

Directorate General of health Services
Central Drugs Standard Control Organization
Test Licence Section

Pre-screening for Test Licence in Form-11

1. Form- 12 as per D & C Act and Rules.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
2. TR 6 Challan as per D&C Act and Rules. (For first drug Rs.100 and Additional Rs. 50 per Strength/Dosage Form)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
3. Notarized justification/Utilization Break Up	<input type="checkbox"/> YES	<input type="checkbox"/> NO
4. Copy of Form 25/28/29* or DSIR approval (Attested by Authorized Signatory Person) *in case of Bulk API Form-29 must	<input type="checkbox"/> YES	<input type="checkbox"/> NO
5. Official Regulatory Guidelines/supportive documents for production of The drugs for testing and analysis (*In case of large quantities of Bulk API and Formulations)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
6. Undertaking for purpose of Test and Analysis	<input type="checkbox"/> YES	<input type="checkbox"/> NO
7. Authorized signatory letter (Issued by Director/Head of Institution/proprietor only)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
8. BE NOC in case of Bulk API for BE study	<input type="checkbox"/> YES	<input type="checkbox"/> NO

Remarks:-.....

DATE:

Authorized Signatory