Template Letter of Confirmation of Same Formulation for Clinical and Commercial Lot

[Manufacturer’s letterhead]

[Date]

Director
Drug Programs Policy and Strategy Branch
Ontario Public Drug Programs Division
Ministry of Health and Long-Term Care
3rd Floor, 5700 Yonge Street
Toronto, ON M2M 4K5

Dear Director:

RE: [Product name/generic name, strength, and dosage form (the “Product”) manufactured by <name of manufacturer> (“the Manufacturer”).

This is to confirm that the drug formulation for the clinical test lot(s) <product name, manufacturer name> is identical to the commercial lot(s) of the submitted product, <product name/generic name/strength/dosage form> with respect to physical and chemical properties, including strength and dosage form; formulation, including both active and inactive ingredients and their quantities; raw materials and finished product specifications; manufacturing process; manufacturing sites; package format; and size.

In the case that they are different formulations, please use the following paragraph:

This is to confirm that the drug formulation for the clinical test lot(s) and commercial lot(s) for <insert drug product name> are NOT the same. The differences in formulation are highlighted in the submitted old and new Certified Product Identification Document (CPID). Clinical evidence has been provided to demonstrate that the two formulations are equivalent.

[Signature]

[Name and Title of Senior Company Official]

I have the authority to bind the Manufacturer