Method validation
Do you have a formal program covering validation of analytical methods?

Yes ☐ No ☐

Do you document the successful verification of pharmacopoeia test methods in your laboratory?

Yes ☐ No ☐

Do you validate modified pharmacopoeia test methods to assure that all tests are valid under your laboratory conditions?

Yes ☐ No ☐

Do you validate non-pharmacopoeia test methods to assure that all tests are valid under your laboratory conditions?

Yes ☐ No ☐

Do you have a system in place to assure that only the current pharmacopoeia test are used?

Yes ☐ No ☐

Standards
What kind of standard do you used when performing the assay of the product(s) of interests?

Pharmacopoeia Standard	Yes ☐	No ☐
Secondary / in house Standard	Yes ☐	No ☐
Third party Standard	Yes ☐	No ☐

If you use pharmacopoeia Standard(s) please state:
Source of standard (USP, BP): _____
Lot No. of Standard currently in use: _____

If you use Secondary / in house Standard, please provide details of how the standard was characterized.
Lot No. of Standard currently in use: _____
Please enter characterization of Secondary / in house Standard or submit a certificate of analysis to the responds:

Please enter the recommended storage conditions for the above-mentioned Standard(s)?

Name of Standard	Temperature	Humidity	Light

Please mark the time interval of monitoring the storage conditions?

Deep freezer	Continuously	Daily	Weekly
Refrigerator			
Ambient			