

NORTH CENTRAL RAILWAY

Sub: - Procedure for Registration of drugs manufacturing companies.

1. Open tendering is done for registration with terms & conditions desired. Wide publicity in news papers given & loading and documents on NCR website is done. Documents required for registration are.
 - Valid Drugs manufacturing license.
 - WHO/GMP
 - Non - conviction Certificate.
 - ISO - 9000
 - Product List
 - Annual turn over for last 3yrs.
2. Comparative chart is prepared and a screening/technical committee of doctors nominated by CMD scrutinizes the documents. Committee recommends the firms to be registered.
3. CMD if accepts recommendations of screening committee firms are given registration after realizing a fee of Rs. 100/- as cost of paper.
4. Registration is done for a period of 2yrs which is extended after 2yrs, based of performance of the firm.

NCR has registered medicine manufacturing firms in 2004 - 05 and in 2007 - 08. Few reputed firm were registered without tendering process by Chief Medical Director during this period to meet the requirement of North Central Railway in terms of Para 3 of Indian Railway Pharmacopoeia 2002. Renewal of registration was also done as & when required to already registered firms of 2004 - 05.

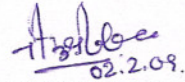
As per new guidelines issued by Railway Board vide letter No. 2006/H/4/1, dated 19/06/2008 (to be implemented in phased manner) registration of firms is to be done for 3yrs on the basis of following criteria.

- Registration fee to be charged Rs. 5000/- for 3 years.
 - The firms should have at least 5 years of standing in the manufacturing and marketing except for new molecule or newly imported medicines.
 - Valid Drugs manufacturing license.
 - Valid GMP/WHO - GMP Certificate.
 - The average annual turnover of the firm for the previous three years should be Rs. 50 crores and above. However it can be Rs. 20 crores if the vendors are 2 (Two) or less for each type of medicine category. Number of product for which firm is registered will depend on annual turnover and is as below:-
1. 50 crores upto 150crores - maximum upto 25 products.
 2. 151 crores upto 500 crores - maximum upto 50 products.
 3. 501 crores upto 1000 crores - maximum upto 75 products.
 4. More than 1000 crores - All products.

- Non - conviction certificate major punitive action taken/contemplated against the firm should be submitted.
- Besides ISO 9000 Certification. As a supporting documents, market share of the item as per the latest ORG - MARG LIELSEN analysis or National/Central Health Ministry report can be taken into consideration by the individual railways for registration of the firms and performance report issued by other government organization may be submitted by the firm as desirable documents.

Now, the first time registration will be done by Railway Board.

The firm applying for registration will be inspected as per guideline issued by Railway Boards letter No. 2006/H/4/1, dated 19/06/2008, by committee nominated by zonal CMD.


02.2.09.

Dy. CMD (H & Plg.)
North Central Railway