

Manual 020

5.3 Contents of an evaluation request

Supporting Information (where available and as appropriate to the request):
Details of any ACQ calculations including therapeutic dose information (MED, NED, MTD, or MDD) and safety factors used to calculate the ACQ
Other Clinical and/or safety (toxicity) data
Quantities involved (including smallest batch size if available)
Proposed siting location
Manufacturing process
Synthetic schemes (API or intermediates)
OEL data
Cleaning Validation, or other Cleaning data