# DR7 HACCP Plan

**Facility Name:** Invicta Nutraceuticals LLC
**Address:** 870 E Crescentville Rd, Cincinnati, OH 45246
**HACCP Coordinator:** Jason Brown
**Date:** 11/1/24
**FDA Establishment Identifier (FEI):** 3032196082

## 1. Product Description

**Products:**

- **DR7 Pain Cream**: A topical analgesic for temporary pain relief.
- **DR7 Pain Salve**: A topical analgesic salve for muscle and joint discomfort.
- **DR7 Pain Roll-On**: A topical analgesic roll-on for convenient application to relieve aches and pains.
- **DR7 Snore Rub (Breathe Easy Ointment)**: Marketed as a nighttime ointment to improve breathing and support nasal comfort.

## 2. Process Flow Diagram

**Production Steps:**

1. **Raw Material Receipt and Storage**:
    - Ingredients stored in a food-grade clean room.
    - Packaging (jars, lids, labels, product boxes, master cases) stored in the warehouse.
2. **Weighing and Mixing**:
    - Ingredients measured and mixed in food-grade mixing equipment.
3. **Depositing and Filling**:
    - Mixed product transferred to depositor to fill jars.
4. **Packaging**:
    - Filled jars and lids assembled in a clean room, labeled, and boxed.
    - Finished goods packed in master cases.

5. **Storage and Shipping**:
    - Pallets moved to the warehouse for storage and shipped according to customer orders.

## 3. Hazard Analysis

**Potential Hazards and Control Measures:**

| Step | Potential Hazards | Control Measures |
|---|---|---|
| Raw Material Receipt | Contaminated ingredients | Supplier audits, COA verification, visual inspection |
| Storage | Cross-contamination, spoilage | Separate storage zones, temperature control |
| Mixing | Foreign objects, contamination | Ingredient screening, equipment inspection |
| Filling | Equipment contamination | Scheduled cleaning and sanitization |
| Packaging | Defective packaging | Visual inspection of jars, lids, labels |
| Storage and Shipping | Damage, contamination | Temperature and humidity control, pallet inspection |

## 4. Critical Control Points (CCPs)

**Identified CCPs:**

1. **Raw Material Receipt**: Verify COAs for all sensitive ingredients (e.g., plant extracts, essential oils).
2. **Mixing**: Monitor equipment temperature and verify mixing times to prevent microbial growth.
3. **Filling and Packaging**: Inspect jars and lids for integrity and cleanliness.
4. **Finished Product Testing**: Conduct microbiological testing to ensure safety and consistency.

## 5. Monitoring Procedures

| CCP | Monitoring Method | Frequency | Responsible Party |
|---|---|---|---|
| Raw Material Receipt | COA verification, visual check | Each shipment | Receiving staff |
| Mixing | Temperature, timing checks | Each batch | Production lead |
| Filling | Equipment inspection | Hourly | QA staff |
| Packaging | Jar, lid, label inspection | Random sampling | QA staff |

## 6. Corrective Actions

**Examples:**

- **Raw Material Receipt:** Reject shipment if COA or visual inspection fails.
- **Mixing:** Reprocess batch or discard if temperature exceeds acceptable range.
- **Filling:** Halt production and repair equipment if malfunction occurs.
- **Packaging:** Replace defective jars or labels immediately.

## 7. Verification Procedures

- Internal audits of monitoring records.
- Regular calibration of scales and mixing equipment.
- Periodic testing of finished products for contaminants and consistency.

## 8. Record-Keeping Procedures

- **Lot Numbers**: Assign lot numbers to all raw materials upon receipt and to finished products. Each lot number is traceable to production date, batch size, and raw material origins.
- **Documentation**: Maintain COAs, mixing batch records, packaging inspection logs, and finished product testing results.

## 9. Cleaning and Sanitization

- **Daily Cleaning**: Clean all equipment and surfaces in the food-grade clean room and warehouse using food-grade cleaners.
- **Sanitization Schedule**: Include weekly deep cleaning of production equipment and storage areas.

## 10. Environmental Monitoring

- **Air Quality Testing**: Conduct monthly microbial tests in the clean room to ensure low contamination risk.
- **Temperature and Humidity Control**: Maintain production and storage areas at 65-75°F and <50% relative humidity.

## 11. Shipping and Storage Conditions

- **Finished Goods Storage**: Store products in a temperature-controlled warehouse at 65-75°F.
- **Shipping Requirements**: Ship products in protective packaging, ensuring temperature exposure does not exceed 85°F.

## 12. Training Program

- Train staff on HACCP principles, GMPs, and monitoring procedures.
- Provide hands-on training for equipment operation and cleaning protocols.
- Conduct annual refresher training and updates as necessary.

## 13. Validation and Reassessment

- Validate the HACCP plan annually or whenever there are changes in processes, equipment, or suppliers.
- Perform mock recalls to test traceability and responsiveness.

**Prepared by:** Jason Brown, HACCP Coordinator
**Date:** 11/1/24