I, the undersigned, declare that I have:

1. the suitable technical or professional qualifications to act in this capacity (for more information, refer to the enclosed *curriculum* vitae).
2. fully examined the data provided by the applicant and have provided references to the literature to support statements made that are not supported by the applicant’s original data. This report presents an objective assessment of the nature and extent of the data.
3. provided a report based on my independent assessment of the data provided.
4. based my recommendations, regarding suitability for registration, on the data provided herewith. I have considered the attached data and have recommended as to suitability for registration of the intended dose forms and presentations according to the proposed product information document.

I further declare that this expert report represents my own view.

Further, I declare the following to be the full extent of the professional relationship between the applicant and myself:

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