Dear Sir/Madam,

I have a comment on section - B**.I Quality changes-** B.I.a) Manufacture -Section g) "Introduction of New manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant API section of the dossier". (page no. 10/92)

The above refer classification is give a meaning of API is supported by CEP. (Generally for all EU submission, API part will be supported by either ASMF or CEP from the API manufacturer)
If yes, then why we have a separate variation classification mentioned under the section B.III. CEP/TSE Monographs. (Page No. 66/92). (Section B.III.1 a) 3- New certificate from new manufacturer)

Hope my question is clear.

Thanks in advance for accepting my comment.

Yours,
Selvaraj.j

Dr. Reddys Laboratories Ltd, India