NSF/ANSI 455-4
GMPs FOR OVER-THE-COUNTER DRUGS CERTIFICATION PROCESS

One annual audit is required for each ingredient and manufacturing, packaging, warehousing or distributing facility wishing to be GMP certified. The annual steps to maintain this certification are listed below.

1. Client submits application to NSF.
2. NSF sends contract to customer for review and signature.
3. Initial full GMP audit:
   > Typically two to three days depending on number of facilities, sizes and locations.
   > Within ten business days following the completion of your initial audit you will receive a grade, audit report, and a list of corrective actions through NSF’s online reporting portal.
4. Based on the number and scope of nonconformances, a grade is assigned.
   > If the facility receives an A or B grade, the facility can be certified after all corrective action plans are approved by NSF.
   > If the facility receives a C grade, a Monitoring Audit is required to verify the implementation of all corrective action plans prior to a facility receiving certification.
   > If the facility receives a failing grade, a new initial audit must be completed with a passing grade prior to a facility receiving certification.
5. GMP Certification:
   > A facility will become GMP certified once it meets all of the requirements of the GMPs as stated in NSF/ANSI 455-4 which is based on 21 CFR 210 and additional retailer requirements.
   > Certified companies are listed on NSF’s website as long as they continue to meet the requirements of certification.
   > Use of the NSF GMP mark is available to GMP certified companies on their website, literature, trade show displays, advertising and marketing material.
6. Annual audit:
   > The facility will receive another certification audit 12 months from the date of their initial audit to renew their certificate.
   > The facility will follow the process outlined in steps 4 and 5 above to maintain their certification for that calendar year.