¹[FORM 45A (See rules 122A and 122DA) Permission to import raw material (new bulk drug substance)

Name of the raw material (new bulk drug substances):

(1)..... (2) (3)

Dated

Signature

Name and Designation of the Licensing Authority.....

Conditions for Grant of Approval / Permission

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

(2) For manufacture of raw material (new bulk drug substance) or its formulation in the country, separate approval under rule 122-B shall be obtained from the Licensing Authority.

(3) The permission to import shall not be used to convey or imply that the raw material

(new bulk drug) is categorized as "life saving or essential drug."]

1. Ins. By G.S.R. 900 (E), dt. 12.12.2001.