

Appendix 2

Example of a risk category assessment of the site depending on level of compliance and inspection frequency

Risk category of the site	GMP compliance rating and related inspection frequency (in months)			
	Acceptable			Unacceptable
	Good	Satisfactory	Basic	
Critical (C)	24	18	12	Determine on a case-by-case basis
High (H)	30	20	15	Determine on a case-by-case basis
Medium (M)	36	24	18	Determine on a case-by-case basis
Low (L)	48	36	24	Determine on a case-by-case basis