308-18  
Mf date Mar 08 2026  
Retest Mar 07 2028  
Batch size 158.6 kg

Molecular Structure



Molecular Formula  $C_{16}H_{14}F_2N_3NaO_4S \cdot 1\frac{1}{2}H_2O$   
Molecular Weight 432.4  
CAS Registry Number 164579-32-2

May 25 2026

| Tests                     | Specifications                                                                                   | Results     |
|---------------------------|--------------------------------------------------------------------------------------------------|-------------|
| Appearance                | White or almost white powder                                                                     | Conforms    |
| Solubility                | Freely soluble in water and in ethanol (96%),<br>practically insoluble in hexane                 | Conforms    |
| Identification            | HPLC, IR, reaction of sodium                                                                     | Positive    |
| Appearance of solution    | 1% aqueous solution should be clear and not more<br>intensely colored than reference solution B6 | Conforms    |
| Optical rotation          | $-0.4 \sim +0.4^\circ$                                                                           | $0.1^\circ$ |
| Related substances (HPLC) | Impurity A $\leq 0.20\%$                                                                         | 0.03%       |
|                           | Impurity B $\leq 0.10\%$                                                                         | ND          |
|                           | Impurity C $\leq 0.10\%$                                                                         | 0.003%      |
|                           | Impurity D & F $\leq 0.20\%$                                                                     | ND          |
|                           | Impurity E $\leq 0.10\%$                                                                         | ND          |
|                           | Unspecified impurity $\leq 0.10\%$                                                               | ND          |
|                           | Total impurities $\leq 0.50\%$                                                                   | 0.05%       |
| Water content (KF)        | $5.9 \sim 6.9\%$                                                                                 | 6.4%        |
| Heavy metals (Pb)         | $\leq 20$ ppm                                                                                    | $< 20$ ppm  |
| Residual solvents         | Acetone $\leq 1000$ ppm                                                                          | ND          |
|                           | Ethanol $\leq 5000$ ppm                                                                          | ND          |
|                           | Methyl formate $\leq 3000$ ppm                                                                   | 108 ppm     |
|                           | Acetonitrile $\leq 410$ ppm                                                                      | 58 ppm      |
|                           | Methanol $\leq 3000$ ppm                                                                         | ND          |
|                           | Ethyl acetate $\leq 5000$ ppm                                                                    | 3056 ppm    |
| Assay (oab)               | $98.0 \sim 102.0\%$                                                                              | 99.5%       |

|                       |                               |
|-----------------------|-------------------------------|
| Packaging and storage | Protected from light.         |
| Conclusion            | Material complies with EP11.0 |