

### Unit 5: Traditional Knowledge, Geographical Indications and the AYUSH Research Bodies

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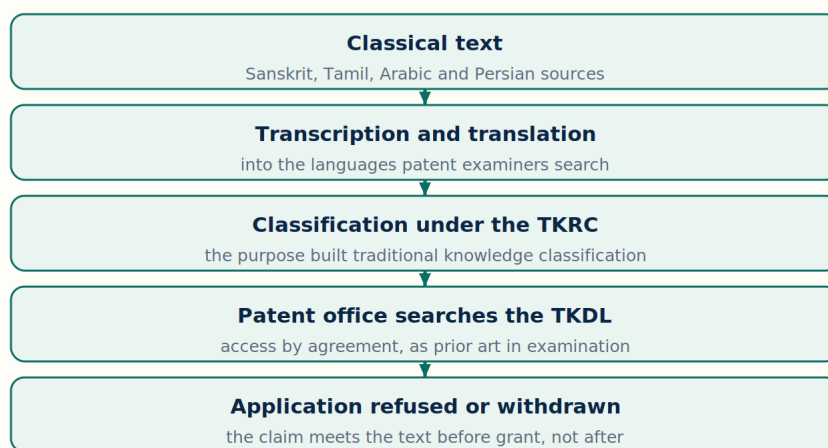
#### 5.1 The Traditional Knowledge Digital Library

The Traditional Knowledge Digital Library, TKDL, is India's defensive answer to a legal problem that the 1990s made famous. Traditional knowledge like that of Units 1 and 3 is old, published in classical languages and collectively held, yet patent offices abroad, searching only modern databases in modern languages, repeatedly granted patents on it to private applicants: the turmeric wound healing patent granted in the United States, the neem fungicide patent granted in Europe and the basmati rice patent are the standard teaching cases, each eventually revoked or narrowed after India proved, from its own classical texts, that the claimed invention was already known. The TKDL, established in 2001 as a joint project of the Council of Scientific and Industrial Research and the government department responsible for the Indian systems, closes the gap at its source. It is a database in which the formulations and practices of the classical texts of Ayurveda, Unani, Siddha and Yoga have been transcribed, translated into the major international languages, English, German, French, Spanish and Japanese among them, and classified under a purpose built system, the Traditional Knowledge Resource Classification, designed to be retrievable by patent examiners in the form their searches take. The library is not public: access is given to patent offices under agreement, for use as prior art in examination, so that an application claiming a classical formulation meets the text that defeats it before the patent is granted, rather than in a revocation fight after.

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How the TKDL defends a classical formulation
  Classical text (Sanskrit, Tamil, Arabic, Persian)
    |
    v
  Transcription and translation into examiner languages
    |
    v
  Classification under the TKRC headings
    |
    v
  Patent office searches the TKDL as prior art
    |
    v
  Application on known knowledge refused or withdrawn
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The examination points are the mechanism and the limit. TKDL is defensive protection: it prevents others from patenting the tradition, it grants the tradition no rights of its own, and it works only where examiners can and do search it. It is, even so, the model the world cites for the documentation defence of traditional knowledge, and it is the natural completion of this subject's arc, because the same classical texts that Unit 1 read as pharmacy are read here as legal evidence.

## How the TKDL defends classical knowledge



Defensive protection: it stops wrongful patents, it grants no rights itself

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Figure: The TKDL defence. The classical text is made searchable in the examiner's own language and classification, so the patent is stopped at examination, not fought after grant.

## 5.2 Geographical indications

Where the TKDL defends knowledge, the geographical indication defends origin. A geographical indication is a sign that identifies a product as originating in a place whose geography, soil, climate or traditional skill gives the product its character, and in India it is protected under the Geographical Indications of Goods (Registration and Protection) Act, 1999, in force since 2003, notwithstanding the syllabus's printing of the head as the Geographical Indication Bill: registration is granted for ten years at a time and renewable, and the registered proprietor and authorised users may exclude others from selling goods under the indication that do not come from the place. Darjeeling tea, the first Indian registration, is the standard example of the mechanism. The relevance to this subject runs through the raw material trade of the ISM and herbal industries: a number of the produce on which traditional pharmacy depends, spices, aromatic and regional specialities among them, trades partly on a place name, and a GI protects the growers of the genuine origin against both foreign appropriation of the name and domestic passing off of material from elsewhere. The student's summary should hold the two instruments of this unit apart: a patent rewards a new invention and is defeated by TKDL prior art, a GI rewards a place and its accumulated practice and is defeated by goods that are not from the place; together they cover the two ways traditional pharmacy can be taken, its knowledge and its names.

## 5.3 Government action in AYUSH and ISM

The third head of the unit is governmental: the bills, measures and institutional building by which the Indian state has raised the systems of this subject from tolerated practice to administered sector. The landmarks the examination expects are structural. The Indian Medicine Central Council Act of 1970 put Ayurveda, Siddha and Unani education and practice under statutory councils, and its successor legislation of 2020 replaced it with the National Commission for Indian System of Medicine, modernising the regulatory frame; Homoeopathy followed the parallel path through its own central council legislation to its own national commission. The Department of Indian Systems of Medicine and Homoeopathy, later the Department of AYUSH, grew inside the health ministry until, in 2014, AYUSH became a ministry of its own, the institutional fact behind every other development in this subject: the pharmacopoeia commission, the research councils of the next sections and the Schedule T enforcement machinery all run through it. Government bills in AYUSH, in the syllabus's phrase, are therefore best understood as a continuing legislative programme:

education and practice regulated, pharmacopoeias given legal force, research funded through statutory councils, and the sector's products brought progressively under the drug law of Unit 4. The direction of travel is one this subject has taught throughout: the systems keep their classical content, and the state steadily builds the modern apparatus of standards, licences and evidence around them.

#### **5.4 CCRAS: research in Ayurvedic sciences**

The Central Council for Research in Ayurvedic Sciences, CCRAS, is the apex research body for Ayurveda under the Ministry of AYUSH, the first of the four councils the syllabus names, and its pattern is the pattern of them all. The councils in their present separate form date from the reorganisation of the earlier combined research council for Indian medicine and Homoeopathy, and CCRAS today runs a network of research institutes across the country. Its mandate is the scientific investigation of the Ayurvedic tradition on the tradition's own material: literary research and publication of the classical texts, surveys and documentation of medicinal plants and of living practice, pharmacological and pharmaceutical studies of Ayurvedic drugs and formulations, and clinical research on Ayurvedic treatments, together with the standards and monographs that feed the pharmacopoeia work of Unit 1. The council is, in effect, the state's instrument for converting the claims of the classical literature into tested knowledge by the methods of this degree, and its published trials and drug research are the standard primary literature an M.Pharm student will cite.

#### **5.5 The sister councils: CCRS, CCRH and CCRU**

The remaining three councils repeat the CCRAS pattern for the other systems of Unit 1, and they are best learned as a set. CCRS, the Central Council for Research in Siddha, serves the Siddha system from its base in Tamil country; it is the youngest of the four in its separate form, the Siddha research units having been carried for many years inside the Ayurveda council's structure before the separate council was constituted, a history that mirrors the Gunapadam tradition's own position as a fully formed system long administered in Ayurveda's shadow. CCRH, the Central Council for Research in Homoeopathy, serves Homoeopathy, running its institutes and its clinical and drug proving and standardisation work, including the verification of the proving pictures on which its materia medica rests. CCRU, the Central Council for Research in Unani Medicine, serves the Unani system, with its institutes, its literary research on the Arabic and Persian corpus and its clinical and pharmacological studies of Unani drugs and regimens. Two further councils complete the AYUSH research family in practice, the council for Yoga and Naturopathy research and the council for Yoga's sister discipline, and the national institutes and pharmacopoeia laboratories stand beside the councils in the ministry's structure; but the syllabus names four, and the four share one description that the examination rewards: each is the apex body, under the Ministry of AYUSH, for the scientific validation, standardisation and propagation of its system, working through its own institute network, journals and research programmes.

## The AYUSH research councils

| CCRAS                   | CCRS                  | CCRH                   | CCRU                 |
|-------------------------|-----------------------|------------------------|----------------------|
| Ayurvedic Sciences      | Siddha                | Homoeopathy            | Unani Medicine       |
| Apex body: Ayurveda     | Apex body: Siddha     | Apex body: Homoeopathy | Apex body: Unani     |
| Institutes across India | Base in Tamil country | Institutes and units   | Institutes and units |
| Literary research       | Youngest separate     | Drug proving work      | Arabic and Persian   |
| Drug standardisation    | council of the four   | Standardisation        | classical corpus     |
| Clinical research       | Clinical research     | Clinical research      | Clinical research    |

Four councils, one pattern: classical claims converted into tested knowledge

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Figure: The four research councils named in the syllabus. Each council is its system's apex research body, and together they convert classical claims into tested knowledge.

### 5.6 How the pieces of the subject fit

The unit, and with it the subject, can now be closed by fitting its pieces together, because the five units were always one argument. The Indian systems are complete traditions, Unit 1, with their own accounts of body, drug and balance, and with practice systems of regimen beside them, Unit 2. Their medicines are classical formulations realised by defined techniques, Unit 3, and now standardised, shelf life tested and made in licensed factories under Schedule T and the GAP, GMP and GLP chain, Unit 4. Their knowledge and their names are defended by the TKDL and the geographical indication, and their claims are progressively examined by the research councils of their own ministry, Unit 5. What a pharmacognosist adds to this inheritance is the discipline of standing: to say of every statement in this field whether it is the classical text speaking, tradition speaking from long use, or evidence speaking from test, and to manufacture, analyse and label accordingly. A graduate who can do that can work anywhere in the ISM industry, the regulator's office or the research institute, without either credulity or contempt.

## Frequently Asked Questions

### Q: What are the fundamental concepts of Ayurveda that every pharmacognosy student must know?

The panchamahabhuta or five elements, the tridosha of vata, pitta and kapha whose balance is health, the seven dhatus, agni the digestive fire, and the five properties by which a drug is judged: rasa, guna, virya, vipaka and prabhava. Unit 1, Sections 1.1 and 1.2 give the full account.

**Q: What is Gunapadam in the Siddha system?** Gunapadam is Siddha pharmacology, the classical study of its drugs: their sources, characters, properties and preparation. It classifies the materia medica by origin into the herbal class, the mineral and metal class called Thadhu or Dhātu drugs, and the animal class called Jeevam, and it prescribes the purification, Suddhi, on which the mineral pharmacy depends. See Sections 1.9 to 1.11.

**Q: What is Suddhi and why does it matter?** Suddhi is the purification process by which a raw drug, above all a metal, mineral or poisonous plant drug, is treated before use, through washing, treatment in liquid media, trituration and calcination, until it passes the classical tests of the purified state. It matters because the safety claim of the Siddha and Ayurvedic mineral medicines rests on this process, so it is the point where classical doctrine, manufacturing discipline and modern safety testing meet. See Section 1.11.

**Q: What is the Ayurvedic Pharmacopoeia of India and what force does it carry?** The API is the official book of standards for Ayurvedic drugs, Part I monographing single drugs and Part II compound formulations, published under the Ministry of AYUSH. Its standards are the legal standards for Ayurvedic medicines manufactured and sold under the Drugs and Cosmetics Act, so a product failing its monograph is not of standard quality in law. See Section 1.7.

**Q: What are the main dosage form families of the Indian systems?** The recurring families are powders (churna, chooranam, safoof), pills (vati, habb, qurs), decoctions (kwatha, kudineer), fermented liquids (asava and arishta), distillates (arka, arq), sweet semi solids (avaleha, majoon, sharbat), medicated fats (taila, ghrita, ennai, nei), the mineral calxes (bhasma, parpam, chenduram), and for Homoeopathy the mother tinctures, dilutions and globules. See Section 1.6 and Unit 3.

**Q: What is potentisation in Homoeopathy?** Potentisation is the preparation process of Homoeopathy: serial dilution of the mother tincture on the decimal or centesimal scale, each step completed by succussion, or serial trituration with lactose for insoluble solids. The system's doctrine holds that the process releases the dynamic power of the substance while removing its material toxicity, and exact labelling of substance and potency is the manufacturer's central duty. See Section 3.5.

**Q: What is Schedule T and what does it require?** Schedule T of the Drugs and Cosmetics Rules prescribes good manufacturing practice for Ayurvedic, Siddha and Unani medicines, and compliance is a condition of the manufacturing licence. It requires authentic raw materials, the prescribed manufacturing process, quality control and an acceptable finished product, through components covering premises, working space by dosage form category, storage, machinery, standard operating procedures, health and hygiene, and documentation and records. See Unit 4.

**Q: What do GAP, GMP and GLP each guard in the ISM industry?** GAP, good agricultural practices, guards the field stage of cultivation and collection; GMP, for this industry Schedule T, guards the factory stage; and GLP, good laboratory practice, guards the testing stage in which identity, quality and safety are proven. Together they form the quality chain from field to laboratory. See Section 4.9.

**Q: What is the TKDL and how does it protect traditional knowledge?** The Traditional Knowledge Digital Library is a database of the formulations of the Ayurvedic, Unani, Siddha and Yoga classical texts, translated into the major international languages and classified so that patent examiners can search it. Patent offices use it as prior art under access agreements, so applications claiming classical knowledge are stopped at examination. It is defensive protection: it prevents wrongful patents but grants no rights itself. See Section 5.1.

**Q: What are CCRAS, CCRS, CCRH and CCRU?** They are the Central Councils for Research in the AYUSH systems, for Ayurvedic Sciences, Siddha, Homoeopathy and Unani Medicine respectively, the apex research bodies of their systems under the Ministry of AYUSH. Each runs research institutes and programmes in literary research, drug standardisation, pharmacology and clinical research for its own system. See Sections 5.4 and 5.5.

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