| **Remarks** |
| --- |
| No. | Reference to section  | Comment  | Reply |
| (1) | <<section no.>>, <<description>> | <<comment by>>: <<comment>> |  |
| (2) | <<section no.>>, <<description>> | <<comment by>>: <<comment>> |  |
| (3) | <<section no.>>, <<description>> | <<comment b >>: <<comment>> |  |
| (4) | <<section no.>>, <<description>> | <<comment by>>: <<comment>> |  |
| (5) | <<section no.>>, <<description>> | <<comment by>>: <<comment>> |  |

In section 5, three alternative options are proposed. Please, choose which of them could be most suitable for CIPAC.

| **Proposed options on previous in-house validation of chromatographic methods (section 5)** |
| --- |
| No.  | Comment  |
| Option 1: Previously obtained validation data can be presented, but not obligatory | <<comment by>>: <<comment>> |
| Option 2: Previously obtained validation data are presented and checked by CIPAC | <<comment by>>: <<comment>> |
| Option 3: Previously obtained validation data are presented and checked by CIPAC or small scale trial data are presented | <<comment by>>: <<comment>> |