EXAMPLE STUDY CHECKLIST –
Certificate in Cosmetic Quality and Stability

Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed; make sure to complete in order.	Item/Unit Do not proceed to the next item until previous item is ticked off/completed
		Watch Microbiology lecture 1
		Read all of section 1 and complete the activities.
		Work on Assessment Questions: Complete Q1.1, 1.2, 1.5, 1.6
		Watch Microbiology lecture 2
		Read all of section 2 and follow our worked example. Also revisit section 1.1.6 of the text. Then practice with Activity 2.3 and check your answers against ours to practice for the assessment.
		Work on Assessment Questions: Complete Q1.9.1, 1.9.2, 1.10.1, 1.10.2 and 1.11
		Watch Microbiology lecture 3
		Read all of sections 3, 4 & 5 of text in detail and complete all activities. Practice with Q3.1 to get ready for the assessment.
		Work on Assessment Questions: Complete Q1.3, 1.4, 1.7, 1.8.1, 1.8.2 and 1.8.3
Only continue to the next unit once you have completed all items in order		

Assessment Questions for Section 1: Plan microbiological control of cosmetic ingredients and manufacturing

1.1 Provide and explain at least 3 reasons why personal care products are so prone to microbial contamination.

1.2 Complete the following table:

Org.	Product Type	Microbial Limits
TGA	Application on skin	
EU	Eye area, mucous membranes & children <3yrs	
EU	Other products	
TGA/EU	Raw materials	

1.3 How would you sample raw materials and finished products? Include details of the equipment, types of agar and methods you would use.

1.4 What items need to be sampled **and** what documents are required as part of a GMP program? In your answer, consider also the testing of product at various stages.

1.5 When, during manufacture, should product be tested? What are the limits for it to be released to the next stage, and then for sale?

1.6 How should packaging/lids be checked, and what are the limits to be accepted?

1.7 Complete the following table:

Raw material	MRC classification	Testing frequency
Hydroxyethylcellulose (NDS gum)		
Sodium laureth sulfate (30% NDS solution: 70% water with preservatives added)		
Water		
Shea butter (N lipid)		
Wheat protein (50% NI solution:50% water with preservatives added)		

1.8 Provide 'ideal' systems and specifications to reduce microbial introduction in respect of:

      1.8.1 the water system

      1.8.2 the air system

      1.8.3 a sanitising system for equipment

1.9 Imagine you are in charge of testing Quality of finished product. These are the results from the last batch of product made, and were consistent for all samples taken from finished product.
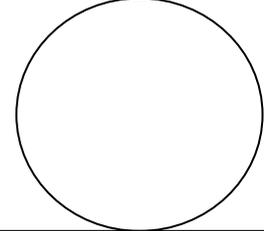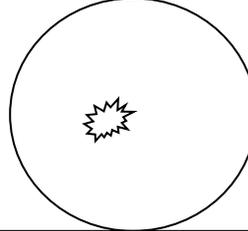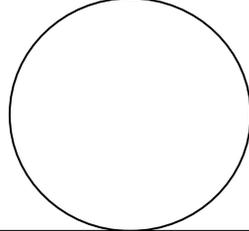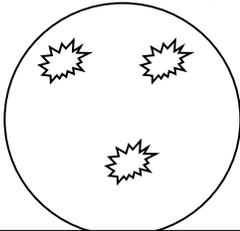
| Tryptic soy agar | Sabouraud Dextrose Agar | Cetrimide Agar | Mannitol Salt Agar |

1.9.1 Interpret the results

Result	Presence
TAMC	
Pseudomonas aeruginosa	
Staphylococcus species	
TYMC	
Candida albicans	

1.9.2 What should you do with this batch?

1.10 Imagine you are in charge of testing Quality of finished product. These are the results from the last batch of product made, and were consistent for all samples taken from finished product.

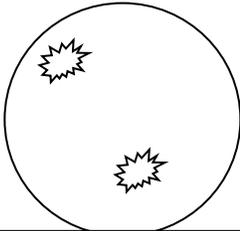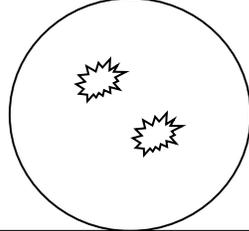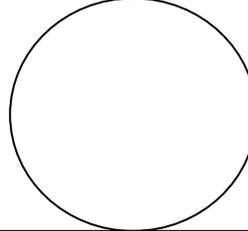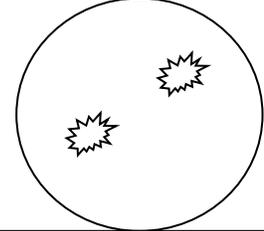| Tryptic soy agar | Sabouraud Dextrose Agar | Cetrimide Agar | Mannitol Salt Agar |

1.10.1 Interpret the results

Result	Presence
TAMC	
Pseudomonas aeruginosa	
Staphylococcus species	
TYMC	
Candida albicans	

1.10.2 What should you do with this batch?

1.11 Provide steps of the investigation you would conduct to investigate the cause of contaminated product in a manufacturing environment.

Pace yourself! Set a due date of 2-3 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed; make sure to complete in order.	Item/Unit Do not proceed to the next item until previous item is ticked off/completed
		Watch Stability testing lecture 1
		Read all of section 1 of the Stability unit. Make sure you complete all activities along the way.
		Work on Assessment Questions: Complete Q2.1 and 2.2
		Watch Stability testing lecture 2
		Watch Testing Video in lecture system
		Read sections 2, 2.1 and 2.2 of the Stability unit.
		Watch Fast Formulations video 1: https://www.youtube.com/watch?v=YhWH-VNWw3U Watch Fast Formulations video 2: https://youtu.be/jcKyvrBT1TM
		Work on Assessment Questions: Complete Q2.3.1 and 2.3.2
		Watch Stability testing lecture 3
		Read section 2.3, all of section 3 and 4. Complete all remaining activities.
		Work on Assessment Questions: Complete Q2.4, 2.5, 2.6, 2.7
Happy studying!		

Assessment Questions for Section 2: Plan and interpret stability testing

2.1 Explain the concept of 'shelf life' and purpose of stability testing.

2.2 Complete the following table of what would be UNSUITABLE to a consumer for the specified product types:

Product Type	Unsuitable changes (to a consumer)
Cream in a jar	
Hair conditioner in a jar	
Body scrub in bottle with flip top cap	

2.3 Using the stability templates following this question, prepare a **real time** and **accelerated** stability testing schedule for **EACH** of the following products. Make sure to show the **expiry limits, time points and test conditions**, as we have shown in the notes and Appendix C & D:

2.3.1 a moisturiser to be stored at 30°C with ideal specifications:
- glossy white medium viscosity cream with characteristic coconut aroma
- pH: 5.5
- specific gravity: 0.85
- viscosity: 40,000 cps

2.3.2 a conditioner to be sold in Australia and NZ stored at 25°C with ideal specifications:
- glossy white slightly translucent high viscosity cream with characteristic vanilla aroma
- pH: 4.5
- specific gravity: 0.89
- viscosity: 60,000 cps

Accelerated Schedule

Product name:	
Formula reference:	
Specification ref:	
Supersedes:	
Storage conditions:	
Predicted expiry:	

			Conditions			
Parameter	**Method**	**Expiry Limit**				
Time points						
Appearance	Visual: SOP 122					
Form	Visual: SOP 122					
Aroma	Inspection: SOP 122					
pH	pH meter: SOP 123					
Specific gravity	Pycnometer: SOP 124					
Viscosity	Brookfield viscometer: SOP 125					
Microbial content	TGA 2008: SOP 127					

Real time schedule

Product name:	
Formula reference:	
Specification ref:	
Supersedes:	
Storage conditions:	
Predicted expiry:	

Parameter	Method	Expiry Limits								
Appearance	Visual: SOP 122									
Form	Visual: SOP 122									
Aroma	Inspection: SOP 122									
pH	pH meter: SOP 123									
Specific gravity	Pycnometer: SOP 124									
Viscosity	Brookfield viscometer: SOP 125									
Microbial content	TGA 2008: SOP 127									

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Accelerated Schedule

Product name:	
Formula reference:	
Specification ref:	
Supersedes:	
Storage conditions:	
Predicted expiry:	

			Conditions			
Parameter	**Method**	**Expiry Limit**				
Time points						
Appearance	Visual: SOP 122					
Form	Inspection: SOP 122					
Aroma	pH meter: SOP 123					
pH	Pycnometer: SOP 124					
Specific gravity	Brookfield viscometer: SOP 125					
Viscosity	HPLC: SOP 126					
Microbial content	TGA 2008: SOP 127					

Real time schedule

Product name:	
Formula reference:	
Specification ref:	
Supersedes:	
Storage conditions:	
Predicted expiry:	

Parameter	Method	Expiry Limits								
Appearance	Visual: SOP 122									
Form	Visual: SOP 122									
Aroma	Inspection: SOP 122									
pH	pH meter: SOP 123									
Specific gravity	Pycnometer: SOP 124									
Viscosity	Brookfield viscometer: SOP 125									
Microbial content	TGA 2008: SOP 127									

2.4 For the following stability testing results:

Product name:			Sulphate free body wash			
Formula reference:			NATFOR-002-0			
Specification ref:			NAT-002-0			
Supersedes:			new			
Storage conditions:			25°C in closed packaging; clear bottle with flip top cap			
Predicted expiry:			2 years from date of manufacture			
			Conditions			
Parameter	**Method**	**Expiry Limit**	**25°C**	**35°C**	**45°C**	**Freeze/thaw**
Time points			t = 1mth; 3 mths; 6mths; 9mths; 12mths;	t = 1mth; 3mths; 6mths;	t = 1mth; 3mths	t = 12 days (6 cycles)
Appearance	Visual: SOP 122	Translucent, off-white low viscosity foaming gel	t = complies; white powdery residue on top; white powdery residue on top + very low viscosity; white powder residue on top + water thin; separated water thin product	t = white powdery residue on top; white powdery residue on top + very low viscosity; separated water thin product	t = separated water thin product; fails	t = @ 4 days (2 cycles); white powdery residue forming on top
Form	Visual: SOP 122	Foaming gel	t = complies; complies; complies; water thin/fails	t = complies; complies; water thin/fails	t = fails	t = @ 4 days (2 cycles); gel with thin residue layer on top
Aroma	Inspection: SOP 122	Citrus, characteristic of essential oils used	t = complies; complies; complies; complies; faint off notes; distinct off notes; fail	t = complies; complies; faint off notes; distinct off notes; fail; fail	t = faint off notes; fail	t = @ 12 days (6 cycles); complies

pH	pH meter: SOP 123	5.3 (4.7 – 5.9)	t = 5.0; 4.7; 4.5; 4.4; 4.3	t = 5.0; 4.5; 4.3	t = 4.5; 4.3	t = @ 6 days (3 cycles); 4.3
Specific gravity	Pycnometer: SOP 124	1.1 (1.0 – 1.2)	t = 1.1; 1.1; 1.1; 1.1; 1.1	t = 1.1; 1.1; 1.1	t = 1.1; 1.1	t = @ 12 days (6 cycles); 1.1
Viscosity	Brookfield viscometer: SOP 125	Spindle TF96@10rpm@ 25°C;12,000cps (10,500 – 13,500)	t = 12,000; 10,000; 2,000; 100; 100	t = 12,000; 2,000; 100	t = 100; 100	t = @ 6 days (3 cycles); 150
Microbial content	TGO77: SOP 127	TAMC NMT 100cfu/g; TYMC NMT 10cfu/g; *S. aureus*: not detected/g; *P. aeruginosa*: not detected/g.	t = complies; complies; complies; complies; complies; complies; complies	t = complies; complies; complies; complies; complies; complies	t = complies; complies	t = complies

2.4.1 prepare graphs to track changes and determine the approximate shelf life of this product.

2.4.2 what is the most likely cause of instability for this product?

2.4.3 what could be done to reduce/prevent these types of changes?

2.5 For the following stability testing results:

Product name:				Naturals Body Lotion			
Formula reference:				NATFOR-001-0			
Specification ref:				NAT-001-0			
Supersedes:				new			
Storage conditions:				25°C in closed packaging; white HDPE tube with flip top cap			
Predicted expiry:				2 years from date of manufacture			
				Conditions			
Parameter	**Method**	**Expiry Limit**		**25°C**	**35°C**	**45°C**	**Freeze/thaw**
Time points				t = 1mth; 3 mths; 6mths; 9mths; 12mths;18mths; 24mths	t = 1mth; 3mths; 6mths; 9 mths; 12 mths; 18mths	t = 1mth; 3mths	t = 12 days (6 cycles)
Appearance	Visual: SOP 122	Glossy, white, low viscosity lotion		t = complies; complies; complies; slight yellowing; distinct yellowing; distinct yellowing; distinct yellowing	t = complies; complies; slight yellowing; distinct yellowing; distinct yellowing, distinct yellowing	t = slight yellowing; distinct yellowing	t = @ 6 days (3 cycles); yellowing and separation evident
Form	Visual: SOP 122	Lotion		t = complies; complies; complies; complies; runny lotion; runny separated milk like; fail	t = complies; complies; runny lotion; runny separated milk like; fail; fail	t = complies; runny milk like	t = @ 6 days (3 cycles); separation evident
Aroma	Inspection: SOP 122	Characteristic lavender aroma with no off notes		t = complies; complies; complies; complies; faint off notes; distinct off notes; fail	t = complies; complies; faint off notes; distinct off notes; fail; fail	t = faint off notes; fail	t = @ 6 days (3 cycles); aroma showing definite off notes

pH	pH meter: SOP 123	5.5 (4.95 – 6.05)	t = 5.5; 5.3; 5.1; 4.9; 4.3; 3.8; 3.0	t = 5.3; 4.9; 3.8; 3.0; 2.7; 2.5	t = 5.0; 3.8	t = @ 6 days (3 cycles); 3.8
Specific gravity	Pycnometer: SOP 124	0.950 (0.855 – 1.045)	t = 0.95; 0.95; 0.95; 0.95; 0.95; 0.95; 0.95	t = 0.95; 0.95; 0.95; 0.95; 0.95; 0.95	t = 0.95; 0.95	t = 0.95
Viscosity	Brookfield viscometer: SOP 125	Spindle TF96@10rpm@ 25°C; 45,000cps (40,000 – 50,000)	t = 45,000; 43,000; 41,000; 39,000; 35,000; 29,000; 20,000	t = 43,000; 41,000; 35,000; 20,000; 8,000; 2,000	t = 41,000; 29,000	t = @ 6 days (3 cycles); 27,000
Microbial content	TGO77: SOP 127	TAMC NMT 100cfu/g; TYMC NMT 10cfu/g; *S. aureus*: not detected/g; *P. aeruginosa*: not detected/g.	t = complies; complies; complies; complies; complies; complies; complies	t = complies; complies; complies; complies; complies; complies	t = complies; complies	t = complies

2.5.1 prepare graphs to track changes and determine the approximate shelf life of this product.

2.5.2 what is the most likely cause of instability for this product?

2.5.3 what could be done to reduce/prevent these types of changes?

2.6 Below is an example body lotion formula. This lotion has shown signs of separation, changes in fragrance and colouration and viscosity after 6 months. The product is packed in a clear plastic bottle with flip top cap. Suggest ways to improve the stability of this product and provide reasons why you have made those suggestions.

Example body lotion

PHASE	ADDED %w/w	RAW MATERIALS	FUNCTION
A	To 100	Purified water	Solvent
A	5.0	Glycerin	Humectant/solvent
B	4.0	Cetearyl alcohol, ceteareth-20	Emulsifier blend
B	0.5	Stearic acid	Emulsifier
B	9.0	Grapeseed oil	Emollient
B	2.0	Almond oil	Emollient
B	2.0	Shea butter	Emollient
C	0.5	Calendula extract	Skin feel/advertising claims
C	0.5	Chamomile extract	Skin feel/advertising claims
D	0.2	Germall plus	Preservative
D	0.5	Vanilla essential oil	Fragrance
E	q.s	Citric acid	pH adjustment

METHOD
1. Combine ingredients in phase A and heat to 65 - 70°C.
2. Combine ingredients in phase B and heat to 65°C.
3. Add phase B to phase A and stir. Emulsify and stir while cooling.
4. When cooled below 30°C add ingredients from phase C and D; stir under low shear until mixed thoroughly. Adjust pH to 5.5 – 5.8.

2.7 Below is an example face scrub formula. This abrasive particles in this formula have floated to the top of the product over 6 months, and now block the nozzle of the tube it is packed in. Parts of the product also flow freely while other parts of the formula a thick gel. The product is packed in an opaque plastic bottle with flip top cap. Suggest ways to improve the stability of this product and provide reasons why you have made those suggestions.

Example face scrub

PHASE	ADDED %w/w	RAW MATERIALS	FUNCTION
A	To 100	Purified water	Solvent
A	0.5	Liquid Germall plus	Preservative
A	2.0	Natrosol 250HHR	Rheology modifier
B	12.0	Hostapon KCG	Emulsifier blend
B	9.0	Genagen CAB	Emulsifier
B	3.0	Lamesoft PO65	Emollient
C	3.5	Ecobeads Lapis	Abrasive beads
C	0.5	Ginger lily fragrance	Fragrance
D	q.s	pH adjuster	pH adjustment

METHOD
1. Combine ingredients in phase A and stir until a smooth, clear gel forms.
2. Combine ingredients in phase B. Add to phase A and stir through until homogenous.
3. Add phase C to phase A/B and stir through until homogenous.
4. Adjust pH to 5.0 – 5.5