

General Information

1	Company Name	Perfect Pharmaceutical Consultants Pvt. Ltd.
2	Company Address	“Prestige Classics” D–Wing, Off. No. G 4 & 5 Opp. Dr. Kanitkar’s Hospital; Dawa Bazar, Chinchwad Stn. Chinchwad; Pune–411019 Maharashtra; INDIA
3	Website	www.perfect-consultants.com
4	Years in Business	20
5	Privately owned/ Public Company	Private Ltd company
6	Number of employees	20
7	Number of employees in the field of registration procedure	15
8	Office located in	Address same as above
9	Knowledge in the chemical and pharmaceutical industry	Well versed with the current Regulatory requirements worldwide for Drug Registration.
10	Experience in the field of Active pharmaceutical ingredient API registration	Total 12 Years Experience in preparation of DMF, Registration & Answer to post submission queries, GMP Audits, etc.
11	References of successfully registered products with the drug controller	Aceclofenac, Pregabalin, Olmesartan, Docetaxel, Topotecan, Sulbactam, etc.
12	Experience in other useful fields	US-DMFs, EDMFs, CTDs, Dossiers, etc.

Contact Details

13	Main Contact	Mr. R. M. Gupta
14	Position and background of the main contact	Managing Director (M. Pharm. Tech)
15	Contact details of the main contact	E-mail :- gupta1@vsnl.com Mob. :- +91-9371020504
16	Deputy	Mr. S. Vishweshwar
17	Position and background of the deputy	Executive Director (M. Pharm.)
18	Contact details of the deputy	E-mail :- gupta2@eth.net Mob. :- +91-9370080448

Registration Procedure

1	Please describe (in short sentences) your process, for registration of a NEW API with the DCGI	The first step is to register API as per schedule Y (Not required, if the molecule is more than 4 year old in Indian market). The next step is to register the overseas manufacturing site & product and finally to apply for Form-10 to import the product in to the country.
2	Which are the requirements by the DCGI for the registration of a NEW generic API	This will depend on whether the drug is still considered a new drug (Less than 4 year old) typically, the company needs to provide information on sub-acute toxicity study (Can be done in India if it not available with the exporter) in Rat & Mice. : API material needs to be tested at government laboratory.
3	Please describe (in short sentences) your process, for the RENEWAL of the registration of an API with the DCGI	<p>Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.</p> <p>As per Rule 28, a Form 10 Licence unless, it is sooner suspended or cancelled, shall be valid for a period of three years from date of its issue.</p> <p>Provided that if an application for a fresh licence is made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application.</p>
4	Which are the requirements by the DCGI for the registration RENEWAL of a generic API	As the registered manufacturers have already submitted the requisite documents at the time of initial registration, it has been decided by this Directorate in consultation with the Ministry of Health that for issue of fresh registration certificate for the already registered drugs, the following information / documents may be submitted by the applicant for examination :-

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| | <ul style="list-style-type: none">a. An application in Form 40.b. US\$ 1500 in respect of site registration and US\$ 1000 per drug or equivalent in Indian rupees may be credited Bank of Baroda under Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" and a copy of the receipt along with treasury challan in TR6 shall be submitted along with the application. It may be ensured that the TR6 challan issued by the Bank shall be for the exact amount specified above.c. Schedule D (I) duly filled.d. Schedule D (II) duly filled along with the following documents :-<ul style="list-style-type: none">a. A copy of the current / valid manufacturing licence of the manufacturer issued by the Drug Regulatory Authority where the manufacturer is located.b. A copy of the current / valid WHO GMP certificate / Free Sale Certificate / CPP issued by the Drug Regulatory Authority of the respective country.e. Original Registration Certificate to be surrendered.f. The applicant may not submit the following documents: -<ul style="list-style-type: none">i. Power of Attorney (except in those cases where there is a change in the Indian Agent).ii. Plant Master File (subject to the condition that there is no change in the Plant).iii. Drug Master File (subject to the condition that there is no change in the process in manufacture of the drug)iv. Stability data (unless there is |
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		<p>change in stability and a shorter shelf life is assigned to the drug).</p> <ul style="list-style-type: none"> v. Quality control test reports. vi. Packing details unless there is a change in the packaged dosage form or in the package insert. <p>The manufacturer can either register additional drug (s) or delete any existing drug (s) at the time of fresh application. However, if additional drugs are added, then all requirements as specified in the Drug Rules shall be fulfilled.”</p>
	<u>Duration</u>	
5	Expected duration for the registration of a NEW generic API	3 – 9 Months
6	Expected duration for the RENEWAL of the registration	Maximum 3 Months