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

Checklist for Market authorization/New drug approval

S.No.	Content	Remarks
1	Introduction about the company (Breif Description about the company)	☐ Yes ☐ No
2	Administrative Headquaters (Provide address of company Headquaters)	☐ Yes ☐ No
3	Manufacturing Facilities (Provide address of company (Headquaters)	☐ Yes ☐ No
4	Whether the Firm as submitetd the 2 hard and 2 soft copies of the said product	☐ Yes ☐ No
5	Module 1	☐ Yes ☐ No
6	Module 2	☐ Yes ☐ No
7	Module 3	☐ Yes ☐ No
8	Module 4	☐ Yes ☐ No
9	Module 5	☐ Yes ☐ No
10	Manufacturing Facilities (Provide address of company (Headquaters)	☐ Yes ☐ No
11	Form -44 and TR challan	☐ Yes ☐ No
12	Regulatory permissions/approvals a) No objection certificate for Form -29 as issued by Central License) b) Form 29 as issued by State Licensing Authority. c) Permission -to conduct toxicology permission (For r-DNA products)	☐ Yes ☐ No
13	List of countries where the drug product has been licensed and summary of approval countries	☐ Yes ☐ No
14	Product Description (A breif Description class to which it belongs) a) Name of the product b) Generic name/INN name c) Route of administration d) Dosage of strength e) Qualitative and quantitative composition Commercial presentation	☐ Yes ☐ No
	Module 2	☐ Yes ☐ No
15	Introduction	☐ Yes ☐ No
16	Quality overall summary	☐ Yes ☐ No
17	Overview of non clinical studies	☐ Yes ☐ No
18	Non clinical Summary	☐ Yes ☐ No
	Module 3	☐ Yes ☐ No
19	Table of contents for Module 3	☐ Yes ☐ No
20	Quality contents	☐ Yes ☐ No
21	Drug substance(s): Information must be submitted for each drug substance in the product.	☐ Yes ☐ No

22	General information starting materials and raw materials	☐ Yes ☐ No
23	Manufacturing process for drug substance	☐ Yes ☐ No
24	Characterization of drug substance	☐ Yes ☐ No
25	Quality control of drug substance	☐ Yes ☐ No
26	Reference standards	☐ Yes ☐ No
27	Container closure system	☐ Yes ☐ No
28	Stability of drug substance	☐ Yes ☐ No
29	Drug product	☐ Yes ☐ No
30	Description and composition of drug product	☐ Yes ☐ No
31	Pharmaceutical development	☐ Yes ☐ No
32	Manufacture of drug product	☐ Yes ☐ No
33	Control of excipients (adjuvant, preservative, stabilizers and others)	☐ Yes ☐ No
34	Control of drug product	☐ Yes ☐ No
35	Reference standards of materials	☐ Yes ☐ No
36	Container closure system	☐ Yes ☐ No
37	Stability of drug product	☐ Yes ☐ No
38	Appendix	☐ Yes ☐ No
39	Details of equipment and facilities for production of drug	☐ Yes ☐ No
40	product: master formula, batch record and set release	☐ Yes ☐ No
41	documentation in respect of consistency batches	☐ Yes ☐ No
42	Safety evaluation of adventitious agents	☐ Yes ☐ No
48	Bibliographic Reference	☐ Yes ☐ No
	Module 4	☐ Yes ☐ No
49	Reports on studies	☐ Yes ☐ No
50	Pharmacology	☐ Yes ☐ No
51	Pharmacodynamic studies (immunogenicity of product)	☐ Yes ☐ No
52	Pharmacodynamic studies of adjuvant (if applicable)	☐ Yes ☐ No
53	Pharmacokinetics	☐ Yes ☐ No
54	Pharmacokinetic studies (in case of new adjuvant, new modes of administration)	☐ Yes ☐ No
55	Toxicology	☐ Yes ☐ No
56	General toxicology information on:	☐ Yes ☐ No
57	Special toxicology (for products to which it applies)	☐ Yes ☐ No
58	Toxicity of new substances used in formulation (new adjuvant,	☐ Yes ☐ No
59	stabilizers, additives)	☐ Yes ☐ No
60	Special considerations	☐ Yes ☐ No
61	Bibliographic references	☐ Yes ☐ No
	Module 5	☐ Yes ☐ No
62	Table of contents of the Module	☐ Yes ☐ No
63	Contents: Reports of clinical studies	☐ Yes ☐ No
64	Phase I studies	☐ Yes ☐ No
65	Phase II studies	☐ Yes ☐ No
66	Phase III studies	☐ Yes ☐ No
67	Bridging Studies	☐ Yes ☐ No
68	Special considerations	☐ Yes ☐ No
69	Adjuvant (s)	☐ Yes ☐ No

70	Phase IV studies and / or Pharmacovigilance Plan (if	☐ Yes ☐ No
71	applicable)	☐ Yes ☐ No
72	Non-inferiority studies (for combined vaccines, or approved	☐ Yes ☐ No
73	vaccines prepared by new manufacturers)	☐ Yes ☐ No
74	Co-administration studies with other vaccines	☐ Yes ☐ No
75	Case Report Forms and Individual Patient Listings	☐ Yes ☐ No
76	Bibliographic references:	☐ Yes ☐ No
77	Abbreviations	☐ Yes ☐ No