

Lab Approval

Checklist of documents to be sent with the application

Sl. No.	Criteria	Requirements for approval of laboratory as per drugs & Cosmetics Rules 1945, Rule - 160B	Checklist of documents to be sent with the application
1	Application in Form 47	Application in Form 47 of D & C Rules 1945 to the Licensing Authority with an inspection fees of six thousand Rupees in the form of Challan	<ol style="list-style-type: none"> 1. Copy of Application in Form-47 2. Copy of Challan of six thousand Rupees
2	Experts employed by the laboratory	<ol style="list-style-type: none"> 1. Expert in Ayurveda, Siddha or Unani possessing degree qualification 2. One Chemist (Bachelor of Science/ Pharmacy/ Ayurvedic Pharmacy) 3. One botanist / Pharmacognosist (Bachelor in Science-Medical/ Pharmacy/ Ayurvedic Pharmacy) 	<ol style="list-style-type: none"> 1. List of technical experts employed by laboratory for testing of ASU drugs with copy of their qualification and experience certificates. 2. Appointment letter and Joining letter of the technical experts 3. Affidavit by the experts regarding their employment in Laboratory.
3	Equipment available in the laboratory	<ol style="list-style-type: none"> 1. Total of 50+ equipment in the sections of chemistry, pharmacognosy & microbiology are recommended. 2. Instrument like HPLC, HPTLC, AAS could be arranged by tie up with other laboratories. 	<ol style="list-style-type: none"> 1. List of equipment available with the laboratory 2. Copy of MoU or consent letter of other approved or NABL accredited laboratory consenting to carry tests of HPLC/ HPTLC/AAS for the applicant laboratory (If HPLC /HPTLC/AAS are not available with the laboratory)
4	Provision of Separate sections in laboratory	<p>Separate sections with total area of at least 800 square feet are required for :</p> <ol style="list-style-type: none"> 1. Chemistry 2. Pharmacognosy 3. Ayurveda, Siddha & Unani 4. Microbiology 5. Sample room 6. Office cum record room 	Layout map of the laboratory clearly showing 6 sections with total area as specified.
5	Reference books available with the laboratory	<p>Applicant must have:</p> <ol style="list-style-type: none"> 1. Books of standard recognised under the provisions of the act & rules made thereunder. 2. Books required in connection with the testing of analysis of products for testing of which approval is required 	List of reference books available with the applicant including all the till date published Pharmacopoeias, Formularies & TILC Atlas of Ayurveda, Siddha & Unani

6	Reference samples available with the laboratory	Applicant must have: Reference samples of standard ASU drugs that may be required in connection with the testing or analysis of the products for which approvals applied for.	List of reference samples of Herbal, Mineral/ Metal and Animal origin available with the laboratory
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List of Pharmacopoeias and Formularies published

1. Ayurvedic Pharmacopoeia of India Pt. I-Vol I to VIII
2. Ayurvedic Pharmacopoeia of India Pt. II-Vol I to III
3. Atlas of Macroscopic & Microscopic Characters of Ayurvedic Pharmacopoeia drugs (API P-I, V-I)
4. Macroscopic & Microscopic Atlas of Pharmacopoeia Drugs (API-P-I, Vol-V)
5. Ayurvedic Pharmacopoeia of India Pt. I to III
6. Unani Pharmacopoeia of India Pt. II-Vol I to II
7. Unani Pharmacopoeia of India Pt. II-Vol I to II
8. National Formulary of Unani Medicine Pt. I to VI
9. Siddha Pharmacopoeia of India Pt. I-Vol. I to II
10. Siddha Formulary of India Pt. I to I