

January 2025

To Whom It May Concern

PRECIPITATED CALCIUM CARBONATE –

ACTIVE PHARMACEUTICAL INGREDIENTS (API) SUITABILITY STATUS

This letter is to certify that Specialty Minerals Inc., Lifford facility is registered as an API Business under the MHRA Registration API 27886, and FDA Registration 3001854763. The facility complies with cGMP (Q7 – Current Good Manufacturing Practices for Active Pharmaceutical Ingredients Guidance) under the Medicines and Healthcare Product Regulations Agency (MHRA). Our EP/USP Precipitated Calcium Carbonate products Sturcal®, Calopake® and MultiFex® product families, are considered APIs and manufactured from limestone quarried in Derbyshire, UK.

Our Lifford facility is also ISO 9001, ISO14001 and ISO 22000 (Food Safety Management System) certified, which includes Hazard Analysis Critical Control Point (HACCP), under the guidance of Lloyds Register. Sturcal®, Calopake® and MultiFex® product families are also Kosher and Halal certified.

Should you require further information on the status of our products then please do not hesitate to contact the undersigned on +44 121 252 4520 or email at zoe.shackleton@mineralstech.com

Yours sincerely



Zoë Shackleton
Quality Manager