EAEU Regulatory Requirements and CTD Dossier Preparation for Marketing Authorization of Cerebroprotein Hydrolysate for Injection: A Review

Nishant Yadav[1], Ritu[2]
[1]*Research Scholar, BDM College of pharmacy, Chhuchhakwas, Jhajjar, Haryana- 124106*
[2]*Corresponding Author Assistant Professor, BDM College of pharmacy, Chhuchhakwas, Jhajjar, Haryana- 124106*

Abstract*—Cerebroprotein Hydrolysate for Injection is a complex biological-derived medicinal product for which comprehensive documentation of quality, safety, and efficacy is essential for regulatory evaluation. Marketing authorization within the Eurasian Economic Union (EAEU) requires compliance with harmonized regulatory requirements and submission of a structured Common Technical Document (CTD) dossier. This review aims to provide an overview of the EAEU regulatory framework applicable to Cerebroprotein Hydrolysate for Injection and to discuss the major requirements for preparation and submission of a CTD dossier for marketing authorization. The EAEU has established common principles and rules for the registration and circulation of medicinal products among its Member States. The regulatory framework includes requirements for registration, expert assessment, quality documentation, safety and efficacy evaluation, labeling, and post-marketing obligations. Decision No. 78 of the Council of the Eurasian Economic Commission provides the principal procedural framework for registration and examination of medicinal products. The CTD dossier should present administrative information and comprehensive scientific evidence in a standardized format covering quality, non-clinical, and clinical documentation. Particular emphasis is required on product-specific pharmaceutical development, manufacturing processes, characterization and control of the active substance and finished product, analytical procedures, specifications, stability data, and relevant safety and efficacy evidence. Appropriate consistency and traceability of information across CTD modules are essential for regulatory assessment. Major challenges include interpretation and implementation of evolving EAEU requirements, generation of adequate product-specific data for complex biological-derived preparations, ensuring consistency of technical information across the dossier, compliance with administrative and labeling requirements, and responding appropriately to questions raised during regulatory assessment. Continuous monitoring of amendments to EAEU regulations and guidelines is therefore important for maintaining submission compliance. A complete, scientifically justified, and EAEU-compliant CTD dossier provides the essential evidence base for regulatory assessment of Cerebroprotein Hydrolysate for Injection. Effective regulatory planning, product-specific scientific documentation, rigorous quality data, and adherence to current EAEU requirements can facilitate a transparent assessment of the product's quality, safety, and efficacy and support the marketing authorization process.

***Index Terms*—Cerebroprotein Hydrolysate; EAEU; Common Technical Document; CTD; Marketing Authorization; Regulatory Affairs.**

I. INTRODUCTION

Cerebroprotein Hydrolysate is a peptide-rich biological preparation derived from porcine brain tissue and has been investigated for its neuroprotective and neurorestorative properties in several neurological disorders. In the literature, the preparation is commonly described as Cerebrolysin and consists predominantly of low-molecular-weight peptides and amino acids obtained through controlled hydrolysis and purification of porcine brain material [1–3]. Its proposed biological activity is associated with neurotrophic-like effects, including modulation of neuronal survival, neuroplasticity, neurogenesis,

synaptic function, and cellular responses to injury [1,2]. Experimental and clinical studies have investigated its use in conditions such as ischemic stroke, traumatic brain injury, dementia, and other neurological disorders; however, the magnitude and consistency of clinical benefit vary among indications and studies [2–5]. From a pharmaceutical-development perspective, Cerebroprotein Hydrolysate represents a complex biological/peptide preparation in which product quality is closely related to the characteristics of the starting biological material, manufacturing process, purification, and control strategy. Recent analytical research has demonstrated the complexity of the peptide composition of Cerebrolysin and has explored advanced analytical approaches, including nano-liquid chromatography coupled with mass spectrometry, for identification and characterization of its active peptide components [6]. Therefore, characterization of the active substance, control of critical quality attributes, consistency between manufacturing batches, and establishment of appropriate analytical procedures are important considerations for development of an injectable Cerebroprotein Hydrolysate product.

The regulatory development of such a product requires integration of pharmaceutical quality, non-clinical, and clinical information into a structured marketing authorization dossier. Within the Eurasian Economic Union (EAEU), medicinal products intended for circulation on the common EAEU market are subject to Union-level requirements for registration and assessment. The Agreement on Common Principles and Rules for the Circulation of Medicinal Products within the EAEU establishes the framework for harmonized regulation of medicinal products and provides for common requirements concerning registration, assessment, quality, preclinical and clinical studies, and pharmacovigilance [7]. The EAEU regulatory framework also provides for the preparation and assessment of registration dossiers in the Common Technical Document (CTD) format. The CTD-based approach provides a standardized structure for presenting evidence supporting the quality, safety, and efficacy of a medicinal product. For Cerebroprotein Hydrolysate for injection, the quality documentation is particularly important because the product is derived from a biological source and contains a complex mixture of peptides and amino acids. The pharmaceutical-development section of the EAEU CTD specifically addresses the scientific rationale for formulation and manufacturing development, critical material attributes, critical process parameters, quality attributes, manufacturing-process development, container-closure considerations, and the control strategy [8]. Consequently, preparation of a scientifically justified Module 3 dossier is essential for demonstrating consistent product quality.

In addition to quality documentation, the non-clinical and clinical sections of the CTD should provide an integrated assessment of the pharmacological properties, toxicological profile, clinical efficacy, and safety of the product. Published PubMed-indexed studies indicate that Cerebrolysin has been evaluated in neurological conditions including stroke, traumatic brain injury, and dementia [1–5]. Nevertheless, the clinical literature is not completely uniform, and systematic reviews have reported variability in clinical outcomes depending on the indication, study design, patient population, treatment timing, and outcome measures [3–5]. Such evidence should therefore be critically evaluated rather than presented solely as evidence of therapeutic efficacy.

For marketing authorization purposes, the scientific information generated during product development must be translated into a complete CTD dossier containing appropriate administrative, quality, non-clinical, and clinical documentation. The EAEU pharmaceutical-development guidance specifically states that its recommendations support preparation of Section 3.2.P.2, Pharmaceutical Development, of a marketing authorization application in CTD format [8]. In addition, EAEU requirements emphasize the assessment of safety, efficacy, quality, benefit-risk considerations, and relevant post-authorization activities as part of the regulatory evaluation process [7,9]. Accordingly, the regulatory development of Cerebroprotein Hydrolysate for Injection requires an integrated approach combining characterization of the complex biological/peptide substance, control of the manufacturing process, establishment of suitable quality specifications and analytical methods, evaluation of non-clinical and clinical evidence, and systematic compilation of these data within the EAEU CTD framework. The present review therefore focuses on the regulatory requirements applicable to

Cerebroprotein Hydrolysate for Injection and discusses the preparation of the CTD dossier, with particular emphasis on the quality/CMC section, non-clinical and clinical documentation, and the information required to support marketing authorization within the EAEU regulatory framework.

1.1 Importance of Marketing Authorization

Marketing authorization is an essential regulatory process for ensuring that medicinal products placed on the market meet predefined requirements for quality, safety, and efficacy. It provides the regulatory basis for evaluating the pharmaceutical quality, manufacturing process, non-clinical evidence, clinical evidence, and overall benefit–risk profile of a medicinal product before its approval for commercial distribution. Within the Eurasian Economic Union (EAEU), a harmonized regulatory framework has been established to ensure common principles for the registration and assessment of medicinal products intended for circulation within the Union [10,11]. For Cerebroprotein Hydrolysate for Injection, marketing authorization is particularly important because the product is a complex peptide-containing preparation derived from biological material, requiring appropriate characterization, manufacturing controls, analytical testing, and evidence supporting its quality, safety, and efficacy.

1.2 Role of the CTD Dossier

The Common Technical Document (CTD) provides a standardized framework for compiling and presenting the scientific and regulatory information required for marketing authorization. The CTD organizes the documentation into modules covering administrative information, summaries of quality, non-clinical and clinical data, quality/CMC information, non-clinical study reports, and clinical study reports. The EAEU registration framework incorporates CTD-based requirements for the submission and assessment of medicinal products, thereby facilitating a structured and systematic regulatory review [11]. For Cerebroprotein Hydrolysate for Injection, the CTD dossier is particularly important for documenting pharmaceutical development, manufacturing processes, characterization of the active substance and finished product, specifications, analytical procedures, process controls, container-closure systems, and stability studies. The EAEU Guidelines on Pharmaceutical Development provide specific recommendations for the preparation of pharmaceutical-development information corresponding to CTD section 3.2.P.2 [12].

1.3 Need for EAEU Registration

The establishment of the EAEU common pharmaceutical market has resulted in harmonized regulatory requirements for medicinal products across participating Member States. Registration under the EAEU framework is therefore required for medicinal products intended for circulation through the common pharmaceutical market and involves assessment according to common Union requirements [10,11]. The EAEU registration procedure enables regulatory authorities to evaluate the submitted evidence concerning product quality, safety, and efficacy using a standardized regulatory framework. For Cerebroprotein Hydrolysate for Injection, compliance with these requirements is important for ensuring that the product dossier adequately addresses the quality characteristics of a complex biological/peptide preparation and provides sufficient supporting evidence for regulatory assessment.The review focuses on the regulatory framework governing medicinal-product registration within the EAEU and systematically discusses the information required for preparation of the CTD dossier. Particular emphasis is placed on pharmaceutical development and quality/CMC documentation, including the characterization of the active substance and finished product, manufacturing-process controls, analytical procedures, specifications, container-closure considerations, and stability studies. In addition, the review discusses the relevant non-clinical and clinical documentation and highlights the major regulatory considerations that should be addressed when preparing a marketing authorization application for Cerebroprotein Hydrolysate for Injection under the EAEU framework.

II. EAEU REGULATORY FRAMEWORK

2.1 EAEU Pharmaceutical Regulatory System

The Eurasian Economic Union (EAEU) is a regional economic integration organization comprising the Republic of Armenia, Republic of Belarus, Republic of Kazakhstan, Kyrgyz Republic, and Russian

Federation. The EAEU was established under the Treaty on the Eurasian Economic Union, which entered into force on 1 January 2015. The Union aims to facilitate the free movement of goods, services, capital, and labor and to establish coordinated and harmonized policies in specified economic sectors [13,14]. The pharmaceutical regulatory system of the EAEU was developed to establish a common market for medicinal products and harmonize regulatory requirements among Member States. The principal legal framework includes the Treaty on the Eurasian Economic Union (2014), the Agreement on Common Principles and Rules for the Circulation of Medicinal Products within the EAEU (2014), and regulatory decisions and guidelines adopted by the Eurasian Economic Commission (EEC) [14,15,16]. The common pharmaceutical market provides a unified framework for registration, examination, manufacturing, quality control, pharmacovigilance, and regulatory supervision of medicinal products.

The EAEU pharmaceutical system involves both supranational institutions, principally the Eurasian Economic Commission, and the authorized regulatory bodies and expert organizations of individual Member States. The EEC develops and coordinates Union-level regulatory requirements, while national competent authorities and expert organizations participate in registration, assessment, inspections, pharmacovigilance, and other regulatory activities [15,17]. The EAEU common pharmaceutical information system includes the Unified Register of Registered Medicinal Products and databases related to pharmacovigilance, quality defects, suspended or withdrawn medicinal products, authorized persons, and pharmaceutical inspectors.

The EAEU framework also incorporates common pharmaceutical-practice requirements, including principles related to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), and Good Pharmacovigilance Practice (GVP) [16,18]. These requirements are particularly relevant to complex biological or peptide-containing products such as Cerebroprotein Hydrolysate for Injection because control of the manufacturing process, starting materials, analytical procedures, product quality, and post-marketing safety must be appropriately documented.

2.2 EAEU Member States and Regulatory Authorities

The EAEU currently consists of five Member States: Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia [13]. Each Member State maintains its national competent authorities and expert organizations responsible for medicinal-product regulation and participates in the implementation of the common EAEU pharmaceutical framework. The official EAEU pharmaceutical portal provides information concerning the authorized bodies and organizations responsible for the common medicinal-product market [17]. At the Union level, the Eurasian Economic Commission (EEC) plays a central role in establishing common regulatory requirements and coordinating implementation of the common pharmaceutical market. At the national level, authorized bodies and expert organizations conduct regulatory and scientific assessment of applications and registration dossiers, including evaluation of quality, safety, efficacy, inspections, and pharmacovigilance activities [15,17]. The distribution of responsibilities between the EEC and national authorities allows the EAEU to maintain a common regulatory framework while retaining national regulatory structures for implementation and supervision. The five Member States and their participation in the common medicinal-product regulatory system can be summarized as follows:

Table 1. EAEU Member States and Their Role in the Common Pharmaceutical Regulatory System

EAEU Member State	Role in the EAEU Pharmaceutical Regulatory Framework
Republic of Armenia	Participates in the registration, scientific assessment, regulatory supervision, and pharmacovigilance of medicinal products through its competent national authorities and designated expert organizations.
Republic of Belarus	Participates in medicinal-product registration, scientific and quality assessment, regulatory supervision, and implementation of EAEU pharmaceutical requirements through competent national authorities and expert organizations.
Republic of Kazakhstan	Participates in registration and assessment procedures, regulatory oversight, pharmaceutical inspections, and pharmacovigilance within the

	EAEU common pharmaceutical market.
Kyrgyz Republic	Participates in medicinal-product registration, regulatory assessment, quality and safety surveillance, and implementation of common EAEU pharmaceutical requirements.
Russian Federation	Participates in registration and scientific assessment of medicinal products, regulatory supervision, pharmaceutical inspections, and pharmacovigilance within the EAEU framework.

The EAEU official pharmaceutical portal identifies the authorized bodies and organizations of all five Member States and provides access to the Union-level medicinal-product regulatory information resources [17].

2.3 Marketing Authorization Pathway

The EAEU marketing authorization pathway is based on the Rules for Registration and Examination of Medicinal Products for Medical Use, initially established by Decision No. 78 of the Council of the Eurasian Economic Commission dated 3 November 2016, together with subsequent amendments [15,19]. The regulatory procedure involves submission and scientific assessment of a registration dossier, examination of the medicinal product, assessment of its quality, safety and efficacy, and issuance of a registration certificate when the applicable requirements are satisfied.

Under the EAEU framework, medicinal products can generally be registered through either the mutual recognition procedure or the decentralized procedure, depending on the regulatory circumstances and applicant's strategy [19]. In the mutual recognition procedure, the medicinal product is first assessed and registered in the selected Reference State, after which the applicant may request recognition of that assessment and registration in other selected Member States. In the decentralized procedure, the application is submitted simultaneously to multiple Member States, with one Member State designated as the Reference State and the others participating as recognition/Concerned States [19].

The regulatory assessment includes verification of dossier completeness and scientific assessment of the submitted evidence. The assessment may include examination of the quality documentation, non-clinical and clinical information, laboratory testing, and, where required, pharmaceutical inspection [19]. The Reference State prepares an expert assessment report addressing the quality, safety, and efficacy of the medicinal product. A positive benefit–risk assessment and satisfactory demonstration of quality, safety and efficacy are fundamental to registration.

The EAEU rules have subsequently been amended to improve the regulatory process. For example, amendments adopted in 2023 addressed experience gained during implementation of the Union registration rules, including procedures for bringing marketing authorization applications into compliance with Union requirements and additional safety measures. Further amendments in 2024 introduced changes concerning variations to marketing authorization applications and strengthened harmonized approaches to pharmacovigilance inspections [20,21].

2.4 Reference and Concerned Member States

A central concept in the EAEU registration procedure is the designation of a Reference State. The Reference State is the EAEU Member State selected by the applicant in which the primary scientific assessment of the medicinal product is conducted and the expert assessment report is prepared [19]. The Reference State therefore has a leading role in evaluating the registration dossier and preparing the scientific conclusions concerning the product's quality, safety, and efficacy. Other Member States selected by the applicant for registration may participate as recognition states, often referred to in regulatory discussions as Concerned States. These states review the assessment performed by the Reference State and undertake the procedures necessary for registration within their respective territories [19]. The applicant may therefore select the Reference State and, where applicable, the other Member States in which authorization is sought. Only one Member State acts as the Reference State for a particular procedure [19].

In the mutual recognition procedure, the Reference State completes the primary assessment first, followed by recognition by the selected Member States. In the decentralized procedure, the application is submitted simultaneously to the selected Member States, while the Reference State coordinates the principal scientific assessment [19]. This structure is intended to reduce duplication of scientific

assessment and support harmonized regulatory decisions across participating EAEU Member States.

2.5 Major EAEU Regulatory Requirements

The EAEU regulatory framework requires an applicant to submit a comprehensive registration dossier containing adequate information to demonstrate the quality, safety, and efficacy of the medicinal product. The registration dossier is prepared in a CTD-based structure and includes administrative information, summaries, pharmaceutical/quality information, non-clinical documentation, and clinical documentation [15,19].

For a product such as Cerebroprotein Hydrolysate for Injection, the principal regulatory requirements include:

- Administrative documentation: application forms, applicant/manufacturer information, proposed product information, labeling and packaging documentation, and other administrative materials [19].
- Quality/CMC documentation: information on the active substance, starting materials, manufacturing process, process controls, characterization, specifications, analytical procedures, validation, container-closure system, and stability [15,19].
- Pharmaceutical development: scientific justification for formulation and manufacturing development, identification of critical quality attributes, evaluation of manufacturing-process parameters, and establishment of an appropriate control strategy [22].
- Non-clinical documentation: pharmacological and toxicological evidence appropriate to the medicinal product and its proposed use [19].
- Clinical documentation: clinical evidence supporting the safety and efficacy of the medicinal product for the proposed indications and patient population [19].
- GMP compliance: manufacturing facilities and processes must comply with applicable Union pharmaceutical-practice requirements, with pharmaceutical inspections performed where required [18,19].
- Risk management and pharmacovigilance: appropriate safety-monitoring information and, where required, a risk-management plan must be incorporated into the regulatory documentation [17,19,21].
- Product information: approved product characteristics, instructions for medical use, labeling, and packaging information must comply with applicable EAEU and national-language requirements [19].
- Stability and quality control: the dossier should demonstrate that the medicinal product maintains its specified quality throughout the proposed shelf life and that the analytical methods used for quality control are appropriate and reproducible [18,22].

For Cerebroprotein Hydrolysate for Injection, these requirements are particularly significant because the product is a complex peptide-containing preparation derived from biological material. Consequently, the registration dossier should provide a scientifically justified description and control strategy for the starting material, manufacturing process, product characterization, analytical methods, specifications, batch consistency, and stability. The pharmaceutical-development section should demonstrate that the selected formulation and manufacturing process consistently produce a medicinal product meeting its predefined quality requirements [22]. The EAEU regulatory framework provides a harmonized pathway for medicinal-product registration based on coordinated scientific assessment and common regulatory requirements. The use of a Reference State together with participating recognition/Concerned States allows the assessment of a medicinal product to be coordinated across multiple Member States. For Cerebroprotein Hydrolysate for Injection, successful preparation of the marketing authorization dossier therefore requires alignment of the product's pharmaceutical development, quality-control strategy, non-clinical evidence, clinical evidence, and pharmacovigilance documentation with the applicable EAEU requirements [15,19,22].

III. COMMON TECHNICAL DOCUMENT (CTD) DOSSIER REQUIREMENTS

The Common Technical Document (CTD) is a harmonized format developed by the International Council for Harmonisation (ICH) for the submission of information supporting the registration of human medicinal products. The CTD is organized into five

modules: Module 1 is region-specific, whereas Modules 2–5 are intended to be common across ICH regions. This structure facilitates regulatory review by presenting administrative, quality, non-clinical, and clinical information in a standardized manner.[23,24,25]

3.1 Module 1: Administrative and Regional Information

Module 1 contains administrative and prescribing information that is specific to the regulatory region in which the application is submitted. Unlike Modules 2–5, its exact content and format are determined by the relevant national or regional regulatory authority.[23,24]

Typical information included in Module 1 comprises:

- Application and administrative forms.
- Cover letter and application-specific correspondence.
- Table of contents for the regional submission.
- Proposed prescribing information, product information, labeling and package leaflet.
- Information regarding the applicant, manufacturer and manufacturing sites.
- Certificates and regulatory declarations required by the respective authority.
- Information concerning patent, pediatric, environmental or other region-specific requirements, where applicable.
- Risk-management and pharmacovigilance documents when required by the jurisdiction.
- Regional clinical-trial or regulatory documents, where applicable.

Thus, Module 1 ensures that the dossier satisfies the legal, administrative and region-specific requirements of the country or regulatory region in which marketing authorization is sought.[23,24]

3.2 Module 2: CTD Summaries

Module 2 provides summaries and overviews of the detailed information contained in Modules 3, 4 and 5. It is designed to allow regulatory reviewers to understand the key scientific information and conclusions without initially reviewing every detailed study report.[23,26]

According to the ICH CTD structure, Module 2 contains the following sections:

3.2.1 CTD Table of Contents

Provides a comprehensive table of contents for Modules 2–5 and enables the reviewer to locate individual documents and sections efficiently.[23]

3.2.2 CTD Introduction

Provides a brief introduction to the medicinal product, including:

- Pharmacologic class.
- Mechanism of action.
- Proposed clinical indication.
- Therapeutic use.
- Dosage form and route of administration.

The ICH guideline recommends that the introduction generally should not exceed one page.[23]

3.2.3 Quality Overall Summary

The Quality Overall Summary (QOS) provides a concise summary of the information presented in Module 3. It covers the drug substance, drug product, manufacturing processes, control strategy, specifications, analytical procedures, container-closure system and stability data. The QOS should highlight important quality attributes and explain the rationale for major quality-related decisions.[27]

3.2.4 Nonclinical Overview

This section provides an integrated critical assessment of the nonclinical information, including:

- Pharmacology.
- Pharmacokinetics.
- Toxicology.
- Relevant safety findings.
- Relationship between nonclinical findings and proposed clinical use.

3.2.5 Clinical Overview

The Clinical Overview provides a critical assessment of the clinical development program. It integrates information concerning:

- Clinical pharmacology.
- Pharmacokinetics and pharmacodynamics.
- Dose-response relationships.
- Clinical efficacy.
- Clinical safety.
- Benefit–risk considerations.

3.2.6 Nonclinical Written and Tabulated Summaries
This section summarizes the nonclinical studies and generally includes:

- Pharmacology.
- Pharmacokinetics.
- Toxicology.

Both written and tabulated presentations are used to facilitate regulatory assessment.[23,26]

3.2.7 Clinical Summary
The Clinical Summary provides an integrated summary of the clinical evidence and includes information on:

- Biopharmaceutic studies.
- Clinical pharmacology.
- Clinical efficacy.
- Clinical safety.
- Literature references.
- Synopses of individual clinical studies.[26]

3.3 Module 3: Quality/CMC
Module 3 contains the detailed Chemistry, Manufacturing and Controls (CMC)/quality information required to demonstrate that the drug substance and drug product can be consistently manufactured and controlled to the required quality standard.[27,28]
The principal organization is:
3.3.1 Table of Contents of Module 3
Lists all quality documents and sections contained in Module 3.

3.3.2 Body of Data
The body of quality information is generally divided into:

3.3.3 S Drug Substance
Information concerning the active pharmaceutical ingredient (API), including:

- General information and nomenclature.
- Manufacturer(s).
- Description of manufacturing process and process controls.
- Control of materials.
- Controls of critical steps and intermediates.
- Process validation/evaluation.
- Characterization of the drug substance.
- Control of the drug substance.
- Reference standards or materials.
- Container-closure system.
- Stability data.

3.3.4 P Drug Product
Information concerning the finished medicinal product, including:

- Description and composition.
- Pharmaceutical development.
- Manufacture.
- Process controls.
- Control of excipients.
- Control of the finished product.
- Reference standards.
- Container-closure system.
- Stability studies.

3.3.5 A Appendices
May include additional information such as:

- Facilities and equipment.
- Adventitious-agent safety evaluation.
- Excipients of human or animal origin, where applicable.

3.3.6 R Regional Information
Contains additional quality information required by a particular regulatory region.

3.3.7 Literature References
Contains references supporting the quality information provided in Module 3.[27,28]
The overall purpose of Module 3 is to establish that the proposed product has an appropriate identity, strength, quality, purity and stability, supported by suitable manufacturing processes and analytical controls.

3.4 Module 4: Non-clinical Studies
Module 4 contains the detailed nonclinical study reports supporting the safety assessment of the medicinal product. These studies provide information on pharmacological activity, pharmacokinetics and toxicological effects before and during clinical development.[23,29]

3.4.1 Table of Contents
Provides the table of contents for the nonclinical study reports.

3.4.2 Study Reports
The principal categories include:

3.4.2.1 Pharmacology
- Primary pharmacodynamics.
- Secondary pharmacodynamics.
- Safety pharmacology.
- Pharmacodynamic drug interactions, where applicable.

3.4.2.2 Pharmacokinetics
- Analytical methods and validation.
- Absorption.
- Distribution.
- Metabolism.
- Excretion.
- Pharmacokinetic drug interactions.
- Other pharmacokinetic studies, where relevant.

3.4.2.3 Toxicology
- Single-dose toxicity.
- Repeat-dose toxicity.
- Genotoxicity.
- Carcinogenicity, where applicable.
- Reproductive and developmental toxicity.
- Local tolerance.
- Other toxicity studies, including studies relevant to specific products.

3.4.2.4 Literature References
Provides literature references supporting the nonclinical assessment.[29]
The nonclinical package is intended to characterize the pharmacological activity and potential toxicities of the medicinal product and to provide an appropriate scientific basis for human exposure.

3.5 Module 5: Clinical Studies
Module 5 contains the detailed clinical study reports and related clinical information supporting the efficacy and safety of the medicinal product. It provides the primary clinical evidence used by regulatory authorities in evaluating the proposed indication.[23,26]

3.5.1 Table of Contents
Contains the table of contents for Module 5.

3.5.2 Tabular Listing of All Clinical Studies
Provides a tabulated overview of clinical studies, including relevant study identifiers, design, population, treatment and study status.

3.5.3 Clinical Study Reports
This section generally includes:

3.5.3.1 Reports of biopharmaceutic studies
- Bioavailability studies.
- Comparative bioavailability/bioequivalence studies.
- In vitro–in vivo correlation studies, when applicable.
- Other biopharmaceutic studies.

3.5.3.2 Reports of studies pertinent to pharmacokinetics using human biomaterials
- Plasma protein binding.
- Hepatic metabolism.
- Other studies using human biomaterials.

3.5.3.3 Human pharmacokinetic studies
- Healthy-volunteer pharmacokinetic studies.
- Patient pharmacokinetic studies.
- Intrinsic/extrinsic factor studies.
- Drug–drug interaction studies.

3.5.3.4 Human pharmacodynamic studies
- Healthy-subject pharmacodynamic studies.
- Patient pharmacodynamic studies.

3.5.3.5 Reports of efficacy and safety studies
- Controlled clinical studies.
- Uncontrolled clinical studies.
- Analyses of clinical data.
- Long-term and other relevant safety/efficacy studies.

3.5.3.6 Reports of post-marketing experience
Where applicable, information from post-marketing clinical experience is provided.

3.5.3.7 Case report forms and individual patient listings
These are included when required by the applicable regulatory authority.

3.5.3.8 Literature References

Contains published literature references relevant to the clinical evaluation.[26,29]

Module	Title	Purpose
1.	Administrative and Regional Information	Region-specific administrative, legal and prescribing information
2.	CTD Summaries	Summarizes quality, nonclinical and clinical information
3.	Quality/CMC	Drug substance, drug product, manufacturing, controls and stability
4.	Nonclinical Study Reports	Pharmacology, pharmacokinetics and toxicology
5.	Clinical Study Reports	Human pharmacology, efficacy and safety evidence

This five-module structure is the internationally harmonized framework established by ICH. Module 1 is region-specific, while Modules 2–5 constitute the common scientific core of the CTD.

IV. CEREBROPROTEIN HYDROLYSATE-SPECIFIC REQUIREMENTS

4.1. Composition and Characterization

Cerebroprotein Hydrolysate is a complex mixture of low-molecular-weight peptides and other nitrogen-containing components obtained from animal-derived protein material. Therefore, its quality assessment requires adequate characterization of the source material, peptide composition, molecular-weight distribution, physicochemical properties and relevant biological characteristics. The starting material should be appropriately identified and controlled, with specifications for parameters such as protein/peptide content, moisture, ash, pH and other product-specific characteristics. Because the product is a complex mixture rather than a single chemically defined molecule, a combination of analytical methods may be necessary to establish its identity, purity and consistency. [30,31]

4.2. Manufacturing Process

The manufacturing process should be adequately described and controlled from raw-material selection through extraction/hydrolysis, purification, concentration, formulation, filling and packaging. Critical process parameters and critical quality attributes should be identified, and appropriate in-process controls should be established. Where animal-derived materials are used, controls for the source, collection, processing and potential contamination of the starting material are particularly important. Manufacturing controls should demonstrate that the process consistently produces material meeting predetermined quality specifications. [31,33]

4.3. Quality Control and Specifications

Quality control should include suitable identity, purity, potency/biological activity, physicochemical and microbiological tests, as applicable. Depending on the established product profile, testing may include peptide/protein content, molecular-weight profile, pH, appearance, microbial limits, bacterial endotoxins, sterility where applicable, residual process-related impurities and other relevant contaminants. Analytical procedures should be appropriately validated to demonstrate their suitability for the intended purpose.[24,25,27]

4.4. Batch-to-Batch Consistency

Because Cerebroprotein Hydrolysate is a complex biological-derived preparation, demonstrating batch-to-batch consistency is an important quality requirement. Manufacturing batches should be compared using predefined critical quality attributes and appropriate analytical methods. Consistency should be demonstrated for parameters such as composition, molecular-weight distribution, physicochemical characteristics, microbiological quality and, where relevant, biological activity. Process validation and continued process monitoring can provide additional evidence that manufacturing remains under adequate control.[32,33]

4.5. Stability

Stability studies should establish the quality, safety and performance of Cerebroprotein Hydrolysate throughout its proposed shelf life. Studies should be performed using representative batches and the proposed container-closure system under appropriate long-term and accelerated conditions. Stability-indicating parameters should be monitored at predefined intervals, including physical appearance, pH, peptide/protein-related characteristics, potency or

biological activity where applicable, degradation products and microbiological quality. The resulting data should support the proposed storage conditions, shelf life and in-use period.[35]

4.6. Safety and Efficacy Evidence

Safety and efficacy should be supported by an integrated package of nonclinical and clinical evidence. Nonclinical studies should characterize pharmacological effects and potential toxicities, while clinical studies should provide evidence regarding the intended therapeutic indication, dose, efficacy and adverse-event profile. For an animal-derived complex product, safety assessment should additionally consider risks associated with the biological source material and potential adventitious or transmissible agents. The overall evidence should demonstrate that the product's quality attributes and manufacturing process are adequately controlled and that the available clinical evidence supports its proposed use.[30,32,36]

V. PACKAGING, LABELLING AND PHARMACOVIGILANCE

For Cerebroprotein Hydrolysate, packaging, labelling and post-marketing safety monitoring should be incorporated into the regulatory dossier in accordance with applicable regional requirements. The CTD framework places region-specific administrative and product-information requirements in Module 1, while quality and stability information supporting the marketed product is presented in the relevant quality sections.[37]

5.1. Container-Closure System

The container-closure system should be described and justified with respect to its ability to protect Cerebroprotein Hydrolysate from contamination, moisture, light and other environmental factors that could adversely affect product quality. Information should include the type and composition of the primary container, closure components, secondary packaging and relevant compatibility considerations. The selected packaging system should be supported by stability data demonstrating that the product remains within its approved specifications throughout the proposed shelf life.[38,39]

5.2. Labelling and Package Leaflet

The product label and package leaflet should provide clear and accurate information necessary for the safe and appropriate use of the medicine. Depending on the applicable regulatory jurisdiction, this generally includes the product name, active ingredient, strength, dosage form, route of administration, indications, dosage and administration instructions, contraindications, warnings and precautions, adverse reactions, storage conditions, batch number, expiry date and manufacturer details. Product information is generally submitted as part of the region-specific CTD requirements and must comply with the relevant national or regional regulations. [37,40]

5.3. Storage Conditions

The recommended storage conditions should be established from appropriate stability studies performed on representative batches in the proposed container-closure system. The label should specify the appropriate temperature and other storage precautions, such as protection from light or moisture, where supported by the stability data. Stability studies should also evaluate the effect of relevant environmental conditions and establish an appropriate shelf life for the finished product. [38,39]

5.4. Pharmacovigilance Requirements

Pharmacovigilance activities should be established to facilitate the detection, assessment, understanding and prevention of adverse effects and other medicine-related problems. A pharmacovigilance system should collect and evaluate safety information arising from clinical use and identify important known risks, potential risks and missing information. For products requiring enhanced monitoring, an appropriate pharmacovigilance plan and risk-minimisation measures should be implemented according to the requirements of the relevant regulatory authority.[41]

5.5. Post-Marketing Surveillance

Post-marketing surveillance is important because the safety profile of a medicine may change as exposure increases and the product is used in a broader patient population than that represented in pre-approval studies. Safety information obtained after marketing should therefore be continuously evaluated, and

newly identified safety signals should be appropriately investigated and communicated to regulatory authorities when required. For Cerebroprotein Hydrolysate, surveillance may include adverse-event reporting, periodic safety evaluation, assessment of product-quality complaints and investigation of unexpected safety signals.[41]

VI. REGULATORY CHALLENGES

The regulatory pathway for Cerebroprotein Hydrolysate in the Eurasian Economic Union (EAEU) may present challenges because the product is a complex biological-derived preparation and therefore requires adequate control of its composition, manufacturing process, quality, safety and clinical performance. EAEU medicinal-product regulation is based on common Union requirements for registration, assessment, quality and clinical studies, while national requirements may still be relevant in specific areas.[42,43]

6.1 EAEU-Specific Requirements

A major challenge is ensuring that the dossier complies with the EAEU Rules for Registration and Assessment of Medicinal Products for Medical Use, adopted by Decision No. 78 of the Council of the Eurasian Economic Commission in 2016. The EAEU framework establishes common requirements for the structure and content of registration dossiers and for the assessment of medicinal products.[42] For Cerebroprotein Hydrolysate, particular attention may be required for the documentation of the biological source, manufacturing controls, quality attributes, safety evaluation and clinical evidence. EAEU requirements also incorporate common approaches to pharmaceutical development and quality management.[43,44]

6.2 Dossier Preparation and Documentation

Preparation of an EAEU registration dossier requires systematic compilation of administrative, quality, non-clinical and clinical information in the required format. The applicant must ensure consistency between manufacturing information, specifications, analytical methods, stability data and clinical documentation. For a complex peptide/biological-derived product, an important challenge is providing adequate characterization and scientifically justified specifications rather than relying only on general identification or content tests. The EAEU pharmaceutical-development guidance specifically addresses preparation of the pharmaceutical-development section of the CTD dossier.[44]

6.3 Translation Requirements

Translation of the dossier and product information can create an additional regulatory burden when the applicant is submitting documentation originating from another country. Technical documents, prescribing information, labelling and other regulatory materials must be prepared in the languages and formats required by the applicable EAEU regulatory procedure and participating Member State. Particular care is required for terminology, units, analytical specifications, manufacturing descriptions, warnings and clinical information, because inconsistencies between language versions can result in requests for clarification or correction during assessment.

6.4 Quality and Characterization Challenges

One of the principal scientific challenges for Cerebroprotein Hydrolysate is establishing a sufficiently comprehensive quality and characterization profile. A complex hydrolysate may contain multiple peptide fractions rather than one chemically defined active substance. Consequently, demonstrating consistent identity, composition, purity and biological characteristics can require multiple complementary analytical techniques. The EAEU framework also provides for harmonized pharmacopoeial requirements, while transitional situations may involve references to pharmacopoeias of individual EAEU Member States where an appropriate EAEU Pharmacopoeia monograph is unavailable.[45]

6.5 Clinical Evidence Requirements

Clinical evidence must adequately support the proposed indication, dosage, efficacy and safety of the medicinal product. EAEU clinical-trial requirements are intended to harmonize approaches among Member States and are linked to the common registration and assessment framework.[46]

For Cerebroprotein Hydrolysate, clinical evidence may be particularly important because regulatory assessment must consider whether the available

studies adequately establish a clinically meaningful benefit and characterize adverse events. Studies conducted outside the EAEU may therefore need to be presented with sufficient methodological, ethical and regulatory documentation to allow appropriate assessment.

6.6 Regulatory Deficiencies and Responses

During regulatory assessment, authorities may identify deficiencies concerning quality documentation, analytical methods, manufacturing controls, stability data, non-clinical studies or clinical evidence. Deficiencies may also arise from inconsistencies between different sections of the dossier. The applicant should respond to regulatory questions using clear, evidence-based and traceable responses, supported by revised documents, additional analyses or supplementary data when justified. Changes to the dossier should be controlled so that all affected sections remain internally consistent. The EAEU regulatory framework provides for expert assessment of registration dossiers and associated documentation as part of the marketing-authorization process[42].

Preparation of the Common Technical Document (CTD) for submission in the Eurasian Economic Union (EAEU) is not merely an administrative exercise; it requires systematic integration of pharmaceutical quality, non-clinical, clinical, and regulatory information. The EAEU Rules for Registration and Expertise of Medicines for Medical Use, approved by Decision No. 78 of the Council of the Eurasian Economic Commission in 2016, specify the structure and content of the registration dossier and require information to be organized according to CTD modules 1–5 [47]. This modular structure facilitates regulatory review by providing a consistent presentation of administrative information, summaries, quality documentation, non-clinical reports, and clinical study reports. In practical terms, CTD preparation requires early coordination among regulatory affairs, analytical development, manufacturing, quality assurance, non-clinical, and clinical teams to ensure that information is complete, internally consistent, and appropriately cross-referenced. The EAEU framework also provides for joint recognition of relevant study and inspection results within the Union, which can support a harmonized registration approach across Member States [48]. A major consideration in EAEU submissions is that the registration dossier should reflect the specific characteristics of the medicinal product rather than relying solely on generic or previously submitted information. Module 3, for example, requires detailed product-specific information concerning the active pharmaceutical ingredient, formulation, manufacturing process, specifications, analytical methods, packaging, and stability. Modules 4 and 5 similarly require appropriate non-clinical and clinical evidence supporting the proposed product, indication, dosage, and route of administration [47]. The EAEU guidance on pharmaceutical development further emphasizes that product-specific development information should demonstrate how formulation and manufacturing variables influence critical quality attributes and the final product quality profile [49]. For specialized products, additional product-specific considerations may apply; for example, EAEU guidance for inhalation and nasal products highlights the importance of physical characteristics of the active ingredient and excipients, such as particle size, shape, density, and crystallinity, where these characteristics can affect product performance [50]. Therefore, a successful dossier should establish a clear scientific relationship between the proposed product, its manufacturing process, quality attributes, and the evidence supporting its safety and efficacy. Successful EAEU submission requires a regulatory strategy that integrates scientific evidence with the specific procedural requirements of the Union. First, applicants should identify the appropriate registration pathway and determine the applicable EAEU requirements before dossier compilation. Second, the CTD should be prepared using a document-management system that ensures consistency of product names, strengths, manufacturing sites, specifications, analytical methods, stability data, and clinical information across all modules. Third, applicants should perform a comprehensive gap assessment against Decision No. 78 and relevant EAEU guidelines before submission. Particular attention should be given to Module 1 administrative documents, Russian-language product information and labeling, Module 3 quality data, and the supporting non-clinical and clinical evidence [47]. Regulatory scientific advice, where appropriate, may also help clarify complex

product-specific requirements before submission. In addition, applicants should maintain a clear strategy for responding to questions raised during the expert assessment and should ensure that any requested clarification is supported by traceable source data. The EAEU framework has continued to develop through additional guidance and amendments, making continuous monitoring of regulatory updates important for maintaining submission readiness [49,51]. Overall, the practical success of an EAEU CTD submission depends on early regulatory planning, product-specific scientific justification, rigorous data consistency, and compliance with the current EAEU regulatory framework. A well-structured CTD can facilitate efficient assessment by allowing reviewers to readily identify the evidence supporting product quality, safety, and efficacy, while reducing the potential for deficiencies arising from incomplete or inconsistent documentation.

VII. CONCLUSION

The preparation of a complete, scientifically justified, and EAEU-compliant Common Technical Document (CTD) is fundamental to the successful marketing authorization of Cerebroprotein Hydrolysate for Injection within the Eurasian Economic Union (EAEU). A well-structured CTD should provide comprehensive and consistent evidence addressing the product's quality, safety, and efficacy, while meeting the administrative and technical requirements established under the EAEU regulatory framework. Particular attention should be given to product-specific pharmaceutical development, manufacturing processes, quality specifications, analytical procedures, stability data, non-clinical evidence, and clinical documentation. The scientific rationale supporting the proposed product should be clearly presented across the relevant CTD modules to facilitate an effective regulatory assessment. For Cerebroprotein Hydrolysate for Injection, the quality dossier is particularly important because the product is a complex biological-derived preparation, and adequate characterization, control of manufacturing processes, batch-to-batch consistency, and appropriate safety evaluation are essential for demonstrating reproducible product quality. Product-specific data should therefore be generated and presented in accordance with applicable EAEU requirements rather than relying exclusively on generalized or literature-based information. Furthermore, careful cross-checking of information across all CTD modules, compliance with EAEU administrative and labeling requirements, and timely responses to regulatory queries can reduce deficiencies during the assessment process. In conclusion, EAEU-compliant CTD preparation should be regarded as an integrated scientific and regulatory process rather than simply a documentation exercise. A complete and evidence-based dossier for Cerebroprotein Hydrolysate for Injection can provide a transparent scientific basis for regulatory evaluation and support the demonstration of consistent quality, acceptable safety, and therapeutic efficacy required for marketing authorization in the EAEU. Continuous monitoring of amendments to EAEU regulations and guidelines is also essential to ensure that the dossier remains aligned with current regulatory expectations.

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