

## Requirement for API Information During Product Registration Renewal (Non- Anti Infective) Updated Apr 2019

API Information	From API Manufacturer	From FP Manufacturer
S1 General Information	X	✓
S2 API Manufacturer	✓	✓
S2.2-S2.6 Closed Part Information	X	X
S3 Characterisation & Impurities	X	X
S4.1 Specification	✓	✓
S4.2 Analytical Procedure	X	X
S4.3 Validation of Analytical Procedures	X	X
S4.4 Batch Analysis & COA	✓	✓
S4.5 Justification of Specification	X	✓
S5 Reference Standard	X	✓
S6 Container Closure System	X	X
S7 Stability	X	X
GMP Certificate (API Manufacturer)	✓	X

Foot Note:

X – Optional

✓ – Required