FOCUS LABORATORIES

cGMP Certification Statement

Registration

FOCUS Laboratories is registered with the FDA as a Drug Establishment. Formal registration number is 3006576330. FOCUS Laboratories is a Contract Testing Laboratory and not a drug manufacturer. Therefore we are not required to, nor do we maintain a Drug Master File.

Debarment Notification

FOCUS Laboratories has not been debarred by the FDA nor is currently involved in any debarment proceeding with the FDA. Determined by a signed and dated certification statement, no person employed by FOCUS Laboratories has currently or in the past five years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. FOCUS Laboratories has not, and will not, use the services of any person debarred under Section 306 of the Generic Drug Enforcement Act of 1992.

Good Manufacturing Practices

FOCUS Laboratories has implemented current Good Manufacturing Practices (cGMPs) as stated in the code of Federal Regulations. These regulations apply to the facility or controls to be used for the "Manufacture, Processing, Packing or Holding of Drugs". Although our facility does not perform these functions and are therefore not subject to these practices, we do operate within the following sections of the regulations: 21 CFR Parts 210 and 211, Subpart B, Subpart C, Subpart D, Subpart E, Subpart I, and Subpart J.

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