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

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. USDMF Edition: 06 Calcitriol Module 2 QOS

2.3 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.