

File No: BIO/CT/24/000113
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

The Drugs Controller General, India
Directorate General of Health Services,

To

M/s Cadila Pharmaceuticals Limited,
1389, Trasad Road, Dholka,
Ahmedabad, Gujarat (India) -382225

Subject: Permission for conducting a clinical trial titled "A Phase-I, open label clinical trial to assess the safety and immunogenicity of Quadrivalent Human Papillomavirus (HPV) Vaccine in healthy subjects." [Protocol No.: CRSC24001, Version No.: 01, Date 08/07/2024]"- regarding.

Reference: Your Application No. BIO/CT04/FF/2024/44605 dated 06-SEP-2024 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2024/44605 dated 06-SEP-2024, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Quadrivalent Human Papillomavirus (HPV) Vaccine" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs Rules, 1945 and communication of Central Licensing Authority.

Please acknowledge receipt of the same.

Yours faithfully,

**(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)**

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Cadila Pharmaceuticals Limited 1389, Trasad Road, Dholka – 382 225, Dist: Ahmedabad Gujarat State, India Telephone No.: 912714221481 FAX: 912714221848 to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: CRSC24001, Version No.: 01, Date 08/07/2024 in the below mentioned clinical trial sites.

CT No.: CT- 08/2025

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
Stamp

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Quadrivalent Human Papillomavirus (HPV) Vaccine	
Therapeutic Class	Vaccine	
Dosage form:	Vaccines (Liquid) Injection	
Composition:	Each dose of 0.5ml contains :	
	Name of ingredients	Quantity
	Active ingredients	
	Human Papillomavirus Type 6L1 protein	20 micrograms(μg)
	Human Papillomavirus Type 11L1 protein	40 micrograms(μg)
	Human Papillomavirus Type 16L1 protein	40 micrograms(μg)
	Human Papillomavirus Type 18L1 Protein	20 micrograms (μg)
	Inactive ingredients	
	Sodium Phosphate dibasic heptahydrate	2.23 mg
	Sodium Phosphate monobasic monohydrate	0.56 mg
	Polysorbate80	50 μg
	L- Histidine	0.78 mg
	Aluminium hydroxide	0.5 mg
	Sodium chloride	9.56 mg
Sodium borate	35 μg	
Indication(s):	For prevention of the diseases caused by Human Papilloma virus (HPV).	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Apollo Hospital International Ltd., Site Office Building, near ICICI ATM, Plot No. - 1A, Bhat, GIDC Estate, Gandhinagar, Ahmedabad-382428, Gujarat, India.	Apollo Hospital International Ltd. Plot No. -1A, Bhat, GIDC Estate, Gandhinagar, Ahmedabad- 382428, Gujarat, India. [ECR/30/Inst/GJ/2013/RR-24]	Dr. Maharshi Desai

In addition to point 3, the permission is subject to following condition(s):

1. The Phase-I clinical trial should be conducted as per approved protocol titled "A Phase-I, open label clinical trial to assess the safety and immunogenicity of Quadrivalent Human Papillomavirus (HPV) Vaccine in healthy subjects [Protocol No.: CRSC24001, Version no.: 01 dated 08.07.2024]
2. The firm is required to constitute a DSMB to review the safety data.
3. Firm is required to submit Ethics Committee approval for Phase-I clinical trial.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.

5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi

Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
Stamp

