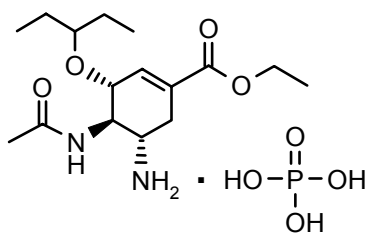


## SPECIFICATIONS

|                                                                                                   |                                     |
|---------------------------------------------------------------------------------------------------|-------------------------------------|
| Description                                                                                       |                                     |
| Appearance                                                                                        | powder or powder with lumps         |
| Colour                                                                                            | white to off-white                  |
| Identity                                                                                          |                                     |
| Oseltamivir                                                                                       | corresponds                         |
| Phosphate                                                                                         | corresponds                         |
| Specific optical rotation, 589 nm<br>25°C, C = 1 % (m/V) in water<br>(anhydrous and solvent-free) | -30.7° to -32.6°                    |
| Water                                                                                             | max. 0.5 %                          |
| Residual solvents (GC)                                                                            |                                     |
| Acetone                                                                                           | max. 0.1 %                          |
| Ethanol                                                                                           | max. 0.1 %                          |
| n-Heptane                                                                                         | max. 0.1 %                          |
| Methylene chloride                                                                                | max. 500 ppm <sup>1</sup>           |
| Heavy metals                                                                                      | max. 10 ppm                         |
| Organic impurities                                                                                |                                     |
| Ro 64-0802                                                                                        | max. 0.3 %                          |
| Ro 64-1637                                                                                        | max. 100 ppm                        |
| Tributylphosphine oxide                                                                           | max. 0.1 %                          |
| Other impurities                                                                                  | each max. 0.1 %<br>total max. 0.4 % |
| Total of all impurities                                                                           | max. 0.7 %                          |
| Assay (HPLC)<br>(anhydrous and solvent-free)                                                      | 98.0 - 101.5 %                      |



Ro 64-0796/002

C<sub>16</sub>H<sub>28</sub>N<sub>2</sub>O<sub>4</sub> 1:1 H<sub>3</sub>PO<sub>4</sub>

M<sub>r</sub> = 410.408

<sup>1</sup> Methylene chloride is only tested for in reworked active substance