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| **Document reference: BF-678** | |
| **Document name: Briefing form for DEV-4208: Planned omission of solution preparation.** | |
| **Issue: 01** | |
| **CA/PA Reference: DEV-4208** | |
| **Briefing description: Analysts are reminded to be very careful when deciding whether certain solutions given in monograph methods need not be prepared.**  **Omission of certain solutions may be permissible if full testing is not required. For example in the Assay – Content of Phospholipids analysis of Lecithin to USP, the Lysophosphatidylcholine standard need not be prepared the samples are not intended for use in the manufacture of injectable dosage forms (as per note in the method).**  **Another example would be where the Assay only of Mannitol is being performed to EP. Those solutions which are used solely as part of the Related substances test (usually run at the same time as the Assay) would then not need to be prepared.**  **Any planned omission should be very carefully considered, and advice of senior analysts/staff should be sought where the analyst has any doubts.** | |
| All personnel / departments listed on this form confirm they have understood the content of the briefing as described above by acknowledging the document in Q-Pulse. This briefing form is used to record training of personnel on a major update to a particular procedure, as a result of an audit observation, a deviation or as a general briefing that requires to be documented.  Copies of briefing forms must be attached to the appropriate actions in Q-Pulse or be cross referenced to the BF record in the Document Module of Q-Pulse. | |
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