

**Format for providing details of Service Level Standards for issuance of License/Permit/Certificate/Other Authorization (LPCOs) by Participating Government Agencies (PGAs)**

**Name of the PGA: Central Drugs Standard Control Organization, FDA Bhawan, New Delhi**

S.No.	Name of LPCO	Application Form No. and legal basis	Brief on why the LPCO is issued	Chapter tariff headings covered under LPCO	Name of all items covered under LPCO	Legal basis for issuance of LPCO (specify relevant provisions of Acts/Rules)	Documents Required to be submitted by beneficiary for application of LPCO	Mode of applications (online or physical)	Name designation and address of issuing authority	Time required for issuance from date of application	Fee charges applicable for issuance of LPCO. Whether payable online or physical	One time usable or for multiple use	Does the LPCO require quantity/value debiting	Mode of issuance physical online	Specimen of LPCO in .pdf
<b>Registration Certificate for Drugs</b>															
1	Registration certificate (Form 41)	Form 40 (Rule 24A of Drugs of Cosmetics Rules, 1945)	For issue of Registration Certificate for Import of Drugs into India under the Drugs and Cosmetics Rules 1945	--	Drugs as defined under the Drugs and Cosmetics Act, 1940	Chapter III of Drugs Cosmetics Act, 1940	(1) Form 40 (2) Power of attorney (3) Information as per Schedule D (I) (4) Information as per Schedule D (II) (5) Copy of Import permission for new drug (s) in Form-45 (formulation) or in Form-45A (new bulk drug substances) (6) TR-6 Challan/Bharat Kosh receipt of Fees paid (7) Other supportive documents.	Physical and Online through Sugam online licensing system	Dr. S. Eswara Reddy (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	9 months	1500 USD for registration of premises meant for manufacturing of drugs intended for import into India, 1000 USD for registration of single drug, 1000 USD for each additional drug. Payable by Online or by physical mode	Valid for a period of three years	NA	Physical and Online through Sugam online licensing system	Annexure A

	<b>Import License for Drugs</b>														
2	Import License (Form 10 & 10A)	Form 8 & 8A(Rule 24 of Drugs of Cosmetics Rules, 1945)	Application for License to Import Drugs to the Drugs and Cosmetics Rules 1945	--	Drugs as defined under the Drugs and Cosmetics Act, 1940	Chapter III of Drugs Cosmetics Act, 1940	(1) Form 8 & 8A (2) Form 9 undertaking (3) Original Labels/Specimen label (4) Copy of wholesale Licence/ Manufacturing Licence with list of products approved. (5) Copy of Valid RC duly attested by the Indian Agent/ manufacturer (6) TR-6 Challan/Bharat Kosh receipt of Fees paid. (7) Other supportive documents.	Physical and Online through Sugam online licensing system	Dr. S. Eswara Reddy (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	45 Days	INR 1000, for each Drug	Valid for a period of three years but not more than the validity of registration Certificate	NA	Physical and Online through Sugam online licensing system	Annexure B
	<b>Licence to import drugs for the purposes of examination, test or analysis</b>														
3	Licence to import drugs for the purposes of examination, test or analysis (FORM 11)	Form 12 (Rule 34 of Drugs of Cosmetics Rules, 1945)	licence to import of drugs for purpose of examination, test or analysis into India under the Drugs and Cosmetics Rules 1945	--	Drugs as defined under the Drugs and Cosmetics Act, 1940	Drugs Cosmetics Act, 1940	(1) Form 12 (2) Earlier CT NOC issued / Existing test licence along with debit sheet and debit note. (3) Justification of Quantity (4) Upload duly signed Form-12 (5) TR-6	Physical and Online through Sugam online licensing system	Dr. S. Eswara Reddy (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	45 days	INR 100 for each test license, additionally INR 50 for additional quantity. Payable by Online or by physical mode	multiple use	Yes	Physical and Online through Sugam online licensing system	Annexure C

							Challan/Bharat Kosh receipt of Fees paid								
<b>Registration Certificate for Cosmetics</b>															
4	Registration certificate (Form 43)	Form 42 (Rule 129A of Drugs of Cosmetics Rules, 1945)	For import registration of cosmetics	--	Cosmetics as defined under the Drugs and Cosmetics Act, 1940	Chapter III of Drugs Cosmetics Act, 1940	(1) Form 42 (2) Schedule-D III (3) product composition (4) Labels (5) Specification (6) Non- Animal Testing Undertaking (7) Heavy metal undertaking (8) Free sale certificate (9) TR-6 Challan/Bharat Kosh receipt of Fees paid (10) Power of attorney	Online through Sugam online licensing system	Dr. S. Eswara Reddy (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	6 months	USD 250, for each category of cosmetics (online)	Valid for a period of three years	NA	Online through Sugam online licensing system	Annexure D
<b>License to Import Medical Devices</b>															
5	License (Form MD-15)	Form MD-14 ( sub-rule (1) of rule 34 of Medical Devices Rules, 2017)	Application for License to Import Medical Devices as per Medical Devices Rules, 2017	----	Medical Devices as defined under the Medical Devices Rules, 2017	Chapter V of Medical Devices Rules, 2017	(1) Form MD-14 (2) Power of Attorney (3) Self-attested copy of valid whole sale licence or manufacturing licence (4) Free sale Certificates (5) Notarized copy of valid Quality Certificates. (6) Plant Master File (7) Device Master file (8) TR-6	Online through SUGAM online licensing system	Dr. V. G. Somani (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	9 months	1) Import licence for Class A medical device site \$1000; and each distinct device \$50 2) Import licence for Class B I device for site \$2000 ; and each distinct device \$1000 3) Import licence for Class A or Class B IVD medical	Remain Valid in perpetuity, unless, it has been cancelled or suspended	NA	Online through SUGAM online licensing system	Annexure E

							Challan/Bhar at Kosh receipt of Fees paid				site \$1000 each distinct IVD device \$10 4) Import licence for Class C or Class D device site \$3000 each distinct device \$1500 5) Import licence for Class C or Class D IVD device for site \$3000 each distinct IVD device \$500. Payable by Online or by physical mode					
Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training																
6	License (Form MD-17)	Form MD-16(sub-rule (1) of rule 41 of Medical Devices Rules, 2017)	Application for License to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training as per Medical Devices Rules, 2017	---	Medical Devices as defined under the Medical Devices Rules, 2017	Chapter V of Medical Devices Rules, 2017	1. Form MD-16 2. Brief description of the medical device including intended use, material of construction, design 3. Justification of quantity proposed to be imported 4. Test protocol/Ap proved clinical investigation plan if any	Online through SUGAM online licensing system	Dr. V. G. Somani (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	30 Days	Fee for Import licence for test, evaluation or demonstration or training for each distinct medical device. \$100	Valid for a period of three years, unless cancelled	Quantity Imported as per the Utilization Break-up submitted by the firm as per test protocol	Online through SUGAM online licensing system	Annexure F	

							5. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial number 7 of Form-16 and shall not be used for commercial purpose. 6. TR-6 Challan/Bharat Kosh receipt of Fees paid								
<b>License to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients</b>															
7	License (Form MD-19)	Form MD-18 ( sub-rule (1) of rule 42 of Medical Devices Rules, 2017)	Application for License to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients as per Medical Devices Rules, 2017	----	Small quantity of Investigational Medical Devices as defined under the Medical Devices Rules, 2017	Chapter V of Medical Devices Rules, 2017	1. Form MD-18 with certificate of Medical Superintendent of the Government Hospital / Head of Statutory Medical Institution 2. Details of Medical Device, Labels and IFU 3. Regulatory Approval certificates in the country of	Online through SUGAM online licensing system	Dr. V. G. Somani (Licensing Authority ), CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi-110002	----	Rs 500 for each distinct medical device. Payable by online or by physical mode	Remain Valid for a 1 year unless, it has been suspended or revoked	Quantity determined by the Central Licensing Authority after taking into account the recommendation of the hospital concerned for treatment of patient suffering from a life threatening disease	Online through SUGAM online licensing system	Annexure G

							4. origin Justification for quantity proposed to be imported								
							5. TR-6 Challan/Bhar at Kosh receipt of Fees paid								