Product Transfer Protocol

(Reference: SOP _____)

[Insert name of product/s covered by the protocol]

	WRITTEN:	CHECKED:
Signature:		
Position:		
Date:		

	AUTHORISED TO PROCEED:			
	Insert name of transferring site		Insert name of receiving site	
	Quality Assurance	Manufacturing	Quality Assurance	Manufacturing
Signature:				
Position:				
Date:				

	PROTOCOL COMPLETE			
	Insert name of transferring site		Insert name of receiving site	
	Quality Assurance	Manufacturing	Quality Assurance	Manufacturing
Signature:				
Position:				
Date:				

Product Transfer Protocol
(Reference: SOP _____)

Product Formulation & Batch Size

Attach a copy of the current and proposed product formulations and batch size details. Individual ingredient concentrations should remain unchanged irrespective of changes to the batch size. The formulation information should detail actual ingredient quantity including % concentration information. Refer to Appendix 3.

Tick the appropriate box to identify the responsible party

	RESPONSIBILITY	
	Transferring Facility	**Receiving Facility**
Current & Proposed Formulation attached		

Materials / Components Suppliers & Manufacturers

This section should identify any planned changes to packaging or raw materials.

Complete a comparison of current versus proposed packaging components including manufacturer details. Reference any change controls as necessary. Refer to Appendix 4.

Complete a comparison of current raw materials versus proposed materials. This will also include identifying differences in specifications and manufacturers. Reference any change controls and material evaluations as necessary. Refer to Appendix 5.

Include copies of raw material origin (BSE / TSE statements) in Appendix 6.

Tick the appropriate box to identify the responsible party

	RESPONSIBILITY	
	Transferring Facility	**Receiving Facility**
Current & Proposed Starting materials		
Raw material comparison and evaluations		
Raw Material Origin		

Analytical Method Transfer

This section should outline the method validation and transfer strategies to be applied.

The analytical methods used for starting materials originate from standard insert relevant compendia and codex references (BP, USP, FCC etc). The receiving site will use these standard monographs to

Product Transfer Protocol
(Reference: SOP _____)

	RESPONSIBILITY	
	Transferring Facility	**Receiving Facility**
Batch Records		✔

Certificates of Analysis (C of A)

Include C of As for each of the validation batches. Refer to Appendix 12.

Tick the appropriate box to identify the responsible party

	RESPONSIBILITY	
	Transferring Facility	**Receiving Facility**
Validation report and Certificates of Analysis		✔

Appendices

Appendix Number	Appendix Description	Number of Pages
Appendix 1	Documentation Transfer	
Appendix 2	Process / Equipment Description and Critical Parameters	
Appendix 3	Product Formulation and Batch Sizes	
Appendix 4	Packaging Components	
Appendix 5	Raw Material Comparison	
Appendix 6	Raw Material Origin	
Appendix 7	Analytical Method Transfer	
Appendix 8	Validation Strategy	

Product Transfer Protocol

(Reference: SOP _____)

Documentation Transfer List

Insert details of ALL Technical Documents transferred.

Document Number	Version Number	Description	Provided By Initial & date	Received By Initial & date

Appendix 2

Process / Equipment Description and Critical Parameters

Appendix 3

Product Formulation and Batch Sizes

Attach a copy of the current and proposed formulation details

Product Transfer Protocol

(Reference: SOP _____)

MANUFACTURING BILL OF MATERIALS

Complete table with details of all raw materials.

ITEM	Current Product	Transferred Product
Material Description		
Material ID #		
Specification Reference		
Supplier		
Manufacturer		
Standard Quantity per Batch		
Material Description		
Material ID #		
Specification Reference		
Supplier		
Manufacturer		
Standard Quantity per Batch		
Material Description		
Material ID #		
Specification Reference		
Supplier		
Manufacturer		
Standard Quantity per Batch		
Material Description		
Material ID #		
Specification Reference		
Supplier		
Manufacturer		
Standard Quantity per Batch		

Product Transfer Protocol
(Reference: SOP _____)

Appendix 11

Batch Manufacturing Records

Attach copies of the completed manufacturing and packaging batch records from each validation batch