captured on the FM-169 and verified by a second person.

- Finished product, that is serialised and aggregated, requires that once the sample(s) is removed, the batch is re-aggregated. Sampling serialised finished product, after release, should only occur in exceptional circumstances.
- The sampler may then return the form to either a member of the production department or to warehouse staff.
- The material is then stock adjusted production/warehouse personnel trained in Navision Item Journals (refer to SOP-166). Sign FM-169 once the Item Journal is complete and pass FM-169 onto a member of staff authorised to verify the Item Journal entry.
- FM-169 is given to a member of warehouse staff who then completes ELB-032 and files FM-169.

11 BATCH & LOT IDENTIFICATION NUMBERS

11.1 Lot Numbers

11.1.1 General

The primary identification number for material at Pharmaxis is the Lot Number.
Lot numbers issued at Pharmaxis can have 3 formats:

- IGN – Inwards Goods Number
- Manufactured Lot Number
- In-house Label Number

11.1.2 IGN Format

Raw, ancillary and packaging materials receive an IGN (Inwards Goods Number) upon receipt at Pharmaxis.

SOP-201 outlines the procedure for issuing an IGN. The Lot number is based on the following format:

IGNYY-XXX

IGN = Inwards Goods Number
YY – year of manufacture
XXX – sequential numbering

11.1.3 Manufactured Lot Number Format

This number is generated automatically for Intermediate materials, Work-In-Progress and Final products.

The Lot number is generated automatically on initiation/release of a Production Order (SOP-163) in Navision. Production orders are initiated and released prior to carrying out any production of a batch – spray drying, encapsulating, blending and packaging.

The Navision Lot number for **Aridol and Bronchitol Blisters** is based on the following format:

MYY-XXX	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering

Example: **M12-001**

The Navision Lot number for **Aridol Finished Product** is based on the following format:

MYY-XXXCC	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering – same as blister
CC	Country Code
Example: **M12-001AU**	

The Navision Lot number for **Bronchitol Finished Product** is based on the following format:

MYY-XXXBCC	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering – same as blister
B	Bronchitol
CC	Country Code
Example: **M12-001BAU**	

The Navision Lot number for **Aridol Demonstration/Training Pack** is based on the following format:

MYY-XXXDACC	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering – same as blister
D	Demonstration/Training Pack
A	Aridol
CC	Country Code
Example: **M12-001DAAU**	

The Navision Lot number for **Bronchitol Demonstration/Training Pack** is based on the following format:

MYY-XXXDBCC	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering – same as blister
D	Demonstration/Training Pack
B	Bronchitol
CC	Country Code
Example: **M12-001DBAU**	

The Navision Lot number for **Bronchitol Initiation Sample or 7/14 Day and 4 weeks Bronchitol Sample Finished Product** is based on the following format:

MYY-XXXZCC-S	
M	Manufactured

YY	Year of manufacture
XXX	Sequential numbering – same as blister
Z	I - Initiation
	F - 7 day pack
	B - 14 day pack
	G – 4 weeks pack
CC	Country Code
S	Sample
***Example:* M12-001IDE-S or M12-001FDE-S**	

The Navision Lot number for **Bronchitol Initiation Finished Product or 7/14 Day and 4 weeks Bronchitol Finished Product Pack** is based on the following format:

MYY-XXXZCC	
M	Manufactured
YY	Year of manufacture
XXX	Sequential numbering – same as blister
Z	I - Initiation
	F - 7 day pack
	B - 14 day pack
	G – 4 weeks pack
CC	Country code
***Example:* M12-001FAU**	

The Production Order-Job card outlines the lot numbers they are forwarded to QA who then issue the Processing Instruction with the corresponding number.

The QA department must issue all Processing Instructions. The QA department will ensure PIs and associated forms record the issued lot number (entry initialled and dated) on each page. Issued copies of PIs and associated forms are registered by the QA department in *ELB-091 Issuance of Processing Instructions Log.* On entering information into ELB-091for product that is being packaged into a Finished Product batch, the QA Officer issuing batch paperwork will ensure the Batch number has not been previously issued. If it is a duplicate batch a rework is required as per SOP-211.

11.1.4 In-house Label Lot Number Format

This number is generated by Production from ELB-020 In-house Printed Labels Batch Number Log for any labels printed in house.

The lot number is recorded on the Label reconciliation form (FM-097) and also on the "APPROVED" label, CL-001 applied by QA on release of the label batch.

The lot number is based on the following format:

LYYXXX

L = Label
YY – year of manufacture
XXX – sequential numbering

11.2 Batch Numbers

11.2.1 General Information

The batch number is recorded on Navision as the Vendor Lot No. This is a default field name but is referred to and recorded as the batch number on all other documentation.

The secondary identification number employed at Pharmaxis is the Batch Number.

Batch numbers are issued in the following circumstances:

- For raw, ancillary and packaging materials when initially received - the batch number is the vendor Lot number.
- Intermediate products/WIP – no batch number is applied. Only the Lot number is required
- For reworked material the batch number is specific. The details are outlined in SOP-211 – Rework Procedure at Pharmaxis.

For final product the batch number can be either of the following:

- The batch number is as per the blister batch number and in some cases a suffix is included. Refer to section below.
- For randomised batches – in certain blinded clinical trials a kit number is assigned to the batches. The kit number appears on the blister, the carton label and the outer kit label. Randomised kit numbers are provided by an external clinical trial management group to the Production group prior to commencing the manufacture of the product.

11.2.2 Blisters – Aridol/Osmohale/Bronchitol

The batch numbering system for Aridol/Osmohale/Bronchitol blisters will take the format of:

YYXXX e.g. 13001
YY – year of manufacture
XXX – sequential numbering

The batch number originates from the assigned lot number (sec. 11.1). The 'M' is dropped from the lot number in order to create a batch number.

For Aridol/Osmohale the batch number originates with the Lot number for blister 1. Blister 1 Lot number is in the format MYY-XXX as in section 11.1. The corresponding batch number is YYXXX. Blister 2, 3 and the final product are manually assigned the same number as blister 1 on Navision.

11.2.3 Non-commercial Product – Aridol/Osmohale/Bronchitol Demonstration/Training

- Aridol/Osmohale Demonstration/Training:

The batch numbering system for Aridol Demo cartons will take the format as per below:

YYXXXDACC, e.g. 13001DANL,
YY – year of manufacture
XXX – sequential numbering
DA – Demonstration/Training Aridol
CC – country/region code;
note: 'GX' will be used for global packs/region

- Bronchitol Demonstration/Training:

The batch numbering system for Bronchitol Demo cartons will take the format as per below:

YYXXXDBCC, e.g. 13001DBNL,
YY – year of manufacture
XXX – sequential numbering
DB – Demonstration/Training Bronchitol
CC – country/region code; ***note: 'GX' will be used for global packs/region***

The country code may be based on the ISO3166 (ISO 3166-1-alpha-2code element) or as specified by Pharmaxis QA Department. The specific country code for each product is detailed in the corresponding specification for the product. The specification should be checked prior to assigning a batch number.

11.2.4 Commercial Product –Aridol/Osmohale

The Batch numbering system for Aridol cartons (printed on the cartons) will take the format of:

YYXXXCC, e.g. 13001NL,
YY – year of manufacture
XXX – sequential numbering
CC – country code

The country code may be based on the ISO3166 (ISO 3166-1-alpha-2code element) or as specified by Pharmaxis QA Department. The specific country code for each product is detailed in the corresponding specification for the product. The specification should be checked prior to assigning a batch number.

This list states the country names (official short names in English) in alphabetical order as given in ISO 3166-1 and the corresponding ISO 3166-1-alpha-2 code elements.

This list is updated whenever a change to the official code list in ISO 3166-1 is effected by the ISO 3166/MA. The most recent document is available at:

ISO - International Organization for Standardization

http://www.iso.org

11.2.5 Commercial Product -Bronchitol

The batch number originates with the Lot number for the material manufactured. If the Lot number is MYY-XXXBCC as in Section 11.1.3, then the corresponding batch number will be YYXXXBCC unless it's a sample pack the batch number will be YYXXXBCC-S. For example:

Batch number	Finished Product Type
12001BUK	Bronchitol 14 Day Pack for UK
12001IUK	Bronchitol Initiation Pack for UK

12001BDE-S	Bronchitol Sample pack for Germany
12001IDE-S	Bronchitol Initiation Sample pack for Germany
12001FUS	Bronchitol 7 Day Pack US
12001GUS	Bronchitol 4 Weeks Pack US

Table 5: Bronchitol Finished Product types

The batch number and the expiry date will always be printed on the blister strip for commercial product.

11.2.6 Reworked Material

Refer to SOP-211 Rework Procedure at Pharmaxis for further detailed information regarding the procedure.

The batch number for reworked material is based on the original batch number which will have the format YY-XXX. If that material is reworked it will have the following format:

Batch number will be YYXXXRZZZ

e.g. 07177R003, where Z is a sequential number issued from ELB-090.

Note: the country code, whether it exists or not, is removed from the batch number format for a reworked material.

12 ASSIGNING EXPIRY DATES TO MATERIALS PRODUCED BY MANUFACTURING

12.1 Spray Drying Solution

Spray Drying Solution to be used on the day of preparation.

12.2 Spray Dried Mannitol

The expiry date of the spray dried mannitol powder manufactured is 31 days and is calculated from the first day of powder production on the Spray Dryers.

12.3 Spray Dried Mannitol Blend

The expiry date of the spray dried mannitol blend is 60 days from the date of spray drying of the oldest sub batch in the blend.

12.4 Encapsulated Spray Dried Mannitol

The expiry date of encapsulated spray dried mannitol powder is 8 weeks for all capsules for all regions and is calculated from the first day the first capsule is encapsulated.

12.5 Blisters & Finished Product

The expiry date of a finished product is determined using FM-177. The expiry date is taken from the date the first sprayed dried sub-batch is manufactured that went into the blend used for encapsulation.

13 REJECTION OF MATERIALS

13.1 General

All rejected material and product shall be labelled REJECTED and segregated in the designated