

**Central Drugs Standard Control Organization
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)**

**Checklist for NOC for manufacturing of Test Batches for test and analysis under Form-29
(Vaccines and r-DNA products)**

S. No.	Checklist for Screening	Closed Response	Remarks
1	Covering Letter clearly mentioning the purpose of test license for Developmental/Preclinical studies/Clinical Studies	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Name of the Drug/Drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Source of MSL/WSL with their Biosafety Level requirements.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Details of the proposed site: New/Existing.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5	Site plan for manufacture of proposed Drug.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6	List of existing drugs manufactured in the proposed facility (with their BSL requirements), if any.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Details of the manufacturing license (with product permissions) for the proposed site, if any.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8	Details of previous joint inspection of the proposed site 1) Date 2) Purpose 3) Compliance status. (Proposed site shall also include details of particular manufacturing Blocks which was inspected earlier along with the name(s) and type of product(s) produced in this particular manufacturing Block)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9	Process Flow	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10	List of equipment and testing Facility	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11	If Technology Transfer, Details thereof	<input type="checkbox"/> Yes <input type="checkbox"/> No	
12	Name, Qualification experience of personal responsible for manufacturing & testing of trial batches	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13	Undertaking by applicant	<input type="checkbox"/> Yes <input type="checkbox"/> No	