

MONOGRAPH DEVELOPMENT REPLY FORM AND CHECKLIST

Contact Name: _____

Company Name and Address: _____

Monograph Name _____

NO we do not want to contribute to the monograph because (tick as appropriate):

- We do not hold a PL for this product
- We hold a PL but do not produce/market the product
- Other: _____

YES we market this product and would like to contribute to the monograph. We can supply the following information (tick as appropriate):

- Licensed Finished Product Specification
- Identification Method
 - Supporting Validation Data
- Assay Method
 - Supporting Validation Data
- Related Substances Method
 - Supporting Validation Data
- Dissolution Method
 - Supporting Validation Data
- Product Stability Information
 - Names and structures of known synthetic impurities and degradants
 - Forced Degradation Study
 - Real Time/Accelerated Stability Study
 - End of Shelf Life Specification
- Samples
 - Product – minimum 100 units per strength
 - Reference Standard (active) – minimum 1 g
 - Reference Standard (impurities) – minimum 100 mg (if possible)
- We can provide ongoing supplies of the following reference materials:
 - _____ (amount)
 - _____ (amount)
 - _____ (amount)

Any other information:

Note: refer to Supplementary Chapter III of the BP for more guidance