

**Proforma for assessment of Drug Testing Laboratory by the  
inspecting officers under Drugs & Cosmetics Rule 160 E**

S. No.	Points for observation	Observations of inspection team
1.	Name & Full address of the laboratory with telephone, fax No. & email.	
2.	Status; Autonomous/Semi-Govt./Private	
3.	Central financial assistance	
4.	Year of Establishment	
5.	Years of experience in testing of Ayurveda/Siddha/Unani drugs	
6.	Name & Designation of In-charge	
7.	Whether the laboratory has been recognized for the purpose of conducting testing of drugs. If so, the date of recognition from the Central Govt./State Govt.	
8.	(1) Total covered area of the building where testing of Ayurveda, Siddha & Unani drugs will be carried out  (ii) Name of Sections with space specifications  a) Chemistry,  b) Pharmacognosy	

	<p>c) Ayurveda, Siddha and Unani</p> <p>d) Microbiology</p> <p>e) Sample Room</p> <p>f) Office-cum-Record Room</p> <p>(iii) Building; Old/New with remarks</p> <p>(iv) Whether, walls, roof are smooth, cracks free, tiled and plastic painted floor</p> <p>(v) Windows and doors; whether properly closing/sealed properly/locked</p> <p>(vi) Rooms :Whether dust free properly lighted, cooled/AC, curtained</p> <p>(vii) Furniture: working tables/wooden, steel, tiled/cemented, fuming cupboards, exhaust fans, electricity, generator facilities</p> <p>(viii) Whether fire safety measures installed</p>	
9.	<p>Name of the Technical experts/Scientist /Analyst for various section with their qualifications and experience of testing of Ayurvedic, Siddha &amp;Unani drugs;</p> <p>i. Experts of Chemistry</p>	

	<p>ii. Experts of Pharmacognosy</p> <p>iii. Experts of Ayurveda/Siddha/Unani</p> <p>iv. Experts of Microbiology</p>	
10.	Name and qualification of the Authorized Analyst to sign the test report	
11.	<p>List of equipment provided for various sections with following details in tabulated form:</p> <p>i. Date of purchase</p> <p>ii. Date of installation</p> <p>iii. Name of the staff operating it</p> <p>iv. Whether internal/external training to staff given</p> <p>v. Number of operations per month and whether log book maintained</p> <p>vi. Calibration status</p> <p>vii. Whether equipment under</p>	

	AMC	
12.	<p>Number of samples/product tested in the past 2 years            (product wise eg. Vati, Asava, taila, churna, Syrup etc) in case of previous approval</p> <p>Sample source :            Internal/External/Govt.</p> <p>Whether the samples codified</p> <p>Time taken in sample testing</p> <p>Time taken in reporting</p> <p>Whether samples of raw material/plants/animals/mineral /compound formulations/classical/P&amp;P medicines</p> <p>Categories (dosage forms) of compound Ayurveda, Siddha &amp; Unani formulation to be tested may be specified eg. Asava, Avaleha etc.</p> <p>Categories of tests carried out</p>	

	<p>for raw material/finished Ayurveda, Siddha &amp; Unani products in the laboratory.</p> <p>Random checking of test reports</p>	
13.	<p>Fees structure for various tests to be conducted in the laboratory specifically for plant, mineral/metal and animal based drugs and other Ayurveda, siddha &amp; Unani formulations applicable for the approved period.</p>	
14.	<p>Whether reference books including Formularies, Pharmacopoeias and TLC Atlas of Ayurveda, Siddha &amp; Unani drugs are maintained in the laboratory. If so details thereof</p>	
15.	<p>Whether reference samples of standard Ayurvedic, Siddha &amp; Unani Drugs of Herbal, Metal/Mineral and Animal origin are maintained in the laboratory. If so details thereof.</p> <p>Whether reference samples are labeled with regard to :</p>	

	Procurement details, Date of expiry, Analytical Report no. etc	
16.	<p>Observation and recommendations of the inspecting officers, indicating the: Basis of recommendation</p> <p>Reasons for not recommending objectively Avenues for further improvement</p>	
17.	<p>i. Name and signature of State Govt. Inspector of Joint Inspection team</p> <p>ii. Name and signature of Central Govt. Inspector of Joint Inspection team.</p>	