QUALITY OVERALL SUMMARY - CHEMICAL ENTITIES

(Clinical Trial Applications - Bioavailability Studies) (QOS-CE (CTA - BA))

(version: 2004-04-01)

FOREWORD

The *Quality Overall Summary (QOS)* (Module 2.3) is a summary of the Quality Body of Data. This *QOS-CE (CTA - BA)* template can be used by sponsors to summarize the Quality information for Clinical Trial Applications (CTAs) for Bioavailability Studies containing drug substances and their corresponding products of synthetic or semi-synthetic origin that are filed with Health Canada pursuant to Part C, Division 5 of the *Food and Drug Regulations*. This would exclude submissions for Biotechnological/Biological (Schedule D) and Radiopharmaceutical (Schedule C) drugs.

Complete those sections and fields that apply. It is understood that certain sections and fields may not apply and should be indicated as such by reporting “Not applicable” in the appropriate area with an *accompanying explanatory note*. The use of tables to summarize the information is encouraged, where possible. The tables included in this template may need to be expanded, as necessary. These tables are included as illustrative examples of how to summarize information. Other approaches to summarize the information can be used if they fulfill the same purpose. If scanned images are incorporated into the document (e.g., synthetic schemes, molecular structures), sponsors should ensure that a low resolution is used to avoid files that are excessively large. Sponsors should consult the relevant Health Canada guidance documents for further details (e.g., *Quality Guidance: Clinical Trial Applications (CTAs) for Pharmaceuticals*).

Portions of the QOS-CE (CTA - BA) can also be used to summarize the Quality information contained in Clinical Trial Application - Amendments (CTA-As). When filing a CTA-A, the *relevant components of the template* should be completed. Those sections not affected by the change should be deleted.

When completing the QOS-CE (CTA - BA) template, this *Foreword* should be deleted.

MODULE 2.3: QUALITY OVERALL SUMMARY (QOS)

INTRODUCTION

(a) Summary of product information:

Proprietary (Brand) Name of Drug Product	
Non-proprietary or Common Name of Drug Product	
Non-proprietary or Common Name of Drug Substance (Medicinal Ingredient)	
Company (Manufacturer/Sponsor) Name	
Clinical Research Organization (CRO) Name	
Dosage Form(s)	
Strength(s)	
Route of Administration	
Proposed Indication(s)	

(b) Excerpt from Protocol Synopsis:

Trial Title, Number, and Phase	
Trial Objectives	
Study Design	
Study Duration	
Number of Centres/Canadian	
Sample Size	
Drug Formulation	
Dosage Regimen	

(c) Information on the comparator product (*complete either (i) or (ii)*):

(i) Canadian Reference Drug Product:

Proprietary (Brand) Name of Drug Product	
Non-proprietary or Common Name of Drug Substance (Medicinal Ingredient)	
Company Name and Address of Manufacturer	
Dosage Form(s)	
Strength(s)	
Drug Identification Number (DIN)	

(ii) Non-Canadian Reference Drug Product:

Proprietary (Brand) Name of Drug Product	
Non-proprietary or Common Name of Drug Substance (Medicinal Ingredient)	
Company Name and Address of Manufacturer	
Dosage Form(s)	
Strength(s)	
Lot Number	
Expiration Date	
Labelled Storage Conditions	
Country the Reference Drug Product is Marketed in for the Lot to be Used in this Clinical Trial ***(Note: To use the QOS-CE (CTA - BA) template, the reference drug product should be marketed in US, EU, Australia, or Switzerland)***	

2.3.S DRUG SUBSTANCE (NAME, MANUFACTURER)

I. Control of the Drug Substance:

(a) Summary of controls:

Standard claimed for the drug substance (e.g., Professed, House, USP, BP, Ph.Eur.)	
Attestation that the drug substance was manufactured under Good Manufacturing Practices (GMP) conditions	
Attestation that the proposed acceptance criteria for the organic solvents used in the process comply with International Conference on Harmonization (ICH) guidelines	

(b) Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial:

(c) Batch analyses:

(i) Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g, HPLC), and actual results):
(ii) A copy of a certificate of analysis for the drug substance may be found in:

(d) For drug substances or drug substance manufactured with reagents obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), a letter of attestation (with supporting documentation) should be provided confirming that the material is not from a BSE/TSE affected country/area. A copy of the letter may be found in:

2.3.P DRUG PRODUCT (NAME, DOSAGE FORM)

I. Description and Composition of the Drug Product:

(a) Description of the dosage form:

(b) Composition of the dosage form *(complete either (i) or (ii)*):

(i) Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any):

Component and Quality Standard (and Grade, if applicable)	**Strength (label claim)**			
	Quantity per unit	**%**	**Quantity per unit**	**%**
Total	0	0	0	0

(ii) Information on the composition of the dosage form:

Attestation that the non-medicinal ingredients used in the formulation are consistent with those found in the reference drug product, except where the patent laws or availability restricts their use. In such cases of differences, provide supporting documentation indicating the suitability of the ingredients.	
Attestation that none of the excipients which appear in the drug product are prohibited for use in drugs by the Canadian *Food and Drug Regulations*	

II. Manufacture (name, dosage form):

(a) Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial:

(b) List of referenced Drug Master Files (DMFs) and DMF Numbers:

(c) Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions:

III. Control on the Drug Product

(a) Description of the batches to be used in this clinical trial:

Strength and Batch Number	Batch Size	Date and Site of Production

(b) Batch analyses:

(i) Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g., HPLC), and actual results):

(ii) A copy of a certificate of analysis for the drug product may be found in:

(c) Excipients of human or animal origin:

(i) List of excipients that are of human or animal origin (including country of origin):

(ii) Summary of the information (e.g., sources, specifications, description of the testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin:

(iii) For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), a letter of attestation (with supporting documentation) should be provided confirming that the material is not from a BSE/TSE affected country/area. A copy of the letter may be found in:

(d) If any of the information in Section III (subsections (a) to (c)) is not available at the time of filing of the CTA, provide an attestation that this complete information will be submitted in sufficient time (e.g., two calendar days) in advance of the commencement of the bioavailability study to allow for the assessment of the data received: