

Quality Assurance testing under WAC 314-55-102

RJ Lee Group, Inc.

Development of the Program

► Requirements for GLP Checklist

- Align with WAC 314-55-102
- Ensure consistent and valid results
 - Quality management/quality system
 - Premises & buildings
 - Equipment (PPE)
 - Personnel & materials
 - Productions and process control

- Testing based upon *American Herbal Pharmacopoeia: Standards of Identity, Analysis, and Quality Control, Revision 2014*

American Herbal Pharmacopoeia®

Cannabis Inflorescence
Cannabis spp.

STANDARDS OF IDENTITY, ANALYSIS, AND
QUALITY CONTROL

Revision 2014

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Certification Process



*Average time from application submission to granting of provisional status is 96 days. Average time from provisional to audit is 81 days.

Requirements for each Field of Testing

- ▶ Standard Operating Procedure
- ▶ Validation Data/Demonstration of Capability
- ▶ Proficiency Testing (if applicable)

Fields of Testing

▶ Required

- ▶ Moisture Content
- ▶ Potency
- ▶ Foreign matter inspection
- ▶ Microbiological testing
- ▶ Mycotoxin
- ▶ Water Activity
- ▶ Residual solvents

▶ Optional

- ▶ Terpenes
- ▶ Heavy Metals
- ▶ Pesticides

Audit Program overview as of March 2019

- ▶ 1st year: Initial Application review and on-site assessment
- ▶ 2nd year: On-site audit
- ▶ 3rd year: On-site audit
- ▶ 4th year: Documentation review only (on-site audit not required)
- ▶ 5th year: On-site audit
- ▶ 6th year: Documentation review only (on-site audit not required)

Common Quality Program Deficiencies

- ▶ Security procedures not included in SOP's
- ▶ Instructions on Law enforcement interaction and federal laws not included in SOP's
- ▶ Lack of proper safety equipment including spill kits and safety showers
- ▶ No documentation of Software validation/verification
- ▶ Logbook documentation not completed and reviews not documented
- ▶ No process for Approval of suppliers
- ▶ Certificates of traceability not available
- ▶ Lack of use of secondary containers
- ▶ Lack of traceability to NIST standards
- ▶ Lack of Procedure for Management reviews

Costs for Certification

- ▶ Initial Application: \$2,747.00
- ▶ 1st year: Two day on-site auditing plus travel and per diem: \$6,192.00

Total initial licensing effort is \$8,939.00 (+ travel & per diem)

- ▶ 2nd year: Two day on-site auditing plus travel and per diem: \$6,192.00
- ▶ 3rd year: Two day on-site auditing plus travel and per diem: \$6,192.00
- ▶ 4th year: Application renewal-paper work review only, (no on-site audit anticipated) \$1,667.00

**If additional follow-up required for any audit or review the charge will be \$150.00 per hour*