

Manual 019

Appendix 1. Flow sheet: When all manufacture occurs at a single authorized site

Site and Role	Process	Release Activities / Arrangements
Production Site A Manufacturing Authorisation Holder	Bulk Product Formulation, Primary and Secondary Packaging	QP Certification and Release (5.2.1 – 5.2.9, 5.2.13, 5.2.14)
Production Site B Manufacturing Authorisation Holder and Potential Marketing Authorisation Holder	Warehousing and Potential Distribution	None (5.2.2, 5.2.10, 5.2.11-5.2.14)
Marketing Company Marketing Authorisation Holder	Distribution	None (5.2.2, 5.2.10, 5.2.11 – 5.2.14)

Appendix 2. Flow sheet: Different stages of manufacture are conducted at different sites.

Site and Role	Process	Release Activities /Arrangements
Production Site A Manufacturing Authorisation Holder	Bulk Product Formulation (and primary packaging)	QP Confirmation (5.2.6, 5.2.7, 5.2.13, 5.2.14)
Production Site B Manufacturing Authorisation Holder	Primary and Secondary Packing	QP Certification and Release (5.2.11, 5.2.13, 5.2.14)
Production Site B or C Manufacturing Authorisation Holder and Potential Marketing Authorisation Holder	Warehousing and Potential Distribution	None (5.2.2, 5.2.10, 5.2.11-5.2.14)
Marketing Company Marketing Authorisation Holder	Distribution	None 5.2.2