### 3.2.R.1.~~4~~ Pharmaceutical availability studies

3.2.R.1.4.1 Dissolution studies, data and reports

1. Dissolution profiles of the test and reference products
2. Comparative dissolution between foreign reference product and RSA registered innovator product (if applicable)
3. Comparative dissolution between different strengths of the test product (biowaiver of additional strengths)
4. Comparative dissolution between test and reference products (BCS biowaiver)
5. Comparative dissolution data in support of:
* additional or different API manufacturer
* additional or different FPP manufacturer and/or site
* different formulation

being applied for to that of the test product.

3.2.R.1.4.2 1) Other

1. Motivation for exemption of data to substantiate efficacy.

If in the opinion of the applicant no data are required to substantiate efficacy (e.g. parenteral solutions) the rationale for accepting safety and efficacy should be clearly stated and include a discussion on the excipients (refer Biostudies guideline section 4), and comparison of final product characteristics.