



Secondary Raw Material Reference Substance (SRMRS) Summary Sheet

(Ref. [SOP LAB-020](#))

In-house Reference Code					
Ref. Sub. Description					
Raw Material Code					
Laboratory Batch No		Storage Location			
Manufacturer		Supplier			
Manufacturer's Batch No		Storage Temperature Requirement			
Manufacturer's Assay & Assay Description.					
Date sample received by the Laboratory		Quantity received by Lab (originally)		Date bottle first opened	
Manufacturer's Expiry Date		Re-test date (set at 1 year from in-house testing date)			
Date tested/ re-tested in-house for Assay		Finished Goods control method used to test Assay			
Analyst testing Assay		Workbook reference of analyst testing Assay			
%Water Content (WC) or %Loss on Drying (LOD)		Raw Material Control Method used to test WC or LOD			
Analyst testing WC/LOD		Workbook reference of analyst testing WC/LOD			
Assay results & Description		Expressed as needed during use: (To appear on label of bottle after testing)			
		Expressed as in appropriate Pharmacopoeia:			
Breakdown Products Detected? Quantified?					
Physical appearance of SRMRS (see Raw Material control method)					
Analyst who performed assay / entered results from certificate of analysis (please circle)					
Name:		Signature:		Date:	
Please make sure the following are attached to this form:					
<ul style="list-style-type: none"> • Completed Form-340 to show calculations and resulting Chromatograms • Manufacturer's Certificate of Analysis • Copy of Raw Material Specification and Test Report showing in-house testing results. • All other summary sheets & testing results previously done on this bottle of reference substance 					
Pharmacopoeia Limits for SRMRS	BP USP EP (Please circle)	Assay Limit & Description		WC/LOD Limit	
This bottle of SRMRS has been APPROVED / REJECTED (please circle) by second Analyst for use as a Secondary Raw Material Reference Substance.					
Name:		Signature:		Date:	
Date bottle finished or discarded including reason (complete when known)					
Comments					