**PRODUCT INFORMATION**

Raltegravir is an antiretroviral Active Pharmaceutical Ingredient (API) that inhibits HIV integrase. It is clinically used to treat the HIV infection and decrease infection rates by preventing insertion of HIV-1 DNA into the host genome. Raltegravir is the first-in-class integrase inhibitor.

**PRODUCT DETAILS**

- DMF available
- CAS No: 871038-72-1
- Empirical formula: C$_{20}$H$_{20}$FKN$_6$O$_5$
- Molecular weight: 482.51

**CHEMICAL STRUCTURE**

![Chemical Structure](image)

**BENEFITS**

VIO Chemicals offers Raltegravir API manufactured using a non-infringing and competitive process with respect to the prior art in terms of raw material consumptions, atom and step economy.

The process was designed, developed and optimized in-house for lean and scalable manufacturing, providing an additional advantage for high-volume products such as Raltegravir.

VIO Chemicals also offers advantageous and non-infringing crystalline form options, which enable early access to the European market.
<table>
<thead>
<tr>
<th>TEST</th>
<th>METHOD REFERENCE</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>In-house</td>
<td>White or almost white powder</td>
</tr>
<tr>
<td>Identification by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. IR</td>
<td>a. Ph.Eur. 2.2.24</td>
<td></td>
</tr>
<tr>
<td>b. HPLC</td>
<td>b. In house</td>
<td></td>
</tr>
<tr>
<td>c. XRD</td>
<td>c. In house</td>
<td></td>
</tr>
<tr>
<td>d. Reaction of potassium</td>
<td>d. Ph.Eur. 2.3.1 (b)</td>
<td></td>
</tr>
<tr>
<td>Identification by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Ph.Eur. 2.2.24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. In house</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. In house</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Ph.Eur. 2.3.1 (b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. The IR spectrum of the sample KBr dispersion conforms to the reference standard.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. The retention time of sample should match with that of Reference Standard.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. The X-Ray powder diffractogram the sample should match with the reference standard.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. It gives reaction of potassium.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solubility</td>
<td>In-house</td>
<td>Soluble in water, very slightly soluble in ethanol (96%), practically insoluble in heptane.</td>
</tr>
<tr>
<td>Loss on drying (105°C, 3 hours)</td>
<td>Ph.Eur. 2.2.32</td>
<td>Not more than 1.0% w/w</td>
</tr>
<tr>
<td>% Water content (by KF)</td>
<td>Ph.Eur. 2.5.12</td>
<td>Not more than 0.6% w/w</td>
</tr>
<tr>
<td>% Assay (by HPLC)</td>
<td>In-house</td>
<td>98.0-102.0% w/w on anhydrous substance</td>
</tr>
<tr>
<td>% Potassium content (by titrimetry)</td>
<td>In-house</td>
<td>7.5-8.5% w/w on anhydrous substance</td>
</tr>
<tr>
<td>Related substances (by HPLC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impurity C</td>
<td>In-house</td>
<td>Complies with Ph.Eur. limits</td>
</tr>
<tr>
<td>Impurity E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impurity F</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impurity G</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual unspecified impurity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total impurities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residual solvents (by GC)</td>
<td>In-house</td>
<td>According to ICH Q3C guidelines</td>
</tr>
<tr>
<td>Palladium content</td>
<td>In-house</td>
<td>According to ICH Q3D guidelines</td>
</tr>
<tr>
<td>Nickel content</td>
<td>In-house</td>
<td>According to ICH Q3D guidelines</td>
</tr>
</tbody>
</table>