

**PROFORMA FOR APPLICATION FOR REGISTRATION / RENEWAL OF FIRMS
DEALING WITH MEDICINES**

Sl.No.	Description	
A.	MANDATORY DOCUMENTS	
1	5 years market standing /manufacturing certificate as per enclosed performa	
2	Valid Drug License	
3	Valid GMP Certificate	
4	Average audited annual turnover of last 3 years (excluding any 3 rd party manufacturing) <u>year</u> <u>amount in crore</u> <hr/> Average	
5	Non Conviction Certificate mentioning no punitive action taken against the firm in last 5 years.	
6	Product list (Generic & Brand Names to be mentioned) with certification of availability of products in local retail market.	
7	Undertaking to the effect that it will submit testing protocols /standard of supply of the medicines whenever asked for.	
B.	ADDITIONAL DOCUMENTS	
1	ISO-9000 Certificate	
2	ORG-MARG NIELSEN Certificate(market share)	
3	Value of Railway order received during the last three years	
4	Performance report issued by other Govt. Organisation.	
5	Valid WHO-GMP Certificate	
C.	MANDATORY REQUIREMENT FOR REGD. OF IMPORTED PRODUCTS.	
1	Source of mfg. of finished product with quality report	
2	Relation of Indian stockist/authorised importer with foreign companies for last 03 years	
3	Whether the product is sold in USA or other developed Countries.	
4	Authorisation letter by original manufacturer abroad for local agent.	
D.	OTHER INFORMATION	
1	Name & Adresses of mfg. Units	
2	Name & Adresses of other mfg. Units including loan licencse units.	
3	No. of subsidiary units of the firm with particulars & their relationship.	

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4	Firm's own research products.	
5	Firm's own patented products.	
6	Availability of R & D facility (if yes, then Annual expenditure for last three years.)	
7	Any other relevant information	
E.	Declaration /Undertaking as per enclosed proforma	

DECLARATION /UNDERTAKING

I. We hereby certify that we will not resort to anti competitive behavior (including dissisting from cartel formation) in dealing with different units of Indian Railways. In case Indian Railways observe that we are resorting to anti-competetive behavior, we can be delisted from the list of registered vendors from Indian Railways.

II. We are aware that if in any tender to railways, we are supposed to be in cartel with other firms, our offer will be liable to be ignored for placement of order. We are aware that the decision of railway administration in this regard will be final and binding. We are aware that case of suspected cartel formation may also be reported to the Competetion Commission of India (CCI), New Delhi.

Seal of the Firm Representative

Signature of the Firm
(Complete Name & Adress)

Proforma For Market Standing Certificate

This is to certify that M/S _____ are holding license No. _____ valid till _____ for manufacturing/ sale of various kinds of Medical Devices/ Drugs.

It is further certified that the firm is in the field of manufacturing/ marketing of _____ drugs/ medical equipments/ devices/ disposables/ consumables/ _____ (specify if any other item) for last _____ years.

**State Drug Controller,
Certifying and Licensing Authority**

or

Director General Health Services