INCOMING PRINTED CLEAR CAPSULES

	Name	Position	Signature	Date
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1.0 MATERIAL IDENTIFICATION

1.1 Standard Name — Incoming Printed Clear Capsules

1.2 Alternate Name — Printed Clear Capsules, size 3

1.3 Description — Clear, colourless hard gelatin capsules, colour code 43.000. "PXS" and "40mg" are printed in black on the cap and body respectively.

1.4 Packaging — Packaging must be intact for goods to be accepted.

1.5 Dimensions — Overall closed length 15.9mm ± 0.3mm

Dimensions of capsule parts	Body	Cap
Length	13.59mm ± 0.46mm	8.08mm ± 0.46mm
External Diameter	5.57mm	5.82mm

1.6 Weight — 48mg ± 3mg

1.7 CAS number — Not Applicable

2.0 APPROVED SUPPLIER

2.1 Supplier — Capsugel Australia

2.2 Manufacturer — Capsugel Belgium

2.3 Product Code — 100013PXS

3.0 STORAGE CONDITIONS

Store in a clean, dry place in a sealed container within the designated capsule storage area. At least two layers of packaging are required. Conditions must be within 20°C ± 5°C and 50%RH ± 15%

4.0 HAZARD AND SAFETY

Not Applicable

5.0 CERTIFICATES REQUIRED

A signed batch specific certificate of analysis is required (signature may be electronic). Specification and results on certificate of analysis must be as per the attached Capsugel addendum to the product specification sheets.

It is stated on the Certificate of Analysis that the product complies with:

- Commission Directive 2003/63/EC Note for guidance EMA/410/01 compliance demonstrated by "Certificate of Suitability".

6.0 SAMPLING REQUIREMENTS

6.1 Quantity required

Sampling is performed in accordance with the current version of SOP-029. Inspect and sample $\sqrt{n} + 1$ shippers received. The number of samples to be taken are as per the following table. Note pooling will be performed by the sampler[1] in accordance with SOP-066 where "per container" is not stated as such.

Sample	Minimum Testing Quantity (grams)	Minimum Sampling Quantity (grams)
Appearance	10g	16g per container
Identification of Gelatin	2g per container	
Loss on Drying	4g	
QC Retention	28g + 4g per container	32g per container
Microbial Tests	10g	10g
Microbial Retention 1	10g	10g
Microbial Retention 2	10g	10g
Total	72g + 6g per container	30g + 48g per container

[1]Pooling of QC testing samples are to be performed by QC department. Pooling of Microbial testing samples will be performed by QA department during inspection and sampling in cleanroom.

7.0 INSPECTION, TESTING AND ACCEPTANCE LIMITS

As per the result sheets, pages 3 and 4.

Release as per FM-018.

8.0 SHELF LIFE

8.1 Minimum remaining shelf life — Product will only be accepted if it has at least 30 months shelf life remaining.

8.2 Expiry date — Expiry date shall be as specified by the manufacturer. No retest for shelf life extension is permitted beyond the manufacturer's expiry date.

8.3 Retest requirement — If, during storage, temperature or humidity limits are exceeded for more than 24 hours, capsules must be retested for Loss On Drying and be in compliance to the specification in accordance to Result Sheet 1.

9.0 RESULT SHEET

Result Sheet 1 of 2

Lot Number _____

TEST NAME	TEST METHOD	SPECIFICATION	RESULT	RESULT RECORD LOCATION	INITIAL / DATE
Appearance	TM-014 (on 200 capsules)	Capsules are clear, transparent, almost colourless, undamaged, clean and free from foreign particles. "PXS" appears in black print on the cap and "40mg" appears in black print on the body. Capsules are identical to standard capsules.			
Gelatin Identification Test	TM-031	Pass			
Loss on Drying*	TM-015	13.0 – 16.0%			
Microbial Limits (Sample size = 10g of capsules	Total Viable Aerobic Count Total Combined Yeast/Mould Count Tests for S. aureus and P. aeruginosa Bile Tolerant Gram Negative Bacteria Test for pseudomonads **As per FM-210**	$\leq 10^2$ colony forming units per g $\leq 10^1$ colony forming units per g Absence of S. aureus and P. aeruginosa in 1g Absence of Bile Tolerant Gram Negative Bacteria in 1 g Absence of all pseudomonads in 1g			

*Test to be repeated if retesting required due to storage conditions being outside specifications.

Results of tests and inspections are within specification **Sign**_____**Date** _____

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Result Sheet 2 of 2

Lot Number _____

TEST NAME	TEST METHOD	SPECIFICATION	RESULT	RESULT RECORD LOCATION	INITIAL / DATE
Inspection of Certificate of Analysis (CofA)	Visual Inspection	CofA is batch specific and has been signed (electronic signatures acceptable)			
		All results on the Capsugel CofA comply with specifications stated on the CofA and comply with the tests and specifications stated on the attached Technical Reference File Addendum			
		BSE regulations: It is stated on the CofA that the product complies with Commission Directive 2003/63/EC Note for guidance EMA/410/01 compliance demonstrated by "Certificate of Suitability".			

Results of tests and inspections are within specification **Sign**_____**Date** _____

10.0 DOCUMENT CHANGE HISTORY

Version	Date Effective	Section	Description and Rationale
10	07-Jul-23	5.0 & 9.0	Removal of reference to FDA-21 CFR - use of material derived from cattle in medicinal products as per CROPS-23-009.
09	06-Nov-20	All	Document updated to current format TE-017-07 in accordance with SOP-021.
08	07-Nov-18	All	Document updated to current template (TE-017-06) in accordance with SOP-021.
07	07Nov16	All	Document updated to current format TE-017-05 in accordance with SOP-021
		5.0 and Result Sheet 2 of 2	Changes to CofA BSE statement requirements were made in accordance with CR677.
		6.0	Sampling table reformatted for clarity
		8.3	"Retest Date" adequately renamed to "Retest Requirement"
06	21Nov14	All	Document updated to current format TE-017-04 in accordance with SOP-021
		2.3	Product code updated to "100013PXS" from "6357/SP287"
		5.0	Addition of sampling requirement of "√+1 shippers" from batch. Reduced sampling plan based on CR295 – action from CAR561. Table redesigned for clarity.
		Result sheet 1 of 2	Added a note for Loss on Drying – Test to be repeated if retesting required due to storage conditions being outside specification to highlight the testing required in event of environmental excursions. This also reflects the requirement as stipulate in Section 7.3
			Statement "Sample Size = 10g of Capsules" added under Test Name of Microbial Limits testing to ensure the correct amount are provided to external laboratory for testing
		Result Sheet 2 of 2	Statement "Electronic signature acceptable" added as all current CofAs are provided with an electronic signature from the supplier.
05	23Feb12	2.2	Change approved Manufacturer to Capsugel Belgium. Changed manufacturer in error in previous version, as KKR bought Capsugel division from Pfizer. Name of company

Version	Date Effective	Section	Description and Rationale
			manufacturing capsules is Capsugel Belgium.
04	24Nov11	2.1	Change approved supplier from "Pfizer Pty Ltd., Capsugel Division" to "Capsugel Australia Pty Ltd" as per CR368.
		2.2	Change approved manufacturer from "Capsugel, Belgium" to "Kohlberg Kravis Roberts & Co (KKR), Belgium" as per CR368
03	07Jul11	5.0	Update sampling requirements to allow for reduced sampling in accordance with CR No.295
		Attachment	Updated the version of Capsugel addendum added as attachment to this specification
02	06Apr10	All	Format updated to TE-017.
		4.0	Inspection of certificate of analysis is updated as per CR208.
		Result Sheet 1	Result sheet updated as per CR217.
			Microbial testing updated as per CRs 162 and 231

END OF DOCUMENT