VIO CHEMICALS

OUR SCIENCE, YOUR PRODUCT

Raltegravir API

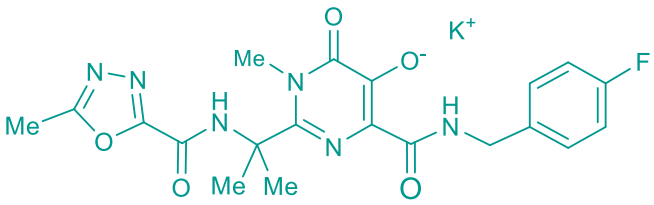
PRODUCT INFORMATION

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: $C_{20}H_{20}FKN_6O_5$
- Molecular weight: 482.51

CHEMICAL STRUCTURE



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.

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