TablE of Contents

[Module 1 Administrative Information 1](#_Toc390848723)

[**Drug Establishment Registration Number** 1](#_Toc390848724)

[**Statement of Commitment** 2](#_Toc390848725)

[US Agent Appointment Letter 3](#_Toc390848726)

[Administrative Page 4](#_Toc390848727)

[ADDRESSES 5](#_Toc390848728)

[Module 2 Quality Overall Summary 1](#_Toc390848729)

[**2.3** **Introduction** 1](#_Toc390848730)

[2.3.S.1 General Information 2](#_Toc390848731)

[2.3.S.2 Manufacture (\*) 3](#_Toc390848732)

[2.3.S.3 Control of Drug Substance 9](#_Toc390848733)

[2.3.S.4 Reference Standards or Materials 12](#_Toc390848734)

[2.3.S.5 Container Closure System 13](#_Toc390848735)

[2.3.S.6 Stability 14](#_Toc390848736)

[Module 3 Quality 1](#_Toc390848737)

[3.2.S.1 General Information 1](#_Toc390848738)

[3.2.S.1.1 Nomenclature 1](#_Toc390848739)

[3.2.S.1.2 Structure 1](#_Toc390848740)

[3.2.S.1.3 General Properties 1](#_Toc390848741)

[3.2.S.2 Manufacture 1](#_Toc390848742)

[3.2.S.2.1 Manufacturer 1](#_Toc390848743)

[3.2.S.2.2 Description of Manufacturing Process and Process Controls 1](#_Toc390848744)

[3.2.S.2.3 Control of Materials (\*) 1](#_Toc390848745)

[3.2.S.2.4 Control of Critical Steps and Intermediates (\*) 1](#_Toc390848748)

[3.2.S.2.5 Process Validation and/or Evaluation (\*) 1](#_Toc390848749)

[3.2.S.2.6 Manufacturing Process Development (\*) 1](#_Toc390848750)

[3.2.S.3 Characterization 1](#_Toc390848751)

[3.2.S.3.1 Elucidation of Structure and other Characteristics 1](#_Toc390848752)

[3.2.S.3.2 Impurities 1](#_Toc390848753)

[3.2.S.4 Control of Drug Substance 1](#_Toc390848754)

[3.2.S.4.1 Specification 1](#_Toc390848755)

[3.2.S.4.2 Analytical Procedures 1](#_Toc390848756)

[3.2.S.4.3 Validation of Analytical Procedures 1](#_Toc390848757)

[3.2.S.4.4 Batch Analysis 1](#_Toc390848758)

[3.2.S.4.5 Justification of Specification 1](#_Toc390848759)

[3.2.S.5 Reference Standard or Materials 1](#_Toc390848760)

[3.2.S.6 Container Closure System 1](#_Toc390848761)

[3.2.S.7 Stability 1](#_Toc390848762)

[3.2.S.7.1 Stability Summary and Conclusions 1](#_Toc390848763)

[3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment 1](#_Toc390848764)

[3.2.S.7.3 Stability Data 1](#_Toc390848765)

[3.2.R.1.S EXECUTED BATCH RECORDS (\*) 1](#_Toc390848766)

**(\*) – INFORMATION IS CONSIDERED CONFIDENTIAL AND IS NOT TO BE DISCLOSED TO THE APPLICANTS.**

**Module 1 Administrative Information**

Table of contents

[Module 1 Administrative Information 1](#_Toc358104500)

[**Drug Establishment Registration Number** 1](#_Toc358104501)

[**Statement of Commitment** 2](#_Toc358104502)

[US Agent Appointment Letter 3](#_Toc358104503)

[Administrative Page 4](#_Toc358104504)

[ADDRESSES 5](#_Toc358104505)

**Drug Establishment Registration Number**

**Module 2 Quality Overall Summary**

Table of contents

[Module 2 Quality Overall Summary 1](#_Toc388256115)

[**2.3** **Introduction** 1](#_Toc388256116)

[2.3.S.1 General Information 2](#_Toc388256117)

[2.3.S.2 Manufacture (\*) 3](#_Toc388256118)

[2.3.S.3 Control of Drug Substance 9](#_Toc388256119)

[2.3.S.4 Reference Standards or Materials 12](#_Toc388256120)

[2.3.S.5 Container Closure System 13](#_Toc388256121)

[2.3.S.6 Stability 14](#_Toc388256122)

**(\*) – INFORMATION IS CONSIDERED CONFIDENTIAL AND IS NOT TO BE DISCLOSED TO THE APPLICANTS.**

1. **Introduction**

**Non-proprietary Name**

Calcitriol

**Proposed Indication**

Used as a calcium regulator and an anti-psoriatic agent.

The proposed active drug substance has a non-proprietary name as Calcitriol. The active drug substance is manufactured at Formosa Laboratories with suitable quality to meet its intended use.