



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

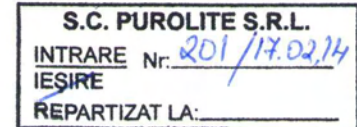
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 4234
Silver Spring, MD 20993

TELEPHONE: (301) 796-3206
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February 12, 2014

Mr. Arvind Verulkar
Plant General Manager
Purolite S.R.L.
Str Aleea, Uzinei Nr. 11
Victoria, Romania 505 700



Reference: FEI 3004201705

Dear Mr. Verulkar:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient manufacturing facility in Victoria, Romania by Investigator Zachery L. Miller on September 16 – 20, 2013.

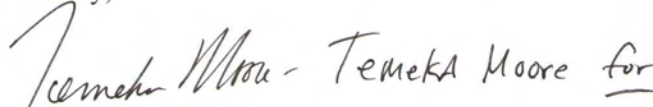
Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,


Alicia Mozzachio
Branch Chief
Division of International Drug Quality

Enclosure: EIR