

Central Drug Standard Control Organization
Directorate General of Health Services
Office of Drugs Controller General (India)
(Medical Device Division)

Checklist for Pre Screening of Applications for Grant of Test License in Form-11

Name of the firm: _____ Date: _____

TR-6 Challan No: _____ Date: _____ Ref.No: _____

S. No.	Administrative /Legal Documents.	Status	
		Yes	No
1.	Covering Letter clearly mentioning the type of test to be performed by using the proposed products- Purpose should be clearly mentioned with page number and Index.		
2.	Form-12 duly Signed & Stamped by the authorized signatory of the firm, mentioning the name & address of the manufacturer, name and address of the testing places and. Name of the product and pack size (number of test per pack) , as per Drugs And Cosmetic Acts And Rules		
3.	TR-6 Challan as per drugs and cosmetic acts and rules, Fee Rs.100 for One product and Rs.50 for each additional product		
4.	Utilization breakup for the proposed quantity of each of the product		
5.	Product Inserts, Label of the proposed product		
6.	Testing protocol of the proposed product		
7.	Valid copy of manufacturing license/wholesale license, if any		
8.	Undertaking stating that the proposed kits are Not For Commercial Purpose		

Signature of the Reviewer with Date

Accepted/Returned due to incomplete application