



Specialty Minerals Lifford  
Lifford Lane, Kings Norton,  
Birmingham B30 3JW.  
Tel (44) 0121 252 4500  
Fax (44) 0121 252 4555

---

August 2024

To Whom It May Concern

**PRECIPITATED CALCIUM CARBONATE – GMP AND CHANGES STATEMENT**

I hereby certify that the Precipitated Calcium Carbonate products sold under the trade names Sturcal F, Sturcal L, Sturcal M, Calopake F, Calopake Extra Light, Calopake 5970, Dicom L100, Calofort U and Multifex MM produced by Specialty Minerals at their Lifford Lane, Kings Norton, Birmingham, England plant comply with the following:

- They are manufactured at a facility and to standards which meet the requirements of the ICH Q7 guidelines to Good Manufacturing Practice (GMP) for active substances for medicinal products for both human and veterinary use.
- All employees of Specialty Minerals Lifford receive annual training on the principles of Good Manufacturing Practice.
- All employees of Specialty Minerals Lifford receive regular training on the principles of good hygiene practice.
- We are regularly audited on the principles and requirements of ICH Q7 guidelines to Good Manufacturing Practice by pharmaceutical customers and consultants acting on their behalf. This is to enable them to meet the requirement of European legislation 2004/27/EC which states that the medicinal product manufacturer must show that “API’s are purchased from a manufacturer who is in compliance with the principles and guidelines of Good Manufacturing Practice”.

Please accept this letter as confirmation that Specialty Minerals will inform you of any planned future changes which may affect the integrity or quality of our products prior to any changes being implemented.

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](mailto:zoe.shackleton@mineralstech.com)

Yours sincerely

Zoë Shackleton  
Quality Manager