EvySaif
Research Solutions

# AYUSH Classification Self-Check

Five factors that decide the regulatory route, each answered from a document you already hold

- ☐ **1. Is every ingredient, including any excipient carrying activity,** named in the classical texts of the First Schedule?
  *Answered from: master formula record*
- ☐ **2. Is the formulation itself a text formulation, or a new combination** of text ingredients?
  *Answered from: master formula record, compared against the text*
- ☐ **3. Is the preparation method one the texts describe, or a modern** extraction process?
  *Answered from: batch manufacturing record*
- ☐ **4. Has any constituent been concentrated beyond what the classical** process yields?
  *Answered from: extract ratio and marker specification*
- ☐ **5. How many bioactive compounds are defined and quantified in the** specification?
  *Answered from: certificate of analysis and product specification*

## Reading the result

| | |
|---|---|
| **Text formulation throughout** | classical ASU medicine, licensed on citation in the texts |
| **Text ingredients, new combination** | patent or proprietary ASU medicine, Rule 158B evidence |
| **Purified fraction, 4+ bioactives** | phytopharmaceutical drug, CDSCO new drug program |
| **Wellness claims only** | FSSAI supplement route available, no disease claims |

**Before relying on the answer**

Final classification is confirmed by the licensing authority. Where the answer is ambiguous, put a written pre-submission query to the authority. Schedule E(1) ingredients add safety study requirements on any route.

**Full roadmap: evysaif.com/blog/ayush-product-licensing-asu-phytopharmaceutical/**

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