Australian Government
Department of Health
Therapeutic Goods Administration

GMP clearance code tables guidance

Manufacturing steps

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TGA Health Safety Regulation

Contents

About this guidance

This guidance helps you navigate the TGA Code Tables to interpret manufacturing steps used to obtain evidence of Good Manufacturing Practice (GMP) via the GMP clearance desktop pathway.

This guidance aims to:

- provide a list of common manufacturing steps that validate within the various TGA product registration/listing systems
- provide an interpretation for the common manufacturing steps from a GMP clearance perspective
- provide clarification around common manufacturing step group terms and the individual manufacturing steps associated with each group which validate in the product registration/listing systems
- reduce validation errors experienced within the product registration and listing systems

Use this guidance in conjunction with:

- GMP clearance guidance
- Clearance Application Assistance Tool (CAAT)
- Prescription medicines guidance
- Over-the-counter (OTC) medicines guidance
- Registered complementary medicine guidance
- Listed medicine guidance

This guidance is **not** intended for:

- clarification of dosage forms or their validation in registration/listing systems
- clarification of manufacturing steps or dosage forms for GMP licences for Australian manufacturing sites
- **biologicals, human blood and blood components and Haematopoietic Progenitor Cells (HPCs)**. Australia has its own manufacturing standard for these product types. However, where the manufacturing site performs only sterilisation of these product types, this guidance may be used.

For more information, refer to Australian manufacturing licences and overseas GMP certification guidance.

GMP clearance pathways

GMP evidence is required for manufacture of a **medicine** or an **Active Pharmaceutical Ingredient (API)** used in a medicine, intended for supply in Australia via the GMP clearance desktop pathway.

GMP clearances are obtained via the:

- Mutual Recognition Agreement (MRA) pathway
- Compliance Verification (CV) pathway

The pathway depends on the location of the manufacturing site and GMP evidence available to support the activities performed at the site.

GMP compliance

All steps of manufacture of registered and listed products are required to be **GMP compliant** unless they are exempt.

However, not all manufacturing steps in a process are necessarily required in a GMP clearance unless the product is to be registered or listed **and** the manufacturing step recorded on the Australian Register of Therapeutic Goods (ARTG).

Evidence to demonstrate GMP compliance for product registration purposes, may be provided by a:

- GMP licence – issued to Australian manufacturers for sites in Australia that manufacture therapeutic goods (excluding medical devices), where either the manufacturer or the goods are not exempt.
- GMP clearance – issued to Australian sponsors where relevant overseas regulator evidence is available for the manufacturing site to a GMP code equivalent to the TGA.

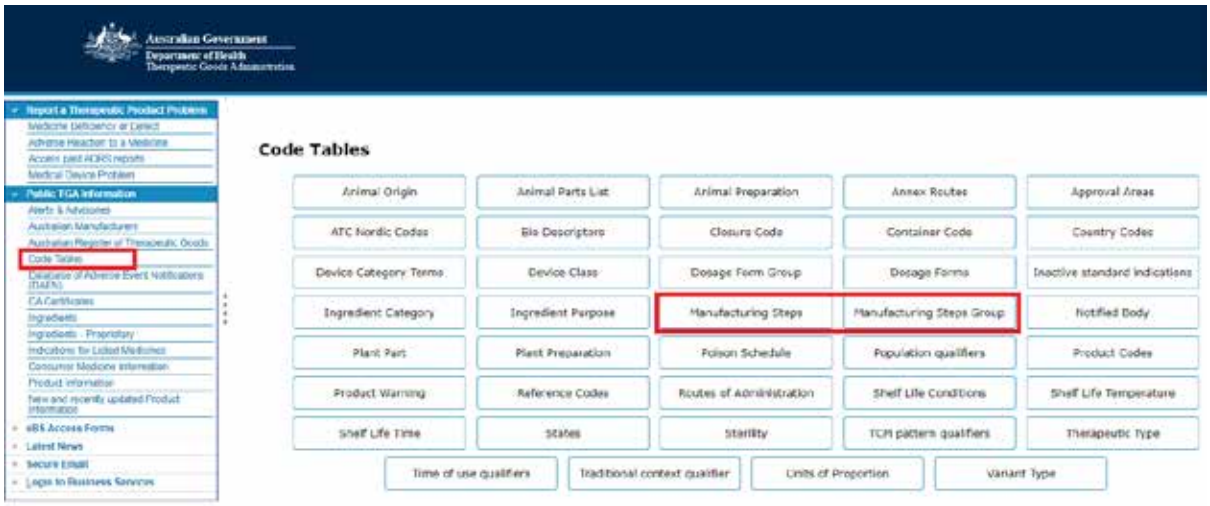
A GMP licence or clearance may cover **one or all** of the necessary manufacturing steps associated with **one or more** product registrations/listings on the ARTG. It is your responsibility to identify the relevant manufacturing steps for the relevant product registration/listing in order to avoid delays to registration/listing and the payment of additional fees.

Manufacturing steps

When applying to register, list or vary a product on the ARTG, you are required to identify the **manufacturing steps that validate** in the various TGA product registration/listing systems.

When preparing a GMP clearance or certification application it is your responsibility to select the manufacturing steps associated with the requirements of the product registration/listing.

A list of the current manufacturing steps and manufacturing steps groups are found within the Code Tables link under the 'Public TGA Information' tab in the TGA Business Services (TBS) page.



Regulatory system validation

The following sections outline the most commonly used manufacturing steps and codes that validate in the respective systems for the various product types:

- Prescription medicines
  - Chemical medicines
  - Biological medicines
- Over the Counter (OTC) and registered complementary medicines
- Listed and assessed listed medicines
- Medicines for Export Only

For clarification on the interpretation of a manufacturing step, or what the manufacturing step covers contact the relevant product regulatory area in the first instance.

Not all manufacturing steps will validate within all product registration/listing systems.

Prescription medicines

The following tables of manufacturing steps and the respective codes are the most commonly used terms associated with the registration or variation of registration of a prescription medicine that is either a **chemical** or **biological** medicine.

These steps and codes will validate within the prescription medicines system. It is not necessary to have all the below steps in a GMP clearance or licence in order to support a product registration or variation of registration. The steps should reflect the product specific steps of manufacture that require listing on the ARTG register.

For more information, refer to evidence of GMP for prescription medicines.

To confirm which steps are required for the registration of your specific product, contact the relevant prescription medicines evaluation team.

Chemical medicines

The following table details the most common manufacturing steps for chemical medicines required for listing on the ARTG, which validate in the prescription medicines system. The sterility of the product as well as the dosage form may affect what manufacturing steps should be covered by a GMP clearance to support the registration or variation of registration of a product as not all steps may be applicable.

Common manufacturing steps and codes for chemical medicines

Manufacturing step	Code
Active material manufacture	ACT
Manufacture of dosage form	MDD
Manufacture of diluent	MOD
Packaging and labelling	MXP
Secondary packaging	MXS
Testing chemical and physical	TCC
Testing microbial	TMM
Testing Sterility	TESST
Testing biological	TBIO
Storage	STOR
Release for supply	MXR
Sterilisation	STER

Interpretation of common manufacturing steps for chemical medicines

The following table provides interpretation of the common manufacturing steps across the ARTG, licences and clearances that validate in the prescription medicine registration system.

Interpretation of manufacturing steps for chemical medicines

Manufacturing step	Interpretation
Active material manufacture	Includes any or all processing steps in the manufacture of an API or drug substance. Includes the following steps for each API type: • non-sterile API: manufacture of the API, packaging/labelling, chemical/physical and microbiological testing. • sterile API: manufacture of the API, packaging/labelling, chemical/physical, microbiological and sterility testing. • biological API: manufacture of the API (cell banking (MCB/WCB manufacture, maintenance and storage), cell culture, harvest and purification, manufacture of intermediates, principle manufacture/synthesis of drug substance), chemical/physical, microbiological and biological testing.

Manufacturing step	Interpretation
Manufacture of dosage form	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.
Manufacture of diluent	Includes all processing steps in the manufacture of a sterile or non-sterile liquid intended for use in reconstitution/dilution of a drug product in preparation for administration (e.g. water for injections). For a GMP clearance application, this activity would be assessed as the manufacture of a sterile liquid injection.
Packaging and labelling	Refers to placing and sealing of the medicinal product within the finished product packaging material which is in direct contact with the product as well as labelling operations.
Secondary packaging	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material.
Testing chemical and physical	Tests which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.
Testing microbial	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.
Testing sterility	Test to confirm substances or preparations are sterile.
Testing biological	Biological, including biochemical or immunochemical, methods are described for the determination of potency or other specific properties of certain substances and preparations where these properties cannot be adequately determined by chemical or physical means.
Storage	The storage of raw materials, (including packaging materials), intermediate materials, bulk products and packed materials prior to release for supply. This storage authorisation is required for storage activities that are performed in facilities which do not automatically include storage in their manufacturing operations. For GMP clearance, this step refers to storage of product prior to release for supply.

Manufacturing step	Interpretation
Release for supply	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. For more information refer to Release for supply of medicines in Australia.
Sterilisation	The process of making something free from viable micro-organisms. Sterilisation is achieved using methods described in the current default standards, and/or those contained in the current Marketing Authorisation.

Biological medicines

The tables below detail the most common manufacturing steps which validate in the prescription medicines system for biological medicines, for both API and finished product manufacture, required for listing on the ARTG. The sterility of the product, dosage form, as well as manufacturing process will effect what manufacturing steps should be covered by a GMP clearance to support the registration or variation of registration of a product as not all steps may be applicable.

Manufacturing steps and codes for biological medicine APIs

Manufacturing step	Code
Manufacture and/or maintenance of master cell bank and/or working cell bank	MWCB
Active material manufacture	ACT
Testing chemical and physical	TCC
Testing microbial	TMM
Testing biological	TBIO
Testing sterility	TESST

Manufacturing steps and codes for biological medicine finished products

Manufacturing step	Code
Manufacture of dosage form	MDD
Manufacture of diluent	MOD
Packaging and labelling	MXP

Manufacturing step	Code
Secondary packaging	MXS
Testing chemical and physical	TCC
Testing microbial	TMM
Testing biological	TBIO
Testing sterility	TESST
Storage	STOR
Release for supply	MXR
Sterilisation	STER

Interpretation of common manufacturing steps for biological medicines

The following table provides interpretation of the common manufacturing steps across the ARTG, licences and clearances that validate in the prescription medicine registration system.

Interpretation of manufacturing steps for biological medicines

Manufacturing step	Interpretation
Active material manufacture	Includes any or all processing steps in the manufacture of an API or drug substance. Includes the following steps for each API type: • non-sterile API: manufacture of the API, packaging/labelling, chemical/physical and microbiological testing. • sterile API: manufacture of the API, packaging/labelling, chemical/physical, microbiological and sterility testing. • biological API: manufacture of the API (cell banking (MCB/WCB manufacture, maintenance and storage), cell culture, harvest and purification, manufacture of intermediates, principle manufacture/synthesis of drug substance), chemical/physical, microbiological and biological testing.
Manufacture and/or maintenance of master cell bank and/or working cell bank	Manufacture, maintenance and storage of a master or working cell bank. This should be selected for sites that only performs these activities.
Manufacture of dosage form	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.

Manufacturing step	Interpretation
Manufacture of diluent	Includes all processing steps in the manufacture of a sterile or non-sterile liquid intended for use in reconstitution/dilution of a drug product in preparation for administration (e.g. water for injections). For a GMP clearance application, this activity would be assessed as the manufacture of a sterile liquid injection.
Packaging and labelling	Refers to placing and sealing of the medicinal product within the finished product packaging material which is in direct contact with the product as well as labelling operations.
Secondary packaging	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material.
Testing chemical and physical	Tests which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.
Testing microbial	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.
Testing biological	Biological, including biochemical or immunochemical, methods are described for the determination of potency or other specific properties of certain substances and preparations where these properties cannot be adequately determined by chemical or physical means.
Testing sterility	Test to confirm substances or preparations are sterile.
Storage	The storage of raw materials, (including packaging materials), intermediate materials, bulk products and packed materials prior to release for supply. This storage authorisation is required for storage activities that are performed in facilities which do not automatically include storage in their manufacturing operations. For GMP clearance, this step refers to storage of product prior to release for supply.
Release for supply	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. For more information refer to Release for supply of medicines in Australia.
Sterilisation	The process of making something free from viable micro-organisms. Sterilisation is achieved using methods described in the current default standards, and/or those contained in the current Marketing Authorisation.

OTC medicines and registered complementary medicines

The following list of manufacturing steps and the respective codes are associated with the registration, listing and variation related to registered OTC and registered complementary medicines. Applications for these types of medicines are made through the non-prescription medicines application system. The steps and codes below are those, which will validate within the non-prescription medicines application system. It is not necessary to have all the below steps in a GMP clearance or certificate in order to support a product registration/listing or variation.

For more information refer to Australian regulatory guidelines for OTC medicines (ARGOM) and the Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines.

Manufacturing steps and codes for OTC and registered complementary medicines

Manufacturing step	Code
API - Active pre-mix#	APIFPPM
Manufacture of dosage form*	MDD
Packaging and labelling*	MXP
Secondary packaging	MXS
Sterilisation^	STER
Testing chemical and physical*	TCC
Testing microbial*	TMM
Release for supply*	MXR

Step required when the step as defined in the table below is undertaken

* Steps required in an OTC medicine application and covered by appropriate GMP evidence

^ Steps required for sterile products only

Interpretation of common manufacturing steps for OTC and registered complementary medicines

The following table provides interpretation of the common manufacturing steps across the ARTG, licences and clearances that validate in the non-prescription medicine application system.

Interpretation of manufacturing steps for OTC and registered complementary medicines

Manufacturing step	Interpretation
API - Active pre-mix	The process of blending or mixing an API (active pharmaceutical ingredient) with one or more excipients to form an API mix. Typical examples are the addition of an antioxidant to an API, or the introduction of an API into a matrix. The manufacture of an API mix is considered to be the first step of the manufacture of a finished product unless required for stability or safety reasons.
Manufacture of dosage form	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.
Packaging and labelling	Refers to placing and sealing of the medicinal product within the finished product packaging material which is in direct contact with the product as well as labelling operations.
Secondary packaging	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material
Sterilisation	The process of making something free from viable micro-organisms. Sterilisation is achieved using methods described in the current default standards, and/or those contained in the current Marketing Authorisation.
Testing chemical and physical	Tests which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.
Testing microbial	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.
Release for supply	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. For more information refer to Release for supply of medicines in Australia.

Listed and assessed listed medicines

The following list of manufacturing steps and the respective codes are associated with the product listing and variation related to listed and assessed listed medicines. Complementary medicines may be either listed or registered, depending on their ingredients and the claims made. Most complementary medicines are listed, however it is important to be certain before proceeding with your GMP clearance or certification application. For further guidance, refer to Pathways for complementary medicine products.

The steps and codes below are those which will validate within the listed and assessed listed medicines system. It is not necessary to have all the below steps in a GMP clearance or certificate in order to support a product registration/listing or variation.

For more information for listed and assessed listed medicines, refer to the Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines.

Manufacturing steps and codes for listed and assessed listed medicines

Manufacturing step	Code
Manufacture of dosage form*	MDD
Packaging and labelling*	MXP
Secondary packaging#	MXS
Testing chemical and physical*	TCC
Testing microbial*	TMM
Release for supply*	MXR

* Steps required in a listed or assessed listed medicine application and covered by appropriate GMP evidence

Secondary packaging may also require a GMP clearance if the step of manufacture is undertaken for the product.

Interpretation of common manufacturing steps for listed and assessed listed medicines

The following table provides interpretation of the common manufacturing steps across the ARTG, licences and clearances that validate in the listed and assessed listed medicine application system.

Interpretation of manufacturing steps for listed and assessed listed medicines

Manufacturing step	Interpretation
Manufacture of dosage form	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.

Manufacturing step	Interpretation
Packaging and labelling	Refers to placing and sealing of the medicinal product within the finished product packaging material which is in direct contact with the product as well as labelling operations.
Secondary packaging	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material.
Testing chemical and physical	Tests which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.
Testing microbial	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.
Release for supply	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. For more information refer to Release for supply of medicines in Australia.

Medicines for Export Only

Export Only medicines are required to be listed on the ARTG before export.

The following list of manufacturing steps and the respective codes are associated with the product listing and variation related to an Export Only medicine. The steps and codes below are those, which will validate within the Export Only medicines system. It is not necessary to have all the below steps in a GMP clearance or certificate in order to support a product listing or variation for an Export Only medicine. It is dependent on the specific product, for example the sterility and dosage form.

For more information refer to Exporting therapeutic goods.

Manufacturing steps and codes for Export Only medicines

Manufacturing step	Code
Active material manufacture	ACT
Manufacture of dosage form	MDD
Packaging and labelling	MXP

Manufacturing step	Code
Secondary packaging	MXS
Sterilisation	STER
Testing chemical and physical	TCC
Testing microbial	TMM
Testing biological	TBIO
Release for supply	MXR

Interpretation of common manufacturing steps for Export Only medicines

The following table provides interpretation of the common manufacturing steps across the ARTG, licences and clearances that validate in the registration/listing system.

Interpretation of common manufacturing steps for Export Only medicines

Manufacturing step	Interpretation
Active material manufacture	Includes any or all processing steps in the manufacture of an API or drug substance. Includes the following steps for each API type: • non-sterile API: manufacture of the API, packaging/labelling, chemical/physical and microbiological testing. • sterile API: manufacture of the API, packaging/labelling, chemical/physical, microbiological and sterility testing. • biological API: manufacture of the API (cell banking (MCB/WCB manufacture, maintenance and storage), cell culture, harvest and purification, manufacture of intermediates, principle manufacture/synthesis of drug substance), chemical/physical, microbiological and biological testing.
Manufacture of dosage form	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.
Packaging and labelling	Refers to placing and sealing of the medicinal product within the finished product packaging material which is in direct contact with the product as well as labelling operations.

Manufacturing step	Interpretation
Secondary packaging	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material.
Sterilisation	The process of making something free from viable micro-organisms. Sterilisation is achieved using methods described in the current default standards, and/or those contained in the current Marketing Authorisation.
Testing chemical and physical	Tests which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.
Testing microbial	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.
Testing biological	Biological, including biochemical or immunochemical, methods are described for the determination of potency or other specific properties of certain substances and preparations where these properties cannot be adequately determined by chemical or physical means.
Release for supply	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. For more information refer to Release for supply of medicines in Australia.

Biologicals, human blood and blood components and Haematopoietic Progenitor Cells

As detailed above, this guidance **is not intended** for the product registration of biologicals. The biologicals regulatory area may be able to assist applicants in the identification of what manufacturing steps are required for registration.

Manufacturing step groups

Manufacturing step groups (group terms) are used to collate individual manufacturing terms together in relation to a process to assist in reducing the number of steps a sponsor needs to select as part of their application.

Group terms themselves do not validate in the registration/listing systems. The individual manufacturing steps within the group term are the components that validate for a product registration/listing or variation.

This means that if you have a product which you want to register, list or vary with a particular area of the TGA, you need to make sure that the individual steps within a particular group term validate in that respective system before picking the group term.

Some group terms contain other groups within them. The following sections include the most commonly used group terms within clearance applications. The group terms contain the various commonly used individual steps which validate in a number of registration/listing systems.

For more information regarding the individual steps that validate within the various registration and listing systems refer to the respective product types.

There are other individual steps that are nominated under these group terms that do not validate in the registration/listing systems. These are not listed below.

Finished Product Manufacture (FMANF)

The manufacturing group term Finished Product Manufacture (FMANF) includes all manufacturing steps of a non-sterile medicinal product including manufacture of dosage form, primary and secondary packaging, chemical, physical and microbiological testing and release for supply.

Common individual manufacturing steps and codes within FMANF that validate for a product registration/listing

Manufacturing step	Code
Release for supply	MXR
Secondary packaging	MXS
Storage	STOR
Manufacture of Dosage Form Group	**MDFG**
Manufacture of dosage form	MDD
Manufacture of human serum albumin*	MHSA
Packaging and Labelling Group	**MXPG**
Packaging and labelling	MXP

Manufacturing step	Code
Secondary packaging	MXS
Testing: Chemical and Physical Drug Testing	**TCCG**
Testing chemical and physical	TCC
Testing: Microbial Testing Group	**TMMG**
Testing microbial	TMM

*only relates to products which contain human serum albumin

Derivatives of FMANF

There are a number of other group terms that are derivatives of the group term Finished Product Manufacture (FMANF).

The intent of these group terms is equivalent to FMANF, excluding a specific step/steps of manufacture which is referenced in the group term title.

Derivatives of FMANF

Manufacturing Group	Code
Full Product Manufacture - excluding chemistry*	FMPEC
Full Product Manufacture - excluding microbiological testing	FMPEM
Full Product Manufacture - excluding testing^	FMPET
Full Product Manufacture - excluding packaging and labelling	FMPPL
Full Product Manufacture - excluding packaging and labelling and release for supply	FMPPLR
Finished Product Manufacturer - excluding release for supply	FPMG
Full Product Manufacture - excluding secondary packaging and labelling	FPMSPL

* *Excluding chemistry*, excludes chemical and physical testing

^ *Excluding testing*, excludes all testing types

Example: Full Product Manufacture - excluding packaging and labelling and release for supply (FMPPLR).

The group term Full Product Manufacture - excluding packaging and labelling and release for supply (FMPPLR) includes all manufacturing steps of a non-sterile medicinal product including manufacture of dosage form, chemical, physical and microbiological testing.

Common individual manufacturing steps and codes within the group term FMPPLR that validate for a product registration/listing or variation

Manufacturing step	Code
Storage	STOR
Manufacture of Dosage Form Group	**MDFG**
Manufacture of dosage form	MDD
Manufacture of human serum albumin	MHSA
Testing: Chemical and Physical Drug Testing	**TCCG**
Testing chemical and physical	TCC
Testing: Microbial Testing Group	**TMMG**
Testing microbial	TMM

Sterile Finished Product Manufacture (SFMANF)

The group term Sterile Finished Product Manufacture (SFMANF) includes all manufacturing steps of a sterile medicinal product including manufacture of dosage form, primary and secondary packaging, chemical, physical and microbiological testing and release for supply. In terms of GMP requirement, microbiological testing also includes sterility testing for sterile products.

Common individual manufacturing steps and codes within the group term SFMANF that validate for a product registration/listing or variation

Manufacturing step	Code
Release for supply	MXR
Secondary packaging	MXS
Sterilisation	STER
Manufacture of Dosage Form Group	**MDFG**
Manufacture of dosage form	MDD
Manufacture of human serum albumin	MHSA
Packaging and Labelling Group	**MXPG**
Packaging and labelling	MXP
Secondary packaging	MXS

Manufacturing step	Code
Testing: Chemical and Physical Drug Testing	**TCCG**
Testing chemical and physical	TCC
Testing: Microbial Testing Group	TMMG
Testing microbial	TMM

Derivatives of SFMANF

A number of other group terms are derivatives of the group term SFMANF. The intent of these group terms is equivalent to Sterile Finished Product Manufacture excluding or in some cases including a specific step/steps of manufacture which is referenced in the group term title.

Derivatives of SFMANF

Manufacturing Group	Code
Sterile Finished Product Manufacture - excluding testing	SFMANFET
Sterile Finished Product Manufacturer - excluding release for supply	SFPM
Sterile Finished Product Manufacture (including parametric release)	SFPMPR

Example: Sterile Finished Product Manufacture - excluding testing (SFMANFET)

The group term Sterile Finished Product Manufacture - excluding testing (SFMANFET) includes all manufacturing steps of a sterile medicinal product including manufacture of dosage form, primary & secondary packaging and release for supply.

Common individual manufacturing steps and codes within the group term SFMANFET that validate for a product registration/listing or variation

Manufacturing step	Code
Release for supply	MXR
Secondary packaging	MXS
Sterilisation	STER
Manufacture of Dosage Form Group	**MDFG**
Manufacture of dosage form	MDD
Manufacture of human serum albumin	MHSA

Manufacturing step	Code
Packaging and Labelling Group	**MXPG**
Packaging and labelling	MXP
Secondary packaging	MXS

Testing (TS)

The group term TS refers to testing conducted to ensure the products comply with their approved specifications and includes chemical, physical and microbiological testing. In terms of GMP requirement, microbiological testing also includes sterility testing for sterile API/products.

Common individual manufacturing steps and codes within the group Testing (TS) that validate for a product registration/listing or variation

Manufacturing step	Code
Testing: Chemical and Physical Drug Testing	**TCCG**
Testing chemical and physical	TCC
Testing: Microbial Testing Group	**TMMG**
Testing microbial	TMM

Interpretation of common manufacturing steps

The following table provides interpretation of some of the common manufacturing steps across the ARTG, licences and clearances. It also indicates which registration/listing systems the manufacturing steps validate.

Interpretation of manufacturing steps and which systems they validate

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Active material manufacture (ACT)	Includes any or all processing steps in the manufacture of an API or drug substance. Includes the following steps for each API type: • non-sterile API: manufacture of the API, packaging/labelling, chemical/physical and microbiological testing. • sterile API: manufacture of the API, packaging/labelling, chemical/physical, microbiological and sterility testing. • biological API: manufacture of the API (cell banking (MCB/WCB manufacture, maintenance and storage), cell culture, harvest and purification, manufacture of intermediates, principle manufacture/synthesis of drug substance), chemical/physical, microbiological and biological testing.	Prescription medicines Export Only medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines
API - Active pre-mix (APIFPPM)	The process of blending or mixing an API (active pharmaceutical ingredient) with one or more excipients to form an API mix.	OTC or registered complementary medicines Biologicals and human blood components *	Prescription medicines Export Only medicines Listed or assessed listed medicines

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Manufacture of dosage form (MDD)	Includes any or all processing steps in the manufacture of a dosage form. Does not include packaging, labelling, testing or release for supply. For sterile products, this term includes primary packaging.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Biologicals and human blood components *	None
Manufacture and/or maintenance of master cell bank and/or working cell bank (MWCB)	Manufacture, maintenance and storage of a master or working cell bank. This should be selected for sites that only performs these activities.	Prescription medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Sterilisation (STER)	The process of making something free from viable micro-organisms. Sterilisation is achieved using methods described in the current default standards, and/or those contained in the current Marketing Authorisation.	OTC or registered complementary medicines Export Only medicines Prescription medicines Biologicals and human blood components *	Listed or assessed listed medicines
Manufacture of diluent (MOD)	Includes all processing steps in the manufacture of a sterile or non-sterile liquid intended for use in reconstitution/dilution of a drug product in preparation for administration (e.g. water for injections). This step is required for prescription medicine listing. In terms of GMP requirement, this step will be assessed similar to a sterile manufacture of liquid injection.	Prescription medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Manufacturers information system

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Storage (STOR)	The storage of raw materials, (including packaging materials), intermediate materials, bulk products and packed materials prior to release for supply. This storage authorisation is required for storage activities that are performed in facilities, which do not automatically include storage in their manufacturing operations. For GMP clearance, this step refers to storage of product prior to release for supply.	Prescription medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines
Packaging and labelling (MXP)	Refers to placing and sealing of the medicinal product within the finished product packaging material, which is in direct contact with the product as well as labelling operations.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Biologicals and human blood components *	None

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Release for supply (MXR)	Refers to batch certification by an Authorised Person (AP) where each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of the product. Please refer to Release for supply of medicines in Australia for more information.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Biologicals and human blood components *	None
Secondary packaging (MXS)	Refers to the placing of the medicinal product, which is already sealed within its primary packaging material within an outer packaging material.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Biologicals and human blood components *	None

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Testing biological (TBIO)	Biological, including biochemical or immunochemical, methods are described for the determination of potency or other specific properties of certain substances and preparations where these properties cannot be adequately determined by chemical or physical means.	Prescription medicines Export Only medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines
Testing chemical and physical (TCC)	Tests, which identify, quantify or characterise chemical and physical properties of a substance or finished dosage form. A chemical test is a qualitative or quantitative procedure designed to identify, quantify, or characterise a chemical compound or chemical group.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines Biologicals and human blood components *	None

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Testing Endotoxin (TEN)	An assay used to detect the presence and concentration of bacterial endotoxins in drugs and biological products.	Biologicals and human blood components *	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines
Testing sterility (TESST)	Test to confirm substances or preparations are sterile.	Prescription medicines Biologicals and human blood components *	OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines

Manufacturing step (Code)	Interpretation	Validates for	Does not validate for
Testing microbial (TMM)	Test to determine the presence or absence of specific objectionable organisms in a product. For sterile products, testing microbial includes sterility testing.	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export only medicines Biologicals and human blood components *	None
Testing Mycoplasma (TMY)	Test to confirm the presence or absence of mycoplasma.	Biologicals and human blood components *	Prescription medicines OTC or registered complementary medicines Listed or assessed listed medicines Export Only medicines

* The validation of manufacturing steps in the biologicals and human blood components registration system are included for information only. This guidance is not intended for these types of products.

Troubleshooting and common issues

A list of common issues that you may experience during product registration and listing, and the corresponding suggested solutions are described in the table below.

Issues and solutions

Issue	Suggested solution
Error message – The clearance entered with clearance ID MI-XXXX-CL-XXXXX-X is not valid for the Manufacturing Step(s): XXXX	Confirm if the step is covered on the GMP clearance. If the step is not listed, you will need to submit a variation application for your GMP clearance to request that this step be added and provide evidence to support the addition of the step. If another site is conducting the manufacturing step then you should list them within the product application and include the GMP clearance details for the site.
Error message – The clearance entered with clearance ID MI-XXXX-CL-XXXXX-X is not valid for the dosage form XXXX	Confirm if the dosage form is covered on the GMP clearance. If the dosage form is not listed, you will need to submit a variation application for your GMP clearance to request that this step be added and provide evidence to support the addition of the specific dosage form.
Error message – The GMP clearance does not cover the required dosage form	Confirm if the dosage form matches the dosage form for your specific product. If the dosage form does not match, you will need to submit a variation application for your GMP clearance to request that this step be added and provide evidence to support the addition of the specific dosage form. If a group term has been selected, ensure that the single dosage form is included within the group term selected.
Error message – The manufacturer details for the requested clearance is confidential	Confirm if the sponsor ID listed in the GMP clearance is the same as the sponsor ID being used in the product listing or registration application. In addition, confirm if the GMP clearance tracking number has been entered correctly. If these details do not match, and you do not hold a GMP clearance for the same sponsor ID as being used in the listing or registration application, you will need to submit an application for a GMP clearance for the relevant site.
Error message – Company name does not have a GMP reference (i.e. no licence/clearance). You must update data within 'Manufacturers'	Confirm if a valid GMP clearance exists for the site of manufacture. Enter current GMP clearance tracking number into the application form against the relevant manufacturer entry. If you do not hold a GMP clearance for the manufacturer, you will need to submit an application for a GMP clearance for the relevant site.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Manufacturing Quality Branch	July 2020

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Reference/Publication #