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Review Article

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A Comparative Study on Regulatory Requirements for Pharmaceutical and Biological Product registration in ASEAN and Asia Pacific Region for Parenteral Dosage Form

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Abstract

Regulatory requirements for pharmaceutical and biological product registration varies significantly across different regions impacting availability of critical parenteral dosage form in that market. This thesis provides a comprehensive comparative analysis of regulatory requirements for registration of parenteral dosage form in emerging markets which include ASEAN and Asia – Pacific region.

The study majorly examines key regulatory framework, submission requirement, review process and lifecycle management. Focusing on how these factors affect development and market entry of parenteral product. The research explores major difference in documentation, quality requirements and product life cycle management across these markets. Data for the study is gathered from extensive review of official regulatory documents and guidelines.

Parenteral means 'Para' + 'Enteral' which means those products that surpasses the intestine and directly enters into systemic circulation. The pharmaceutical parenteral products are derived from synthetic or plant-based API's whereas biological parenteral products are derived from organisms. This thesis covers all types of parenteral registration requirements including, branded, generic and biosimilar. It includes vaccines, pre-filled syringes, bottles, vials, bags, ampoules, etc.

Aim behind considering RoW market is that they are constantly updating and emerging themselves against regulatory challenges. Some of the countries in these regions have adopted ICH guidelines and others maintain unique regional guidelines. Some countries in region like ASEAN follow ACTD. Few countries like India to reduce the task of handling hard copy have established portals while few have established soft copy submission in CD/DVD or USB form while other still need submission in hard copy.

Keywords: Parenterals, RoW, Emerging markets, registration requirements, lifecycle management, biological products, ICH guidelines, ACTD, ASEAN, Asia - Pacific

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1. Introduction

Parenterals: ***Para*** *(Outside)* **+** ***enteron*** *(intestine)*

The route of administration which by-passes the alimentary canal.

They are generally sterile and pyrogen free preparation.

Small Volume Parenterals	Large Volume Parenterals
≤ 100ml volume	> 100ml volume

Routes of administration: Intravenous (IV)**,** Intramuscular (IM)**,** Subcutaneous (SC)**,** Intradermal (ID)

Types of parenteral preparation: Solution**,** Suspension**,** Emulsion**,** Powder for injection**,** Lyophillized powder for injection**,** Infusion fluids

Types for packaging used:

a. Vials
b. Ampoules
c. Glass bottles
d. Plastic bottles
e. Pre-filled syringes
    i. Single Chamber
    ii. Double Chamber
f. Bags
    i. Single Chamber
    ii. Double Chamber
    iii. Triple Chamber

Biological product: A product derived from large complex molecules.

Produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs.

Types: Vaccines, Blood and Blood Components, Allergenics, Somatic Cells, Gene Therapy, Tissues, Recombinant Therapeutic Proteins

Table 1. Regional Division of Countries

Regions	No of countries	Countries
ASEAN The Association of South East Asian Nations	10	Brunei Darussalam, Laos PDR, Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam
Asia – Pacific	11+	China, Japan, India, South Korea, Srilanka, Nepal, Bhutan, Afghanistan, Australia, Bangladesh, Pakistan, etc.

2. ASEAN: The Association of South East Asian Nations

Countries: Brunei Darussalam, Laos PDR, Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam.

2.1 Malaysia (1-3):

Regulatory Authority: NPRA – National Pharmaceutical Regulatory Authority

It follows A-CTD guideline.

Part 1 submission is done in different sections from section A- E.

Part 1 – Administrative and Prescribing Information

Part 2 – Quality

Part 3 – Non-clinical study

Part 4 – Clinical study

Table 2. Registration Requirement Comparison (1-3)

Section	Pharmaceutical Parenteral	Biological Parenteral
Part 1 Administrative and Prescribing Information		
Section A		
ATC Code	To be submitted	-
Route of administration	To be submitted	-
Section C		
Container closure system	To be submitted	
Pack size	Description related to commercial and patient pack size	
Technical specification	To be included	To be included
Section D		
Labels	English/Bahasa Malaysian language only	
PIL/RiMUP	English/Bahasa Malaysian language only	
Mock-Ups	English/Bahasa Malaysian language only	
Section E		
Authorization letter	As per QUEST application form and dossier	-
GMP certificate	For both P and S part of submission as per QUEST document	
PIL/SmPC	Approved in country of origin	To be submitted
Part 2 Quality		
3.2.S.1.2 Structure	Structural formula Relative and absolute stereochemistry Molecular formula, Relative molecular mass	Schematic amino acid sequence Indicating glycosylation or other post transitional modification Relative molecular mass
3.2.S.2.3 Control of Materials	Information on quality and control of raw material, starting material, reagents, intermediate and catalyst should be identified. Letter of attestation to be provided for API, starting material and reagent to be free from risk of transmitting animal spongiform encephalopathies. CEP demonstrating TSE compliance.	Additionally, Control of source and starting materials of biological origin – summary of viral safety information Source, history, and generation of the cell substrate Cell banking system, characterization, and testing
3.2.S.2.4 Control of Critical Steps and Intermediates	Critical steps Intermediates	Critical steps, Intermediates Stability data supporting storage condition
3.2.S.2.5 Process Validation and/or Evaluation	Aseptic processing Sterilization method	Virus validation – data related to removal or in-activation of virus.

3.2.S.3.1 Elucidation of Structure and other Characteristics	Synthetic route and spectral analyses, potential for isomerism, the identification of stereochemistry, the potential for forming polymorphs	Primary, secondary and higher-order structure, post-translational forms, biological activity, purity, and immunochemical properties
3.2.P.2.2 Description of Manufacturing Process and Process Controls	A narrative: quantities of raw materials, solvents, catalysts and reagents reflecting the representative batch scale for commercial manufacture, identification of critical steps, process controls, equipment and operating condition. Alternate processes	Batch and scale definition, Cell culture and harvest, Purification and modification reactions, Filling, storage and transportation.

Mandatory Attachments of Part II (1-3)

- **API**
- GMP Certificate
- CEP as per EDQM database
- DMF with LOA as submitted in QUEST
- Part II S form
- CoA of at-least 2 batches
- Stability study data: long term of at-least 12months, accelerated data of at-least 06months on at-least 03 primary batches

FPP

BMF

CPP

GMP by PIC/S member state or EEA

PVR fulfil the batch size

CoA: min. 02 batches

Stability data: min. 02 batches

Bioequivalence report (Not applicable for parenterals)

2.2 Singapore (4, 5)**:**

Regulatory Authority: HSA – Health Science Authority

It follows A-CTD guideline.

Part 1 – Administrative and Prescribing Information

Part 2 – Quality

Part 3 – Nonclinical study

Part 4 – Clinical study

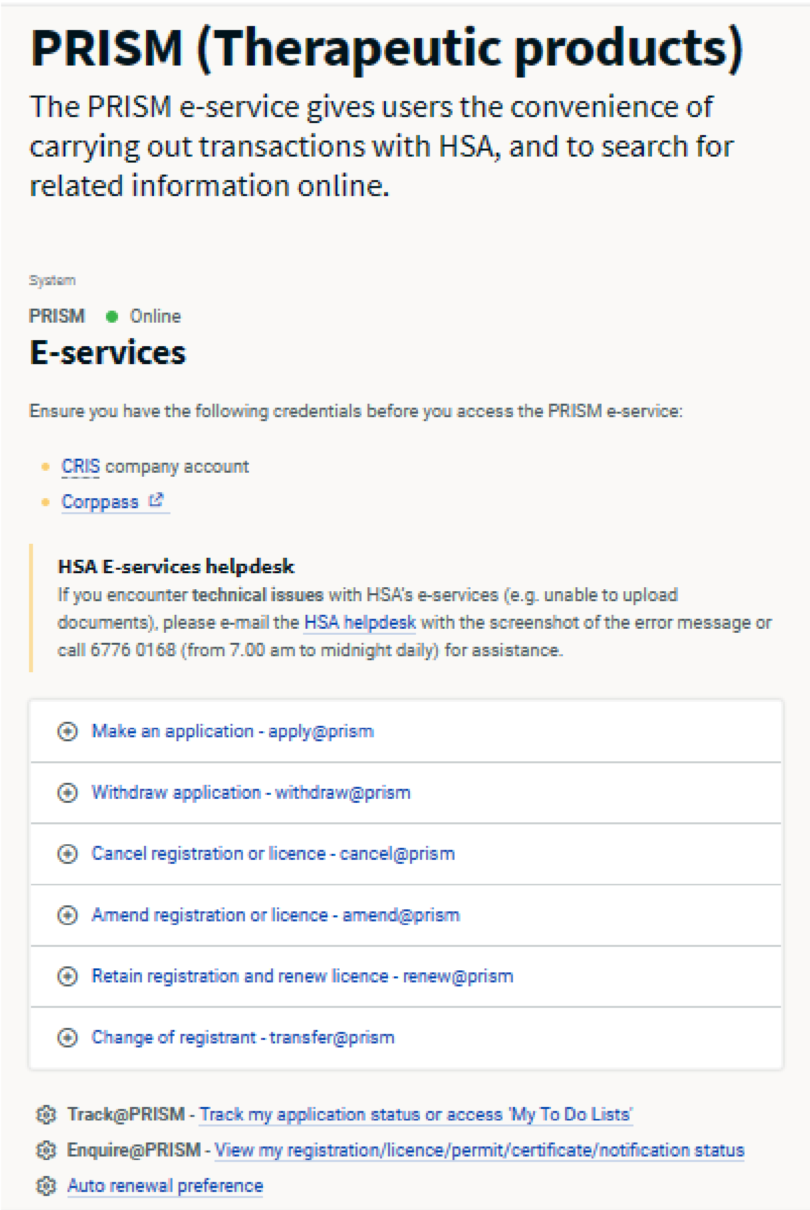

Figure 1. PRISM (5)

Table 3. Registration Requirement of Singapore (4,5)

Section	Pharmaceutical Parenteral	Biological Parenteral
Part 1 – Administrative and Prescribing Information		
QTPP	-	QTPP profile to be established as per SRBP in case of biosimilar product
Application form	To be submitted on PRISM	To be submitted
PIL/CMI	To be submitted	-
Product monograph	To be submitted	Not applicable
Product label	To be submitted in English only	
SPC, PIL	Approved by HSA	-
GMP certificate	For manufacturers outside Singapore	
TPML	For manufacturers registered under HSA, TPML submitted instead of GMP certificate	
CPP	To be submitted in WHO format given by CA of country of origin	
Part 2 - Quality		
3.2.S.1.2 Structure	Structural formula Relative and absolute stereochemistry Molecular formula Relative molecular mass	Schematic amino acid sequence Indicating glycosylation or other post transitional modification Relative molecular mass
3.2.S.2.2 Description of Manufacturing Process and Process Controls	A flow diagram of the synthetic process, A narrative: quantities of raw materials, solvents, catalysts and reagents reflecting the representative batch scale for commercial manufacture, identification of critical steps, process controls, equipment and operating condition. Alternate processes	Batch and scale definition, Cell culture and harvest, Purification and modification reactions, Filling, storage and transportation.
3.2.S.2.3 Control of Materials	Information on quality and control of raw material, starting material, reagents, intermediate and catalyst should be identified. Letter of attestation to be provided for API, starting material and reagent to be free from risk of transmitting animal spongiform encephalopathies. CEP demonstrating TSE compliance.	Additionally, Control of source and starting materials of biological origin – summary of viral safety information Source, history, and generation of the cell substrate Cell banking system, characterization, and testing
3.2.S.2.4 Control of Critical Steps and Intermediates	Critical steps Intermediates	Critical steps, Intermediates Stability data supporting storage condition
3.2.S.3.1 Elucidation of Structure and other Characteristics	Synthetic route and spectral analyses, potential for isomerism, the identification of stereochemistry, the potential for forming polymorphs	Primary, secondary and higher-order structure, post-translational forms, biological activity, purity, and immunochemical properties
3.2.P.2.5 Process Validation and/or Evaluation	Aseptic processing Sterilization method	Virus validation – data related to removal or in-activation of virus.

Table 4. Comparison between ASEAN countries

Parameters	Malaysia (Pharmaceutical Product) (1-3)	Malaysia (Biological Product) (1-3)	Singapore (Pharmaceutical Product) (4,5)	Singapore (Biological Product) (4,5)
Regulatory Authority	NPRA – National Pharmaceutical Regulatory Agency		HSA – Health Science Authority	
GMP inspection	Pre-submission GMP inspection		-	-
Reference product	Malaysian reference product and MAL number		-	-
Label	English/Bahasa Malaysia		To be submitted	
PIL	Called RiUMP, English/Bahasa Malaysia	-	Called CMI	-
Submission	QUEST application		PRISM – Part I submission Part II to IV – PRISM or CD	
CPP	WHO format			
GMP certificate	Submission in QUEST application		To be submitted, TPML in case of local manufacturer	

PIC/S	Equivalent document issued by PIC/S should be submitted		-	-
Other country	Registration certificate from other countries			
PIL/SPC	Reference should be submitted		Submit HSA approved PIL, SPC	
Registration validity	05 years			
Re-registration of product	06months prior the expiry of product		03 -06 months prior expiry	
Fees	to be paid within 30days from date of screening approval	To be paid		
Review timeline	210 – 245 working days	-	-	-
Assessment reports	-	-	From reference agencies	-

3. Asia Pacific Region:

Countries: China, Japan, India, South Korea, Sri-Lanka, Nepal, Bhutan, Afghanistan, Australia, Bangladesh, Pakistan, etc.

3.1 India (6):

- Regulatory Authority: CDSCO – Central Drugs Standard Control Organization
- It follows ICH CTD guidelines.
- It has a portal for submission of documents. – SUGAM Portal.
- Samples: Drug substance and drug product (an equivalent of 50 clinical doses or double the quantity required (whichever is more))
- Samples are sent to Central Drugs Laboratory (CDL) for analysis.

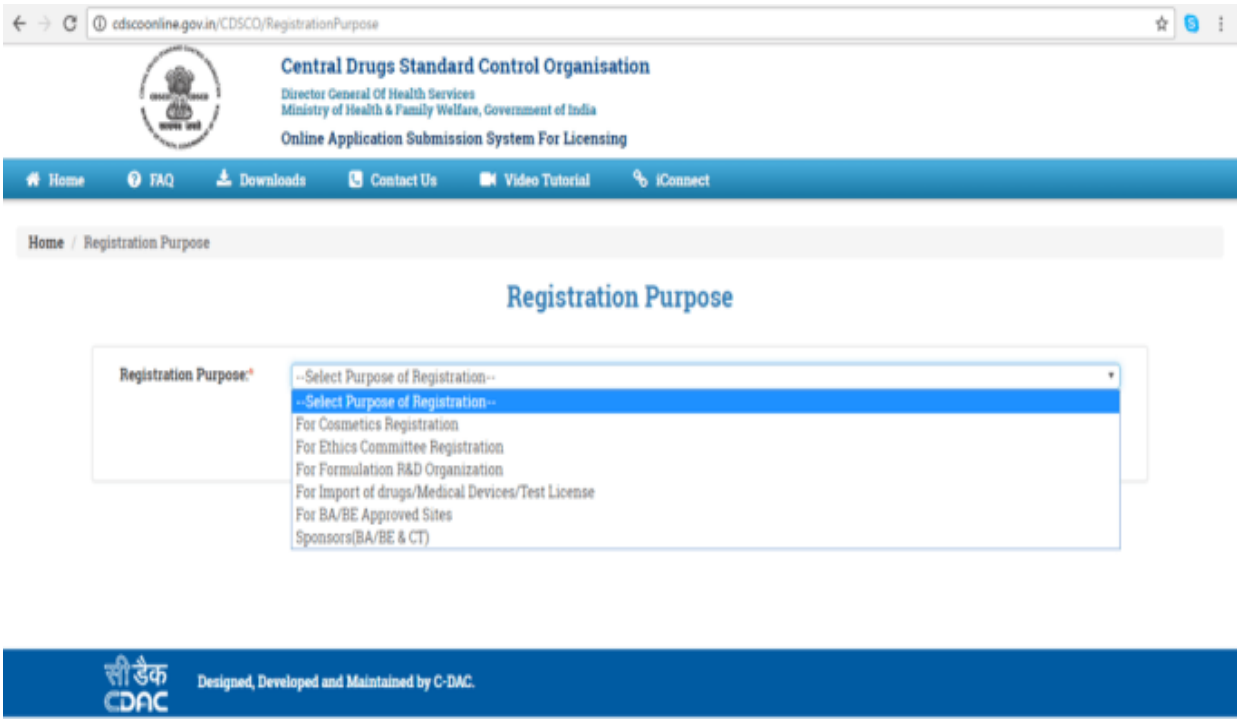

Figure 2. SUGAM Portal

Table 5. Module 1 Registration requirement (6)

Section	Pharmaceutical Parenteral	Biological Parenteral
Application form	Form 40/44	Form 40
Treasury challan	To be submitted	
Copy of drug sale license (import and manufacturing)	Form 20B/21B	
FSC	Only if applicable	-
CPP	In WHO format issued by CA of country of origin	
Testing of imported drug in CDL	Form 11	-
Manufacturing license	Form 25/26/28	
LOA	To be submitted	-
Package insert	In English	In English
SPC	In English	-
PIL	In English	

Samples	To be submitted

Table 6. Registration Requirements for India (6)

Section	Pharmaceutical Parenteral	Biological Parenteral
Module 2 - QOS		
Page limit	Not exceed 40 pages	Not exceed 80 pages
2.3.S.3 Characterisation	Structure, isomerism For chiral drug molecule – specific stereoisomer	Primary and higher order structure Biological activity
CTD Summaries: Includes summary of Module 3,4,5		
2.5.2 Overview of Biopharmaceutics – Includes summary of BA/BE study	Not applicable for parenteral preparation	Not applicable for parenteral preparation
2.7.1 Study of Biopharmaceutic and associated analytical method	Not applicable for parenteral preparation as it involves data related to BA/BE	Not applicable for parenteral preparation as it involves data related to BA/BE
Remaining sections are same for both Biological and pharmaceutical products		
Module 3 Quality		
3.2.1.1.2 Structure	Structural formula Relative and absolute stereochemistry Molecular formula Relative molecular mass	Schematic amino acid sequence Indicating glycosylation or other post transitional modification Relative molecular mass
3.2.1.2.1 Name and address of API(s) Manufacturer	Valid Manufacturing Authorization for the production of APIs. Certificate of GMP compliance (if available)	Facilities involved in creation, testing and storing of the cell banks should be listed
3.2.1.2.2 Description of Manufacturing Process and Process Controls	Synthetic process includes: Weights, Yield ranges, molecular formulae, chemical structures of starting material, intermediates, reagents and drug substance reflecting stereochemistry, identifies operating conditions and solvent	Information on cell bank and cell culture, Harvest, purification and modification reaction including storage condition and shipping condition. Reference ICH Guidelines: Q5A, Q5B, and Q6B
3.2.1.2.3 Control of Materials	Information on quality and control of raw material, starting material, reagents, intermediate and catalyst should be identified. Reference ICH Guidelines: Q6A and Q6B	Control of Source and Starting Materials of Biological Origin Source, history, and generation of the cell substrate Cell banking system, characterisation, and testing Which must include limit of in vitro cell age (LIVCA) Reference ICH Guidelines: Q5A, Q5B, Q5C and Q5D
3.2.1.2.4 Controls of Critical Steps and Intermediates	-	Additional: Stability data supporting storage condition should be provided. Refer ICH Q5C
3.2.1.2.5 Process Validation and/or Evaluation	Aseptic processing Sterilization method Declaration of use/non-use of material of animal or human origin.	Virus validation – data related to removal or in-activation of virus. Must include: Cell growth kinetics and antibody productivity profiles demonstrated for bioreactor for appropriate timeframe, Removal of media components/additives during purification Capacity of purification process to remove contaminating virus.

3.2.1.2.6 Manufacturing Process Development	Description and discussion of process, Explain alternate process, Impurity profile, Reprocessing steps External environmental impact statement Refer: ICH Q3A	Additional or deletion of operational parameters. Freeze/thaw development data used to set number of cycles. Refer to ICH Q5E and ICH Q11
3.2.1.4.1 Specification of the drug substance	Sterility test, Pyrogen test, BET Microbial limit test Bacterial limits Fungal limits Particulate matter	-
3.2.2.2.1 Components of the Drug Product	Drug Substance Excipients	Drug substance
3.2.2.3.5 Process Validation and Evaluation	Validation of sterilization process Validation of Aseptic processing and filling First three production-scale batches must be monitored. Extensive sampling to be performed for parenteral products. Simultaneous process trials to validate aseptic filling for parenteral products that are not terminally sterilized. Acceptance level of contamination: NMT 0.1% Pilot batch size should be atleast 10% in size of production scale batch.	Information on viral safety

3.2 Sri Lanka (7)**:**

Regulatory Authority: NMRA – National Medicines Regulatory Authority: Follows ICH CTD guidelines

Table 7. Types of Registration

New Registration	Re-registration
Module 1 – Administrative and prescribing information	Module 1
Module 2 – Dossier Overall Summary	Summary of Annual Product Report (APR) of the batches marketed in Sri Lanka since the grant of MA
Module 3 – Quality	Product quality review*: Conducted with NLT 12 consecutive batches over span of 12months If not so than, NLT 25 consecutive batches over span of 36 months
Module 4 – Non-Clinical Study	Tabular summary of any variation notified, accepted or pending
Module 5 – Clinical Study	Copy of current API and FPP specification and test method
Samples	Samples of actual product

**** Product quality review includes:***

- Review of starting and primary packaging material of FPP (specifically from new source)
- Tabulated review of QC and IPQC results
- Review of all batches that failed to meet specification
- Review of all critical deviations and related information
- Review of changes carried out process and analytical methods
- Review of results of stability monitoring program
- Review of quality related recalls, returns and complaints
- Review of previous corrective actions
- List of validated analytical and manufacturing procedures, along-with revalidation date
- Summary of sterilization validation for components and equipment, where applicable.
- Conclusion of Annual Product Review
- Commitment letter that the prospective validation will be conducted in future and the protocol.

Table 8. Registration Requirements of Sri Lanka - Module 1 & 2(7)

Section	Pharmaceutical Parenteral	Biological Parenteral
Module 1 Administrative and Prescribing Information		
Application form	To be submitted	To be submitted
CEP	To be submitted if available	-
LOA	To be submitted	-
SmPC	English as per Annex 3	English
PIL	English as per Annex 3	English
PI	English as per Annex 3	English
Module 2 Dossier Overall Summary		
2.3.S.3 Characterisation	Structure, isomerism For chiral drug molecule – specific stereoisomer	Primary and higher order structure Biological activity
2.5.2 Overview of Biopharmaceutics – Includes summary of BA/BE study	Not applicable for parenteral preparation	Not applicable for parenteral preparation
2.7.1 Study of Biopharmaceutic and associated analytical method	Not applicable for parenteral preparation as it involves data related to BA/BE	Not applicable for parenteral preparation as it involves data related to BA/BE
Remaining sections are same for both Biological and pharmaceutical products		
CTD Summaries: Does not includes summary of Module 4,5		

Table 9. Registration Requirements of Sri Lanka - Module 3 (7)

Sections	Pharmaceutical Parenteral	Biological Parenteral
Module 3 - Module		
3.2.1.1.2 Structure	Structural formula Relative and absolute stereochemistry Molecular formula Relative molecular mass	Schematic amino acid sequence Indicating glycosylation or other post transitional modification Relative molecular mass
3.2.1.2.2 Description of Manufacturing Process and Process Controls	Synthetic process include: Weights, Yield ranges, molecular formulae, chemical structures of starting material, intermediates, reagents and drug substance reflecting stereochemistry, identifies operating conditions and solvent	Information on cell bank and cell culture, Harvest, purification and modification reaction including storage condition and shipping condition. Reference ICH Guidelines: Q5A, Q5B, and Q6B
3.2.1.2.3 Control of Materials	Information on quality and control of raw material, starting material, reagents, intermediate and catalyst should be identified.	Control of Source and Starting Materials of Biological Origin Source, history, and generation of the cell substrate Cell banking system, characterisation, and testing
3.2.1.2.4 Controls of Critical Steps and Intermediates	-	Additional: Stability data supporting storage condition should be provided.
3.2.1.2.5 Process Validation and/or Evaluation	Aseptic processing Sterilization method Declaration of use/non-use of material of animal or human origin.	Virus validation – data related to removal or in-activation of virus. Must include: Cell growth kinetics and antibody productivity profiles demonstrated for bioreactor for appropriate timeframe, Removal of media components/additives during purification, Capacity of purification process to remove contaminating virus.
3.2.1.2.6 Manufacturing Process Development	Description and discussion of process, Explain alternate process, Impurity profile, Reprocessing steps External environmental impact statement Refer: ICH Q3A	Additional or deletion of operational parameters. Freeze/thaw development data used to set number of cycles. Refer to ICH Q5E and ICH Q11

3.2.1.2.6 Manufacturing Process Development	Description and discussion of process, Explain alternate process, Impurity profile, Reprocessing steps External environmental impact statement Refer: ICH Q3A	Additional or deletion of operational parameters. Freeze/thaw development data used to set number of cycles. Refer to ICH Q5E and ICH Q11
3.2.1.4.1 Specification of the drug substance	Sterility test, Pyrogen test, BET Microbial limit test - Bacterial limits - Fungal limits Particulate matter	-
3.2.2.2.1 Components of the Drug Product	Drug Substance Excipients	Drug substance

Table 10. Administrative Comparison

Parameters	India (Pharmaceutical Parenteral)(6)	India (Biological Parenteral)(6)	Sri Lanka (Pharmaceutical Parenteral)(7)	Sri Lanka (Biological Parenteral)(7)
Regulatory Authority	CDSCO – Central Drug Standards Control Organization		NMRA – National Medicines Regulatory Authority	
Prequalification GMP inspection	To be carried out before dossier submission		-	-
Application form	Form 40/Form 44	Form 40	To be submitted	
CT/BE	To be submitted if applicable		-	-
Drug sale license	Form 20B/21B	-	-	-
Testing of imported drug product	Form 11		-	-
Manufacturing license	Copy of Form 25/28/26	To be submitted		
Batch release certificate	From National regulatory authority		-	-
Sample	An equivalent of 50 clinical doses or double the quantity required (whichever is more)	-	Conducted with NLT 12 consecutive batches over span of 12months If not so than, NLT 25 consecutive batches over span of 36 months	
Samples testing	Central Drug Laboratory (CDL)		To be conducted	
Registration validity	05 years			
Renewal timeline	06 months prior expiry of the registration			
Application review timeline	06-09 months	-	14 - 28 working days	-
Document submission	SUGAM portal			
Annual Product Report	-		To be submitted for re-registration	-

4. Conclusion

After conducting a comparative study on regulatory requirements for pharmaceutical and biological product registration across various regions including ASEAN and Asia-Pacific specifically for parenteral dosage forms, it's evident that there are variations in the stringency of regulations.

For instance, regions like ASEAN tend to have stringent regulations with thorough documentation and strict adherence to Good Manufacturing Practices (GMP). The Asia-Pacific region also exhibits a high level of stringency in few major countries.

In conclusion, while there are notable differences in regulatory requirements among the studied regions, there is a discernible trend towards harmonization and convergence, driven by globalization, advancements in healthcare technology, and the imperative to ensure patient safety and access to essential medicines.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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