[1][FORM 46A

(*See* rules 122 B and 122 DA)

Permission/ Approval for manufacture of raw material (new bulk drug substance)

Name of the permission/ approval and date of issue.....
M/s ..... of ..... (address) is hereby granted Permission/Approval to manufacture the following raw material (new bulk drug substance) under rule 122B / 122DA of the Drugs and Cosmetics Rules, 1945.

Name of the raw material (new bulk drug substance):
(1) .....
(2) .....
(3) ….....

Dated..... *Signature .....*
Name and designation of Licensing Authority.

Conditions for Grant of Permission /Approval

(1) The raw material (new bulk drug substance) shall conform to the specifications approved by the Licensing Authority.

(2) The raw material (new bulk drug substance) can be sold to only those manufacturers who have permission, in writing, from Licensing Authority, either to use the drug for development purpose/clinical trial-bio-equivalence study or to manufacture the formulation.

(3) For manufacture of the formulation in the country, separate approval under rule 122B shall be obtained from the Licensing Authority.]

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1. Ins. by No.G.S.R. 900 (E), dt. 12.12.2001.