

Annex III

Conditions for lifting the suspension of the marketing authorisation(s)

Conditions for lifting the suspension of the marketing authorisation(s)

SoliCol D3

For the suspension of SoliCol D3 to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holder(s):

The marketing authorisation holder of SoliCol D3 shall provide evidence that the manufacturing process complies with the requirements of Commission Directive 2003/94/EC laying down the principles and guidelines of Good Manufacturing Practice (GMP) as provided for in Article 8(3) of Directive 2001/83/EC.