

|            |                                      |
|------------|--------------------------------------|
| <b>2.1</b> | <b>Table of Contents of Module 2</b> |
|------------|--------------------------------------|

**Table of Contents : Module 2**

| <b>Section</b> | <b>Contents</b>   |
|----------------|---|
| <b>2.1</b>     | <b>CTD Table of Contents</b>                                      |
| <b>2.2</b>     | <b>Introduction</b>   |
| <b>2.3</b>     | <b>Quality Overall Summary (QOS)</b>                              |
| <b>2.3.S</b>   | <b>DRUG SUBSTANCE- Cabazitaxel (CEP#: R0-CEP 2009-270-Rev 01)</b> |
| 2.3.S.1        | General Information   |
| 2.3.S.2        | Manufacture   |
| 2.3.S.3        | Characterisation  |
| 2.3.S.4        | Control of Drug Substance   |
| 2.3.S.5        | Reference Standards or Materials                                  |
| 2.3.S.6        | Container-Closure System  |
| 2.3.S.7        | Stability   |
| <b>2.3.P</b>   | <b>DRUG PRODUCT</b>   |
| 2.3.P.1        | Description and composition of the drug product                   |
| 2.3.P.2        | Pharmaceutical development  |
| 2.3.P.3        | Manufacture   |
| 2.3.P.4        | Control of Excipients   |
| 2.3.P.5        | Control of Drug Product   |
| 2.3.P.6        | Reference standards or materials                                  |
| 2.3.P.7        | Container closure system  |
| 2.3.P.8        | Stability   |

**Table of Contents : Module 2**

| <b>Section</b> | <b>Contents</b>                                     |
|----------------|---|
| 2.3.A          | Quality Overall Summary – Appendices                |
| 2.3.R          | Quality Overall Summary – Regional information      |
| <b>2.4</b>     | <b>Non-clinical Overview</b>                        |
| <b>2.5</b>     | <b>Clinical Overview</b>                            |
| <b>2.6</b>     | <b>Non-clinical Written and Tabulated Summaries</b> |
| <b>2.7</b>     | <b>Clinical Summary</b>                             |

**Table of Contents : Module 3**

| Section                               | Contents  |  |
|---------------------------------------|---|--|
| List of abbreviations used in dossier |   |  |
| 3.1                                   | Module 3 Table of Contents                                |  |
| 3.2                                   | Body of Data  |  |
| 3.2.S                                 | DRUG SUBSTANCE  |  |
| 3.2.S.1                               | General Information                                       |  |
| 3.2.S.1.1                             | Nomenclature  |  |
| 3.2.S.1.2                             | Structure   |  |
| 3.2.S.1.3                             | General Properties  |  |
| 3.2.S.2                               | Manufacture   |  |
| 3.2.S.2.1                             | Manufacturer(s)   |  |
| 3.2.S.2.2                             | Description of manufacturing process and process controls |  |
| 3.2.S.2.3                             | Control of materials                                      |  |
| 3.2.S.2.4                             | Controls of critical steps and intermediates              | The information contained in this section is disclosed in Restricted Part. |
| 3.2.S.2.5                             | Process validation and / or evaluation                    |  |
| 3.2.S.2.6                             | Manufacturing process development                         |  |
| 3.2.S.3                               | Characterization  |  |
| 3.2.S.3.1                             | Elucidation of structure and other characteristics        |  |
| 3.2.S.3.2                             | Impurities  |  |
| 3.2.S.4                               | Control of Drug Substance                                 |  |
| 3.2.S.4.1                             | Specification   |  |
| 3.2.S.4.2                             | Analytical procedures                                     |  |
| 3.2.S.4.3                             | Validation of analytical procedures                       |  |
| 3.2.S.4.4                             | Batch Analysis  |  |

### **Table of Contents : Module 3**

| <b>Section</b> | <b>Contents</b>   |
|----------------|---|
| 3.2.S.4.5      | Justification of Specification                              |
| <b>3.2.S.5</b> | <b>Reference Standards or materials</b>                     |
| <b>3.2.S.6</b> | <b>Container closure system</b>                             |
| <b>3.2.S.7</b> | <b>Stability</b>  |
| 3.2.S.7.1      | Stability summary and conclusions                           |
| 3.2.S.7.2      | Post – approval stability protocol and stability commitment |
| 3.2.S.7.3      | Stability data  |
| <b>3.2.P</b>   | <b>DRUG PRODUCT</b>   |
| <b>3.2.P.1</b> | <b>Description and Composition of the Drug Product</b>      |
| <b>3.2.P.2</b> | <b>Pharmaceutical Development</b>                           |
| <b>3.2.P.3</b> | <b>Manufacture</b>  |
| 3.2.P.3.1      | Manufacturer  |
| 3.2.P.3.2      | Batch Formula   |
| 3.2.P.3.3      | Description of Manufacturing Process and Process            |
| 3.2.P.3.4      | Controls of Critical Steps and Intermediates                |
| 3.2.P.3.5      | Process Validation and/or Evaluation                        |
| <b>3.2.P.4</b> | <b>Control of Excipients</b>                                |
| 3.2.P.4.1      | Specification   |
| 3.2.P.4.2      | Analytical Procedures                                       |
| 3.2.P.4.3      | Validation of Analytical Procedure                          |
| 3.2.P.4.4      | Justification of Specifications                             |
| 3.2.P.4.5      | Excipients of Human or Animal Origins                       |
| 3.2.P.4.6      | Novel Excipients  |

| <b>Section</b> | <b>Contents</b>   |
|----------------|---|
| <b>3.2.P.5</b> | <b>Control of Drug Product</b>                            |
| 3.2.P.5.1      | Specification(s)  |
| 3.2.P.5.2      | Analytical Procedures                                     |
| 3.2.P.5.3      | Validation of Analytical Procedures                       |
| 3.2.P.5.4      | Batch Analysis  |
| 3.2.P.5.5      | Characterisation of Impurities                            |
| 3.2.P.5.6      | Justification of Specification(s)                         |
| <b>3.2.P.6</b> | <b>Reference Standards or Materials</b>                   |
| <b>3.2.P.7</b> | <b>Container Closure System</b>                           |
| <b>3.2.P.8</b> | <b>Stability</b>  |
| 3.2.P.8.1      | Stability Summary and Conclusion                          |
| 3.2.P.8.2      | Post-approval Stability Protocol and Stability Commitment |
| 3.2.P.8.3      | Stability Data  |
| <b>3.2.A</b>   | <b>Appendices</b>   |
| 3.2.A.1        | Facilities and Equipment                                  |
| 3.2.A.2        | Adventitious Agents Safety Evaluation                     |
| 3.2.A.3        | Excipients  |
| <b>3.2.R</b>   | <b>Regional information</b>                               |