AUTHENTIC DRUG SUBSTANCE Certificate of Analysis

Drug Substance:

Raltegravir potassium

Structure:

Starks Lot Number: NG1-44-1

Source: isolated from formulated drug product in May, 2008

Date of this analysis: data presented on this certificate of analysis

were generated in July, 2008

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C₂₀H₂₀FKN₆O₅ Mol. Wt.: 482.5 CAS # 871038-72-1

RESULT
White powder
consistent with literature description (free OH form)
observed: 280-282 °C (d) (uncorrected); literature value 279 °C
none observed by ¹ H NMR
0.3 wt.% inferred from total carbon analysis (49.64% carbon calculated for $C_{20}H_{20}FKN_6O_5 \cdot 0.08 H_2O$; 49.64% carbon found)
0.5 area % by HPLC; ¹ H NMR consistent with HPLC
98.8 ± 0.8 % chemical purity

Caution: this authentic drug substance is not for human use. This sample of authentic drug substance should not be considered as a reference standard of certified assay. Analytical methods described above provide an estimated purity range. Use of this authentic drug substance and estimated purity data is subject to the user's formal agreement with the NIH AIDS Research & Reference Reagent Program.

David F. Starks, Ph.D. Starks Associates, Inc.

Project Director

Approval Date: __

NIAID Contract No. HHSN272200800011C