

Q & A

1. Will NPCB accept partial validation for the same API but different strength that already performed full validation
 - Yes, as long as working concentration covered in the linearity test

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2. How to set acceptance criteria for validation
 - Refer to the journal provided

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3. What can be done for statistic value for precision and robustness that failed
 - Re-test or re-assess the method

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4. How to perform force degradation testing/parameter
 - Get the knowledge from universities or published journal

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6. Raw data for API: will the lab section be asking for “raw data” similar to what have been requested for the DP Analytical Method and Validation data review
 - Basically, the raw data that are requested for API will be similar to those for DP

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7. We understand that there is a new procedure now requiring applicants to submit the API S4 & S5 to the lab section concurrently with the other API full section to registration section. We are concerned that the Timelines are going to be impacted. We also seek to understand what is the rational for doing this?
 - The new procedure is to facilitate the API evaluation process. Previously, the lab section have to wait the registration section to complete evaluation before we can proceed with S4 & S5 evaluation. As for current procedure, the 'waiting time' has been reduced.