Registration of pharmaceutical firms over South Central Railway

Terms and Conditions for registration:

Mandatory conditions : (1) The firm should have at least 5 years of standing in the manufacturing and marketing except for new molecules or newly imported medicines introduced during the last 5 years. (2) Valid G.M.P. Certification as laid down in schedule to the drugs-cosmetics rules. (W.H.O. GMP Certificate will be preferable). (3) Average annual turn-over of the firm for the last 3 financial years should be more than 50 crores or above from the pharmaceutical products only. Turn over from other sales and activities related to non-pharmaceutical products shall not be taken into account. However, turnover criteria can be reduced to 20 crore, if vendors are two or less for each type of medicine category. Information should be supported by the audited statement of the firm. Annual turnover as mentioned above should be from the sale of its own products (manufactured and /or marketed) in domestic market i.e. Indian Market. (4) Firm should submit a declaration that no major punitive action was taken/contemplated against the firm by any Zonal Railway/Central Government/ State Government organization. If information provided is found wrong, then firm can also be de-listed for 3 years all over Indian Railways.

Desirable condition : (1) ISO 9000 certification (2) Market share of the Item as per latest ORG Marg Nielsen analysis. In case information is not available then, especially in case of expensive drugs, the firm should submit details of their supply orders for the previous 3 years for assessment of their market share. These supply orders should normally not be to single institution only. (3) Firms should also submit copy of high value orders covering yearly requirement for the Railway/Unit. (4) Performance report issued by other Government organizations may also be submitted by the firm, if firm has been making supplies to them.

Application form along with General instructions can be obtained from the Assistant Pharmacy Officer, Ground Floor, Office of the Chief Medical Director, South Central Railway, Headquarter Office, Rail Nilayam, Secunderabad-500 071 on any working day between 10 am to 5 pm. Forms can be sent by registered post or can be deposited in person with Assistant Pharmacy Officer on the address as mentioned above.

Registration of pharmaceutical firms over South Central Railway

General Instructions:

(1) Before applying for registration, one should carefully read Application Form and General Instructions.

(2) All the required information should be filled up and necessary documents should be attached with the Application Form.

(3) Annexure supporting/giving any information in respect to any item of application form should be given same No. as is the S.No. of that item in the Application Form.

(4) Application Form should be filled up either in English only.

(5) Acknowledgement of the Application Form may be taken in person when deposited personally or can be got through post, for which a self-addressed envelope with postal stamps affixed on it for registered delivery, may be enclosed along with the Application Form.

(6) A three member Committee of Medical Officers shall do inspection of the manufacturing units of firms asking for registration. For the items not being manufactured by the firm, inspection of manufacturing unit/units shall also be done for registration. Inspection shall be done by Zonal Railway under whose jurisdiction the manufacturing unit is located and report shall be notified to all Zonal Railways.

(7) Number of the products of firms to be registered shall be on the basis of average annual turnover of the firm for the last 3 years from domestic sale of the pharmaceutical products only which shall be as follows – More than 50 crore and upto 150 crore- Maximum upto 25 products. More than 150 crores and upto 500 crores-Maximum upto 50 products. More than 500 crores and upto 1000 crores- 75 products. More than 1000 crores – All products. So, firms should submit list of all of their products to be offered for registration in alphabetical order of active ingredients of the products. One product having same ingredient in different strengths but having same brand name shall be taken as one product only. However, it is not necessary that maximum entitled number of the products offered by companies shall be registered and number of products registered by the South Central Railway may be less than maximum entitlement of the firm (as per turnover criteria), as it will depend upon the need of the South Central Railway and also the products offered by other firms. Products being applied by firms for registration should also be available in open market for retail sale by the same brand name in jurisdiction of South Central Railway, which covers Andhra Pradesh & Maharashtra. Products in paper packing only, for example tablets, syringes should preferably not be offered for registration. Products should be listed in alphabetical order of active ingredient and strength wise (if more than one strength is there) as per format given with the application form.

(8) Zonal Chief Medical Directors shall be the Authority for Registration and renewal for registration shall be done every three years depending upon the performance of the company and need of the Railway. However, for the first time registration, approval of Director General/Railway Health Services, Railway Board shall be obtained.

(9) Where drugs are manufactured abroad and supplied by local firms or manufactured in India with imported raw material, following information shall be mandatory requirement for registration. (a) Source of manufactured raw/finished products and quality report. (b) Relation of Indian agent with the foreign company during the past 3 years. (c) Proof of sale of same products in USA, Europe and other developed countries equivalent to European countries. (d) Authorization letter by OEM abroad in favour of the local agent.

(10) Strip/label/bottle containing drugs to be supplied shall have a prominent printing of “Indian Railways- Not for sale” on it. Firms should preferably put its hologram over products.

(11) Testing of various items supplied shall be got done by the Railways. The unfit batch has to be replaced completely by the firm at its cost including the amount consumed as well. For such offence, the firm can even be deleted from the registered list.

(12) Registration process and procurement process/ policy shall be guided by time to time instructions issued by the Railway Administration and other relevant authorities.

(13) Firm has to make supply to various hospitals/establishments over South Central Railway at their door step.

(14) Details given in format of Application Form for Registration should also be submitted in a soft copy on CD in DOC file.

(15) In case, a firm is having different divisions and is marketing/manufacturing more than one brand with similar active ingredient/composition then it should offer only one brand as not more than one brand of same firm, having similar ingredients and strength shall be registered.

South Central Railway Headquarters Office, Rail Nilayam, Secunderabad

Format of Application Form for registration of Pharmaceutical Firms

1	Name of the firm.	
2	a) Full Address of registered office of the firm b) Full address of Secunderabad office of the firm.	
3	Whether manufacturing only(Attach copy of license)	Yes/No
4	Whether marketing only(Attach copy of license)	Yes/No
5	Whether manufacturing/Marketing both(Attach copy of license)	Yes/No
6	Date of registration of firms (Attach copies of documents)	
7	Whether GMP Certificate attached(copy to be attached)	Yes/No
8	Annual turnover for last 3 years (in crores) for pharmaceutical products in Indian Market only. 20….-…. 20….-…. 20….-…. (Copy of audited statement of accounts to be attached)	---------- ---------- ----------
9	Whether any major punitive action taken/contemplated against the firm by any Railway/Central Government Organization. (If yes, attach details)	Yes/No
10	Whether ISO 9000 certified (If yes, attach documents)	Yes/No
11	Market share of each item offered for registration as per ORG Marg Neilsen survey(To be attached on separate sheet)	Attached/not-attached
12	Details of supply orders to various zones of Indian Railway during last 3 years (Attach copy of Purchase Orders)	Attached/not-attached
13	Number of the products offered for registration as per alphabetical order of active ingredient (attach as Annexure)	Attached/not-attached
14	Details of products offered for registration to be given as per attached proforma as Annexure I	Attached/not-attached
15	In case of Imported products following additional information to be given on attached proforma as Annexure II	Attached/not-attached
16	Affidavit as per attached proforma as Annexure III	Attached/not-attached
17	Any other information and details (Attach)	Attached/not-attached

"I hereby declare that all the information submitte d by me is correct and complete. If any information is found incorrect/wrong/incomplete, my firm may be rejected/deleted from the list of registered firm over South Central Railway".

Authorised Signatory

Signature :

Name :

Official position in firm:

Address :

Phone No. :

E-mail :

Annexure – I

Format for details of the products to be offered for registration.
(In reference to Item No. 14 of Application Form)

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc)	Name of the manufacturer and full address of manufacturing units along with phone nos. and e-mail address.	Name of the marketing firms/companies with full address along with phone nos. and e-mail address.	Market share of products.	No. Of years standing in domestic market
1.							
2.							
3.							

Note : Items should be mentioned alphabetically as per active ingredients of the products, irrespective of the group it belongs to and whether it is tablet or injection or gel or ointment or liquid, etc. When item is composed of more than one active ingredient, then it should be mentioned as per alphabet of ingredient which is mentioned first in the brand name.

Annexure – II

Format for details of the imported products to be offered for registration.
(In reference to Item No. 15 of Application Form)

S.No.	Active ingredients of product. (Composition)	Brand Name	Strength (mg/gm, ml/litre, unit, etc)	Name of the supplier of raw product (wherever applicable)	Name of the supplier of the finished product (wherever applicable)	Quality report attached (yes/no)	Details of sale of product in USA/Europe and other developed countries.	Authorization Letter from Original Manufacturer (Attached or Non-Attached)
1.								
2.								
3.								

Note : Items should be mentioned alphabetically as per active ingredients of the products, irrespective of the group it belongs to and whether it is tablet or injection or gel or ointment or liquid, etc. When item is composed more than one active ingredients, then it should be mentioned as per alphabet of ingredient which is mentioned first in the brand name.

Annexure –III

AFFIDAVIT
(In reference to Item No. 17 of Application Form)

I hereby declare that

1. I am authorized to sign the affidavit on behalf of M/s ……..... in my capacity as ……

2. The firm has not been convicted/has been convicted details of which are attached.

3. The firm has not been/has been delisted by any Central Government/State Government organization, year-wise details of which are as follows:

4. Annual turnover of the firm from sale and marketing of pharmaceutical products only from Indian Market for the last three financial years is as follows:-

Year	
Year	
Year	

Above information is true to my knowledge & belief and is based on facts.

Note: Delete whichever is not applicable in Item 2 and 3.