BDMCA/DPS/02/A

APPLICATION OF REGISTRATION OF MEDICINAL PRODUCTS

QUALITY REQUIREMENTS FOR DRUG SUBSTANCE (PART II – SECTION 1)

PRODUCT: REF.NO.

N.B. This is the recommended format for Part II – Section 1. Spacing should be adjusted by Applicant as and when necessary.

SECTION A

Table of contents for the filed application.

SECTION B

Checklist of tabulated information required for registration of medicinal product.

SECTION C

S1. IDENTITY OF DRUG SUBSTANCE

S1.1 Nomenclature
(State name against appropriate headings. Indicate clearly if heading is not applicable)

S1.1.1 International Non-Proprietary Name (INN)

S1.1.2 Compendial Name
i) British Approved Name (BAN)

ii) U.S Adopted Name (USAN)

S1.1.3 Chemical Abstract Service Registry Number (CAS)

S1.1.4 Laboratory Code, if applicable

S1.1.5 Chemical Name (IUPAC)

S1.2 Structural Formula

S1.2.1 Structural Formula (where applicable)

S1.2.2 Molecular Formula

S1.2.3 Relative Molecular Mass

S1.2.4 Schematic Amino Acid Sequence
(For biotechnological products only)

S1.3 General Properties

S1.3.1 Physicochemical Properties

S1.3.2 Biological Properties
(Biotechnological Products Only)

S2. MANUFACTURE OF DRUG SUBSTANCE

S2.1 Name and Address of Manufacturer

S2.2 Manufacturing Process and Process Control

Brief description of each stage of manufacturing / synthesis process, isolation and final purification of drug substance, including methods, materials used, reaction parameters and conditions, and precautions. Clearly state alternative steps, process and chemicals used.

Bibliography of Manufacturing Process and Process Control

Route of synthesis / chemical reactions / biological reactions, and flow chart for synthesis / manufacture. [ ]

S2.3 Quality Control of Starting Materials

S2.3.1 Specifications and Analytical Control of Materials used in Manufacture of Drug Substance

Materials	Control Specification(s)	Acceptance Limits	Source (For biotechnological products only)

S2.3.2 Criteria for Acceptance or Rejection

S2.4 Control of Critical Steps and Intermediates

S2.4.1 Critical Steps

Critical Steps	Control Specification(s)	Acceptance Limits

S2.4.2 Intermediates

Intermediates	Control Specification(s)	Acceptance Limits

S2.5 Process Validation and/or Evaluation

S2.6 Manufacturing Process Development
(Description of changes made to Manufacturing Process or Site)

S3. CHARACTERISATION

S3.1 Elucidation of Sructure and Characteristics

S3.1.1 Structure of Drug Substance
(Evidence of chemical structure, configuration, conformation, potential isomerism, polymorphism, etc. should be supported by infra-red spectra, UV characteristics, diagnostic chemical reaction, elemental analysis, etc.)

S3.1.2 Characteristics of Drug Substance

S3.1.3 Bibliography [ ]
(Structure and characteristics of drug substance)

S3.2 Impurities

S3.2.1 Research and Development Studies
(Give list and brief discussion of impurities considered and studied during research and development of ingredient. Negative results should also be included.)

S3.2.2 Routine Impurities Control – Summary of impurities monitored or tested for during and after manufacture of ingredient.

Impurities Monitored	Analytical Method Used (E.g. TLC, HPLC, chemical test, IR spectroscopy, atomic absorption, etc)	Acceptance Limits

S3.2.3 Bibliography [ ]
(Research and Development Studies on Impurities; Routine Impurities Control)

S4. QUALITY CONTROL OF DRUG SUBSTANCE

S4.1 Specifications for Drug Substance
(N.B. – If information is substantially the same as that already supplied in Part II – Section 2, Item 5.2, appropriate references may be made)

S4.1.1 Test and Specifications
(Release Specification)

List quality control specifications and tests for the drug substance. Indicate clearly, if test is not performed / specification not checked for every batch of material, the frequency of test or circumstance under which test is done.

Specification (Tests)	Acceptance Limits (B.P/U.S.P./ Manufacture's/etc)	Reference for Specification	Frequency of Test/ Circumstance for test, if not done on every batch

S4.1.2 Source of Drug Substance

S4.1.3 Responsible Laboratory

S4.2 Analytical Procedures

Certificate of Analysis of Drug Substance [ ]

S4.3 Validation of Analytical Procedures

S4.4 Batch Analyses

Experimental data that demonstrates the nine validation characteristics [ ]

Analytical reports of recent batches of active ingredient (about 3 batches) which are representative of material used for manufacture of product seeking registration enclosed. [ ]

Analytical reports for batches used for toxicity tests and clinical work submitted in support of the drug registration application, if different from the above. [ ]

S4.5 Justification of Specification

Specification	Analytical Procedure	Acceptance Criteria	Justification

S5. REFERENCE STANDARDS OR MATERIALS

S6. CONTAINER CLOSURE SYSTEM

S6.1 Immediate Container Closure System / Packaging

Type:

Material :

Capacity (where applicable):

Closure and liner (type and material) :
(where applicable)

Name and Address of Manufacturer:

Specifications:

S6.2 Outer Container(s) / Packaging(s)

Type:

Material :

Capacity (where applicable):

Closure and liner (type and material) :
(where applicable)

Name and Address of Manufacturer:

Specifications:

S6.3 Suitability of Packagings

S7. STABILITY

S7.1 Stability Studies Summary and Conclusion

Outline of stability studies (batches examined, study parameters, length of study characteristics, or degradation products monitored, storage conditions, analytical methods, etc.)	Summary of results and conclusions of study

General Observations and Conclusions on Stability of Active Ingredient

Details of completed stability studies, place of study, protocols, analytical methods, results and conclusions, etc. enclosed. [ ]

S7.2 Post-Approval Stability Protocol and Stability Commitment

On-going / Proposed Stability Studies
(Outline of on-going or proposed stability studies)

Details of on-going/proposed stability studies, protocols, analytical methods, etc. enclosed. [ ]

N.B. Results and conclusions of studies shall be submitted to The Authority on completion of such studies.

S7.3 Stability Data

Report on stability study that includes batches examined, conditions of storage, containers, duration of study, monitoring changes, analytical methods, results from data generated and conclusion.

SECTION D

Summary of Other Data

Bibliography of Relevant Data

N.B. Details of data particulars, full reports of studies including methodology, protocols, analytical methods, results, interpretation, conclusion, copies of papers, articles, etc. referenced and relevant supporting documents shall be kept by the applicant and submitted to the Authority immediately on request.

Manufacturer

SIGNATURE :.....

NAME :.....

OFFICIAL DESIGNATION :.....

Applicant

SIGNATURE :.....

NAME :.....

DATE :.....