**NOVA SCOTIA CRITERIA FOR INTERCHANGEABILITY**

The Nova Scotia Department of Health and Wellness, through its Pharmaceutical Services and Extended Health Benefits branch, approves a schedule of commonly prescribed, interchangeable pharmaceutical products in accordance with Section 9(1) of Chapter 7 of the Acts of 2011, the Fair Drug Pricing Act, and Section 8 of the Drug Plan Regulations.

**INCLUSION CRITERIA**

Pharmaceutical products are considered for interchangeability only when they are the subject of a formal submission which complies with the Nova Scotia Criteria for Interchangeability as outlined in this document.

**EXCLUSIONS**

The following categories are excluded:

* products not assigned a Drug Identification Number (DIN),
* new products that have not received a Notice of Compliance (NOC),
* products not currently available on the Canadian market,
* submissions with Health Canada Assigned Canadian Reference Product (CRP) where the reference product is not marketed in the submitted strength,
* regulated natural health products,
* non-prescription products,
* artificial sweetening agents, dietary supplements,
* soaps, cleaners, and shampoos,
* Subsequent Entry Biologics/Biosimilars,
* injectable medications, such as antineoplastics that are typically used in a hospital setting (consideration for review will be given on a case by case basis at the hospital’s request)

**GUIDELINES FOR INTERCHANGEABILITY**

The determination of "interchangeability" among pharmaceutical products which are sold in Nova Scotia by more than one manufacturer is solely the responsibility of the Department of Health and Wellness.

1. To be considered for interchangeability, the drug product must be the pharmaceutical equivalent of the comparator brand and must:

* contain the same amount(s) of the same active ingredient(s)
* have the same route(s) of administration.

1. The manufacturer's methods, facilities and documentation must be deemed to be acceptable. The drug product must be formulated and produced in accordance with Good Manufacturing Practices.
2. Comparative data pertaining to both the sponsor's product and the originating manufacturer's product will form the basis of the interchangeability assessment.
3. The applicable guidelines for bioequivalence are utilized, for example, Health Canada’s Conduct & Analysis of Comparative Bioavailability Studies and Comparative Bioavailability Standards: Formulations Used for Systemic Effects. A decision regarding interchangeability may be deferred until such time that recognized study design requirements and standards acceptable become available.
4. Factors or issues will be considered which could affect patient safety, acceptance and compliance including, but not limited to:

* product identification features
* non-medicinal ingredients
* integrity and stability of the dosage form
* product name which may cause confusion for the prescriber or dispenser
* palatability (palatability studies may be required on some products)
* packaging and labeling are not routinely reviewed but may be requested at the discretion of the Nova Scotia Department of Health and Wellness
* colored pictures are not routinely reviewed but may be requested at the discretion of the Nova Scotia Department of Health and Wellness

1. Other considerations:

* comparable tablet and capsule formulations of a chemical substance may be considered interchangeable
* different salts and esters of a chemical substance may be considered interchangeable
* products with different delivery systems are generally not considered interchangeable
* colours of solid or liquid dosage forms or shape will not affect interchangeability
* in general, excipients do not affect interchangeability unless there is a particular reason for concern (e.g., allergies with tartrazine).

**REVIEW PROCESS**

Multisource drug products seeking interchangeability status will be evaluated via expedited or full expert advisory review. Although submissions may meet the requirements for an expedited review, expert opinion may be solicited at any time, including full expert advisory review.

The following submissions may be eligible for an expedited review:

1. Products for which Health Canada has declared bioequivalence with a Canadian Reference Product (CRP) /Non-Canadian Reference Product

* **Exclusions** include but are not limited to (drugs exhibiting these characteristics should be submitted according to the guideline for full review):
  + oral dosage formulations for which standard bioequivalence studies (e.g., *Health Canada’s Conduct & Analysis of Comparative Bioavailability Studies and Comparative Bioavailability Standards: Formulations Used for Systemic Effects*) were not the basis of the bioequivalence determination
  + “Old drugs” as defined by the Therapeutic Products Directorate, Health Canada

* + critical dose drugs
  + drugs without a reference product

1. Products which are Cross-Referenced

* Products which are subject to a cross-licensing agreement (i.e. cross-referenced submission) must be declared.

Cross-Referenced Products demonstrating characteristics requiring a full review that are cross-licensed with products already deemed interchangeable in the Nova Scotia Formulary will be eligible for expedited review.

* Cross-Referenced submissions apply only in cases where the submitted product is identical to the cross-referenced/cross-licensed product in all aspects including:
  + strength and dosage form
  + formulation including both active and inactive ingredients and their quantities
  + raw materials and finished product specifications
  + manufacturing processes
  + manufacturing site
* The drug sponsors must provide written notification of any changes in the cross-licensing agreement.

Products which are subject to a cross-licensing agreement and also have a declaration of bioequivalence with a Canadian Reference Product should be submitted according to the guidelines for Cross-Referenced Products.

Submissions not falling into the above categories should be submitted according to the guidelines for full expert advisory review.

**NOTICE OF SIGNIFIGANT CHANGES**

Upon declaration of interchangeability in the Nova Scotia Formulary, the drug sponsor must provide written notification of any change made in the future to the Notice of Compliance, DIN, product name, ownership, manufacturer or distributor, cross-license and/ or distribution agreement, product formulation, site of manufacture, or any other significant product change which could be considered to affect bioequivalence, or interchangeability due to patient safety, acceptance, or compliance. Additional information may be requested to support continued declaration of interchangeability in the Nova Scotia Formulary.

**Notice of change submissions:**

Please include the following documentation:

* Health Canada approval for change (i.e., No Objection Letter, Notice of Compliance)
* Updated product monograph
* If applicable, a letter confirming that there have not been any changes to formulation or bioavailability that could affect bioequivalence.
* If applicable, updated letters of cross-license and updated authorization letter(s) of unrestricted communication (Appendix B)

**Please note:** Notifiable changes filed with Health Canada to update the product monograph to the brands’ product monograph are not required to be submitted unless they fall in any of the above listed categories.

**SUBMISSION REQUIREMENTS**

The following are requirements for submissions. Please note that for any submission, additional information may be requested at any time on a case-by-case basis.

Submissions must not be made until there is product ready for sale and shipment to pharmacies in Nova Scotia. **Incomplete submissions will not be reviewed or retained and must be resubmitted in full.**

**Submission Requirements for Expedited and Full Expert Advisory Review**

1. Cover letter outlining the submission with table of contents
2. Completed Manufacturer Checklist (Appendix A)
3. Notice of Compliance (NOC) or Drug Notification Form for old drugs without NOCs
4. A letter authorizing unrestricted communication regarding the drug product between Nova Scotia and (Appendix B):

* other federal, provincial, and territorial (F/P/T) drug programs
* F/P/T health authorities and related facilities
* Health Canada
* Patented Medicine Prices Review Board (PMPRB)
* Canadian Agency for Drugs and Technologies in Health (CADTH)
* other provincial interchangeability committees and their administrators

1. Health Canada approved product monograph
2. Letter indicating the product is available in sufficient quantity to meet demand and is available to all pharmacies in Nova Scotia (Appendix B).
3. Pricing information

**Additional Documentation Required for Cross-Referenced Submissions**

The following should be provided from both the Manufacturer/Sponsor of the cross-referenced product and of the product being submitted:

* Letter authorizing unrestricted communication as noted above
* Letter(s) of cross-license (Appendix B):
* identifying the manufacturer for both the cross-referenced product and the product being reviewed
* confirming a cross-licensing agreement exists between the manufacturers
* confirming that the product being reviewed is identical to the cross-referenced product in all aspects including strength and dosage form, formulation including both active and inactive ingredients and their quantities, raw materials and finished product specifications, manufacturing processes and manufacturing site.

**Additional Documentation Required for Full Submissions**

Evidence of bioequivalence:

* Clinical Study Report Synopsis
* Health Canada Approved Comprehensive Summary: Bioequivalence (CS-BE)
* Comparative dissolution data with innovator product
* Graph of mean plasma concentrations comparing the two products (regular and semi-log) including an estimate of the variability at each time point.
* Chemistry, manufacturing, and quality control data: Health Canada approved Certified Product Information Document (CPID). In lieu of the CPID, a Master Formula and Final Product Specifications must be provided.
* Completed pharmacokinetic/statistical worksheet (Appendix C)
* Other considerations:
  + For some products such as solutions for parenteral use, oral solutions (e.g., simple solutions, elixirs, syrups, etc.) and topical products, comparative physiochemical properties, pharmacodynamic studies, etc. may be accepted as evidence of bioequivalence.
  + Bioequivalence studies may not be required for each drug product strength if the manufacturer provides appropriate bioequivalence studies and can then provide evidence of proportionality to support bioequivalence of the other strengths being marketed. The master formula and comparative dissolution data must be provided for all strengths of the drug being reviewed.

**SUBMISSION PROCESS**

**Information related to the submission process may be found at:**

[**https://novascotia.ca/dhw/pharmacare/nova-scotia-drug-therapeutic-committee.asp**](https://novascotia.ca/dhw/pharmacare/nova-scotia-drug-therapeutic-committee.asp)

Submissions for interchangeability consideration must be sent through a secure file transfer site. To gain access to the secure site, the manufacturer should email [NS.Interchangeability.Committee@medavie.bluecross.ca](mailto:NS.Interchangeability.Committee@medavie.bluecross.ca) to inform the staff.

The manufacturer will be sent a link to the secure site to submit the documents. After a manufacturer has submitted through this process once, all subsequent submissions can be made the same way, using the same portal link.

**Notification:**

Manufacturers will receive written notification via email of the outcome of the submission review.

Interchangeable products will be listed in the Nova Scotia Formulary. The Nova Scotia Formulary may be accessed in .pdf on the following website: [www.nspharmacare.ca.](http://www.nspharmacare.ca/)

**Deadline for Submission:**

In general, complete submissions are reviewed in order of receipt.

For submissions undergoing full expert advisory review, the next meeting date of the Drugs and Therapeutics Committee will be posted on the NS Department of Health and Wellness website ([www.nspharmacare.ca](file:///C:\Users\bcapipe\AppData\Local\Temp\notes08127F\www.nspharmacare.ca)) and may be subject to change without notice. Ad hoc committee meetings may be called at the sole discretion of the Department of Health and Wellness. Submissions must be received by the Pharmacist Consultant at least four weeks in advance of the next meeting date to ensure inclusion in the next available meeting. Submissions received after the deadline will only be included on the agenda in exceptional circumstances at the discretion of the Committee and/or the Department of Health and Wellness.

**APPEALS PROCESS**

Challenge information will not be considered for drug products that are eligible for, and are reviewed under, the expedited review process for interchangeable drug products and will only be considered for products reviewed through full expert advisory review.

If a manufacturer or other organization (“Challenger”) requests review of their concerns about a company’s (“Applicant”) submission or product listing, these concerns must be provided in writing to the Drugs and Therapeutics Committee.

1. All Challenge Information must include a letter provided by the Challenger authorizing unrestricted communication regarding the Challenge Information between Nova Scotia and:

* other federal, provincial, and territorial (F/P/T) drug programs
* F/P/T health authorities and related facilities
* Health Canada
* Patented Medicine Prices Review Board (PMPRB)
* Canadian Agency for Drugs and Technologies in Health (CADTH)
* other provincial interchangeability committees and their administrators.
* Applicant

1. If written consent is submitted as required, the Challenge Information will be duplicated in its entirety and forwarded to the Applicant, inviting a response (“Applicant Response”).
2. The Applicant Response must be received within 15 calendar days from the date of the letter to the Applicant.
3. If an Applicant Response is not received within the time provided, only the Challenge Information will be provided to the Committee for consideration. If an Applicant Response is received within the time provided, both the Applicant Response and the Challenge Information will be provided to the Committee for consideration. No further information may be submitted to the Committee for consideration.
4. The Applicant Response should only address information contained in the Challenge Information. Anything in the Applicant Response that does not relate to information contained in the Challenge Information may, at the sole discretion of the Committee, be disregarded.
5. The Challenge Information and Applicant Response should be submitted to the attention of the Pharmacist Consultant as outlined on Page 5.
6. In the event the anticipated Applicant submission is not received; Challenge Information will be destroyed 6 months after receipt.

**APPENDIX A**

**MANUFACTURER SUBMISSION CHECKLIST**

**Appendix A**

**Nova Scotia Criteria for Interchangeability**

**Manufacturer Submission Check List**

**Summary of Product Information:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Submission Received Date *(For Office Use):*** | | |  | |
|  | | | | |
| **Generic Name:** |  | | | |
| **Dosage Form:** |  | | | |
| **Manufacturer:** |  | | | |
| **ATC Code:** |  | | | |
| **Submitted Product:** | | **Strength(s):** | | **DIN Number(s):** |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
| **Submitted Product has a Declaration of Bioequivalence to a Canadian Innovator Reference Product:**  **Yes**  **No** | | | | |
| **Comparator Innovator Reference Product (for all submitted strengths) is in the Nova Scotia Formulary:**  **Yes**  **No** | | | | |
| **Comparator Innovator Reference Product:** | | **Strength(s):** | | **DIN Number(s):** |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
| **Submitted Product is subject to a Cross-Licensing Agreement:**  **Yes**  **No** | | | | |
| **Submitted Product is an UItrageneric:**  **Yes**  **No** | | | | |
| **Cross-Licensed Comparator Product (for all submitted strengths) is in the Nova Scotia Formulary:**  **Yes**  **No** | | | | |
| **Cross-Licensed Comparator Product:** | | **Strength(s):** | | **DIN Number(s):** |
|  | |  | |  |
|  | |  | |  |
|  | |  | |  |
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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Bioequivalence is supported by which guideline(s) (check all that apply):** | | | | | |
| Health Canada’s Conduct & Analysis of Comparative Bioavailability Studies and Comparative Bioavailability Standards: Formulations Used for Systemic Effects | | | | | |
| Critical Dose Drugs | | | | | |
| Other (e.g., liquids, inhalers, topicals) Explain: | | | | | |
| Exceptions (e.g., waivers to recognized study design, requirements, and standards.) Explain (include copy of waiver): | | | | | |
| Other Relevant Comments: | | | | | |
| **Please complete the following regarding the submitted product monograph:** | | | | | |
| Date of Health Canada Approval for the submitted product monograph: | | | | **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| Are there differences from the innovator product monograph that relate to stability and storage? Explain: | | | | **Yes**  **No** | |
| **Please indicate if the product(s) demonstrate any of the following characteristics.** | | | | | |
| Is an **oral** dosage formulation for which standard bioequivalence studies, (e.g. Health Canada’s Conduct & Analysis of Comparative Bioavailability Studies and Comparative Bioavailability Standards: Formulations Used for Systemic Effects) were not the basis of the bioequivalence determination. | | | | | **Yes**  **No** |
| Is a Critical Dose Drug [e.g., highly toxic drugs, drugs with a narrow therapeutic range (e.g., cyclosporine, digoxin, flecainide, lithium, phenytoin, sirolimus, tacrolimus, theophylline, warfarin), etc.] | | | | | **Yes**  **No** |
| Is an “Old Drug” as defined by the Therapeutic Products Directorate, Health Canada. | | | | | **Yes**  **No** |
| Products without a reference product | | | | | **Yes**  **No** |
| Note: Products which demonstrate any of the above characteristics will be ineligible for expedited review (including those with a declaration of bioequivalence to a Health Canada Innovator Reference Product). Products which are cross-licensed with products already deemed interchangeable in the Nova Scotia Formulary will be eligible for expedited review. | | | | | |
| **The following submission requirements apply to both expedited and full reviews. Please provide electronic submission as outlined in submission process section.** | | | | | |
| Cover Letter (description of the submission, Table of Contents) | | | | | |
| Notice of Compliance (NOC) or Drug Notification Form (DNF) for old Drugs without NOCs | | | | | |
| For an NOC with Conditions (NOC/c), please include the *Request for Letter of Undertaking* and the *Letter of Undertaking*. | | | | | |
| Health Canada approved product monograph or patient information for Old Drugs | | | | | |
| Letter authorizing **unrestricted communication** regarding the drug product between Nova Scotia and:   * Other federal, provincial, and territorial (F/P/T) drug programs * F/P/T health authorities and related facilities * Health Canada * Patented Medicine Prices Review Board (PMPRB) * Canadian Agency for Drugs and Technologies in Health (CADTH) * other provincial interchangeability committees and their administrators (Appendix B) | | | | | |
| Letter indicating the product is available in sufficient quantity to meet demand and is available to all pharmacies in Nova Scotia with effective date (Appendix B). | | | | | |
| Pricing information | | | | | |
| **Additional documentation required for Cross-Referenced Submissions (from both the Manufacturer/Sponsor of the cross-referenced product and of the product being submitted):** | | | | | |
|  | | Letters authorizing **unrestricted communication** regarding the drug product (as noted above) | | | |
|  | | Letters of cross-license (appendix B):   * identifying the manufacturer for both the cross-referenced product and the product being reviewed * confirming a cross licensing agreement exists between the manufacturers * confirming that the product being reviewed is identical to the cross-referenced product in all aspects *including* strength and dosage form, formulation including both active and inactive ingredients and their quantities, raw materials and finished product specifications, manufacturing processes, and **manufacturing site** | | | |
| **The following are the additional submission requirements for full submissions.** | | | | | |
|  | Evidence of bioequivalence in the **fasting** state (Clinical Study Report Synopsis and graphs of mean plasma concentrations comparing the two products (regular and semi-log) including an estimate of the variability at each time point.) | | | | |
|  | Evidence of bioequivalence in the **fed** state (Clinical Study Report Synopsis and graphs of mean plasma concentrations comparing the two products (regular and semi-log) including an estimate of the variability at each time point.) | | | | |
|  | Completed Pharmacokinetic / Statistical Worksheet (**fasting**) (see Appendix C, Nova Scotia Criteria for Interchangeability) | | | | |
|  | Completed Pharmacokinetic / Statistical Worksheet (**fed**) | | | | |
|  | Comparative dissolution data with innovator product | | | | |
|  | Proportionality (if applicable) | | | | |
|  | Health Canada Approved Comprehensive Summary: Bioequivalence (CS-BE) | | | | |
|  | CPID – including master formula | | | | |
| **For full submissions with physiochemical data used to support bioequivalence please include:** | | | | | |
|  | Physiochemical Comparison Table | | | | |
|  | Waiver of bioequivalence (explanation) | | | | |
|  |  | | | | |
| **By signing this form, you are affirming that the information provided is accurate as of the date entered. Changes to the above information must be submitted in writing.** | | | | | |
| Signature: | | | Date: | | |
| Name / Title: | | | | | |

**APPENDIX B**

**MANUFACTURER LETTER TEMPLATES**

**Template Letter of Unrestricted Communication**

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant

Nova Scotia Pharmacare Programs

230 Brownlow Ave

Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product name, generic name, strength, and dosage form]

This letter authorizes unrestricted communication regarding the drug product between Nova Scotia and:

* other federal, provincial, and territorial (F/P/T) drug programs
* F/P/T health authorities and related facilities
* Health Canada
* Patented Medicine Prices Review Board (PMPRB)
* Canadian Agency for Drugs and Technologies in Health (CADTH)
* other provincial interchangeability committees and their administrators

[Signature]

[Name and Title of Company Official]

**Template Letter Confirming Ability to Supply Product**

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant

Nova Scotia Pharmacare Programs

230 Brownlow Ave

Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product name, generic name, strength, and dosage form]

This letter is to confirm that [name of manufacturer] is currently able to supply the above drug product in a quantity sufficient to meet the anticipated demands for this product and is available to all pharmacies in the Province of Nova Scotia effective [date].

Please provide specific details below for location/distributors of the product in Nova Scotia:

* [Wholesaler/Distributor Name], *and/or*
* Direct from manufacturer (clarify minimum order requirements and any additional charges that would be applied)

In the event pharmacies in Nova Scotia cannot obtain supply, please provide a contact for prompt supply confirmation [Contact Details].

If at any time the manufacturer foresees that it may not meet the supply demand in Nova Scotia for the above drug product, the manufacturer shall, as soon as practicable, notify the Nova Scotia Pharmacare Programs in writing. The manufacturer shall further take all reasonable steps necessary to rectify the aforementioned situation as quickly as possible. Notwithstanding the above, the manufacturer understands and acknowledges that the Nova Scotia Pharmacare Programs may, in its sole discretion and without notice, determine that the manufacturer is unable to meet the demand in Nova Scotia for the above drug product, thereby delist the drug product from the Nova Scotia Formulary, making the drug product no longer eligible for Pharmacare reimbursement.

The terms outline above are agreed to and accepted by [name of manufacturer], as evidenced by the signature below of the authorized representative of the manufacturer.

[Signature]

[Name and Title of Company Official]

**Template Letter of Cross-License**

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant

Nova Scotia Pharmacare Programs

230 Brownlow Ave

Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product A or B name, strength, and dosage form]

Company A has entered into a licensing agreement with Company B relating to the distribution and marketing of Product.Company Ahas licensed Product A to Company B.

Company B will market Product A under Company B’s name, Product B.

Company A manufactures the above product according to the terms of the business agreement between Company A and Company B.

In addition, please note that Company A has information on file with Health Canada in the applicable Drug Submission.

Lastly, this letter is to confirm that, Product B is identical to Product A in all aspects including strength and dosage form, formulation including both active and inactive ingredients, and their quantities, raw materials and finished product specifications, manufacturing processes and manufacturing site.

[Signature]

[Name and Title of Company Official]

**APPENDIX C**

**PHARMACOKINETIC / STATISTICAL WORK SHEET (W1)**

**NOVA SCOTIA DRUGS AND THERAPEUTICS COMMITTEE**

**PHARMACOKINETIC / STATISTICAL WORK SHEET (W1)**

Name of Drug Product/Metabolite:

Name of Original Product:

Date Completed:

Strength/Dosage Form:

**Section 1**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **AUC (0-T)** | **Test Product**  (name/strength/dosage form) | | | **Reference Product**  (name/strength/dosage form) | | | |
| Mean  Standard Deviation  Coefficient of Variation  Ratio of Means  Mean of Ratios  90% Confidence Interval  (potency corrected) |  | | |  | | | |
| ANOVA [S/NS] Subject [ ] Treatment [ ] Sequence [ ] | | | | | | | |
| Distribution of individual ratios  (# subjects test vs. ref.) | <0.7 | 0.7-0.8 | 0.8-0.9 | 0.9-1.1 | 1.1-1.2 | 1.2-1.3 | >1.3 |
|  |  |  |  |  |  |  |
| **Section 2** | | | | | | | |
| **AUC (0-∞)** | **Test Product**  (name/strength/dosage form) | | | **Reference Product**  (name/strength/dosage form) | | | |
| Mean  Standard Deviation  Coefficient of Variation  Ratio of Means  Mean of Ratios  90% Confidence Interval  (potency corrected) |  | | |  | | | |
| ANOVA [S/NS] | Subject [ ] Treatment [ ] Sequence [ ] | | | | | | |
| Distribution of individual ratios  (# subjects test vs. ref.) | <0.7 | 0.7-0.8 | 0.8-0.9 | 0.9-1.1 | 1.1-1.2 | 1.2-1.3 | >1.3 |
|  |  |  |  |  |  |  |

**NOVA SCOTIA DRUGS AND THERAPEUTICS COMMITTEE**

**PHARMACOKINETIC / STATISTICAL WORK SHEET (W2)**

Name of Drug Product/Metabolite:

Name of Original Product:

Date Completed:

Strength/Dosage Form:

**Section 3**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Cmax** | **Test Product**  (name/strength/dosage form) | | | **Reference Product**  (name/strength/dosage form) | | | |
| Mean  Standard Deviation  Coefficient of Variation  Ratio of Means  Mean of Ratios  90% Confidence Interval  (potency corrected) |  | | |  | | | |
| ANOVA [S/NS] Subject [ ] Treatment [ ] Sequence [ ] | | | | | | | |
| Distribution of individual ratios  (# subjects test vs. ref.) | <0.7 | 0.7-0.8 | 0.8-0.9 | 0.9-1.1 | 1.1-1.2 | 1.2-1.3 | >1.3 |
|  |  |  |  |  |  |  |
| **Section 4** | | | | | | | |
| **Tmax** | **Test Product**  (name/strength/dosage form) | | | **Reference Product**  (name/strength/dosage form) | | | |
| Mean  Standard Deviation  Coefficient of Variation |  | | | | | | |

Adapted from:

Ontario Guidelines for Drug Submission and Evaluation. Ontario: Ministry of Health and Longterm Care, 2000.