

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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Administrative Headquarters (Provide address of company Headquarters)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	Manufacturing Facilities (Provide address of company (Headquarters))	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	Whether the Firm as submitetd the 2 hard and 2 soft copies of the said product	<input type="checkbox"/> Yes <input type="checkbox"/> No
5	Module 1	<input type="checkbox"/> Yes <input type="checkbox"/> No
6	Module 2	<input type="checkbox"/> Yes <input type="checkbox"/> No
7	Module 3	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	Module 4	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	Module 5	<input type="checkbox"/> Yes <input type="checkbox"/> No
10	Manufacturing Facilities (Provide address of company (Headquarters))	<input type="checkbox"/> Yes <input type="checkbox"/> No
11	Form -44 and TR challan	<input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
13	List of countries where the drug product has been licensed and summary of approval countries	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Module 2	<input type="checkbox"/> Yes <input type="checkbox"/> No
15	Introduction	<input type="checkbox"/> Yes <input type="checkbox"/> No
16	Quality overall summary	<input type="checkbox"/> Yes <input type="checkbox"/> No
17	Overview of non clinical studies	<input type="checkbox"/> Yes <input type="checkbox"/> No
18	Non clinical Summary	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Module 3	<input type="checkbox"/> Yes <input type="checkbox"/> No
19	Table of contents for Module 3	<input type="checkbox"/> Yes <input type="checkbox"/> No
20	Quality contents	<input type="checkbox"/> Yes <input type="checkbox"/> No
21	Drug substance(s): Information must be submitted for each drug substance in the product.	<input type="checkbox"/> Yes <input type="checkbox"/> No

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

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