



FOR OFFICIAL USE ONLY

Steps of manufacture

It is a requirement for veterinary chemical products that the steps of manufacture are listed for each manufacturing site stated in the application form. For your convenience a copy of the steps of manufacture are listed below.

Please note that any step of manufacture listed for a site should also comply with the [APVMA licence](#), [APVMA issued GMP compliance letter](#) or [overseas documentation](#).

Steps highlighted in green are expected to be covered by at least one manufacturer for all formulation types (with limited exception).

Steps highlighted in yellow are common steps that are often required for many formulation types.

Step of Manufacture	Main manufacturing site	Subcontractor site
Quality assurance (QA) of raw materials	<input type="checkbox"/>	<input type="checkbox"/>
Serum collection	<input type="checkbox"/>	<input type="checkbox"/>
Blood collection	<input type="checkbox"/>	<input type="checkbox"/>
Plasma collection	<input type="checkbox"/>	<input type="checkbox"/>
Colostrum collection	<input type="checkbox"/>	<input type="checkbox"/>
Management and immunisation of donor animals	<input type="checkbox"/>	<input type="checkbox"/>
Bacterial fermentation	<input type="checkbox"/>	<input type="checkbox"/>
Fungal fermentation	<input type="checkbox"/>	<input type="checkbox"/>
Virus cultivation	<input type="checkbox"/>	<input type="checkbox"/>
Chemical synthesis	<input type="checkbox"/>	<input type="checkbox"/>
Formulation including blending	<input type="checkbox"/>	<input type="checkbox"/>
Dry milling	<input type="checkbox"/>	<input type="checkbox"/>
Wet milling	<input type="checkbox"/>	<input type="checkbox"/>
Granulation	<input type="checkbox"/>	<input type="checkbox"/>
Filling	<input type="checkbox"/>	<input type="checkbox"/>

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Step of Manufacture	Main manufacturing site	Subcontractor site
Aseptic filling	<input type="checkbox"/>	<input type="checkbox"/>
Packaging (primary or primary and secondary)	<input type="checkbox"/>	<input type="checkbox"/>
Labelling (primary or primary and secondary)	<input type="checkbox"/>	<input type="checkbox"/>
OR: Secondary packaging only (no primary)	<input type="checkbox"/>	<input type="checkbox"/>
Secondary labelling only (no primary)	<input type="checkbox"/>	<input type="checkbox"/>
Repackaging (primary)	<input type="checkbox"/>	<input type="checkbox"/>
Relabelling (primary)	<input type="checkbox"/>	<input type="checkbox"/>
Strip packaging (primary)	<input type="checkbox"/>	<input type="checkbox"/>
Blister packaging (primary)	<input type="checkbox"/>	<input type="checkbox"/>
Sachet packaging (primary)	<input type="checkbox"/>	<input type="checkbox"/>
Tableting	<input type="checkbox"/>	<input type="checkbox"/>
Tablet coating	<input type="checkbox"/>	<input type="checkbox"/>
Pellet extrusion	<input type="checkbox"/>	<input type="checkbox"/>
Capsule filling from bulk	<input type="checkbox"/>	<input type="checkbox"/>
Aerosol filling from bulk	<input type="checkbox"/>	<input type="checkbox"/>
Freeze-drying	<input type="checkbox"/>	<input type="checkbox"/>
Metal oxidation	<input type="checkbox"/>	<input type="checkbox"/>
Spray-drying	<input type="checkbox"/>	<input type="checkbox"/>
Sterilisation:		
a) Heat	<input type="checkbox"/>	<input type="checkbox"/>
b) Radiation	<input type="checkbox"/>	<input type="checkbox"/>
c) Gas	<input type="checkbox"/>	<input type="checkbox"/>
d) Filtration	<input type="checkbox"/>	<input type="checkbox"/>

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Step of Manufacture	Main manufacturing site	Subcontractor site
e) Chemical	<input type="checkbox"/>	<input type="checkbox"/>
Microbiological reduction treatment:		
a) Heat	<input type="checkbox"/>	<input type="checkbox"/>
b) Radiation	<input type="checkbox"/>	<input type="checkbox"/>
c) Gas	<input type="checkbox"/>	<input type="checkbox"/>
d) Filtration	<input type="checkbox"/>	<input type="checkbox"/>
e) Chemical	<input type="checkbox"/>	<input type="checkbox"/>
Analysis and testing:		
Physical	<input type="checkbox"/>	<input type="checkbox"/>
Chemical	<input type="checkbox"/>	<input type="checkbox"/>
Endotoxin testing	<input type="checkbox"/>	<input type="checkbox"/>
Antibiotic assay	<input type="checkbox"/>	<input type="checkbox"/>
Microbiological	<input type="checkbox"/>	<input type="checkbox"/>
Sterility test	<input type="checkbox"/>	<input type="checkbox"/>
Serological	<input type="checkbox"/>	<input type="checkbox"/>
Immunological	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>	<input type="checkbox"/>
Storage (in process)	<input type="checkbox"/>	<input type="checkbox"/>
Release for supply (final quality release of finished product)	<input type="checkbox"/>	<input type="checkbox"/>
Other type of manufacturing [please specify]	<input type="checkbox"/>	<input type="checkbox"/>