

From: [Gildner, Jean](#)  
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)  
Subject: BLA 125586 Information Request  
Date: Thursday, March 29, 2018 12:29:13 PM  
Attachments: [20180328 IR - Tobin.docx](#)  
[image001.png](#)

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Dear Janice,

Please see attached the following information request. Please respond by April 6, 2018 @ noon.  
Please acknowledge receipt of this request and the ability to meet the deadline.

If you have any questions please feel free to contact me.

Sincerely, Jean

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## DBSQC Information Request for STN 125586/0

We have reviewed your response to the CR letter submitted as STN 125586/0.76, and received on 4 August 2017 in, and have the following Information Requests for your Direct and Indirect Potency assays.

In 3.2.S.5, you provided the following equations:

- (a) One Direct Potency unit = (b) (4) \_\_\_\_\_,  
(b) One Indirect Potency unit = (b) (4) \_\_\_\_\_,  
\_\_\_\_\_, and  
(c) (b) (4) \_\_\_\_\_.

We could not understand how you arrived at these equations based on the definitions of potency units for the Direct and Indirect Potency assays: for the Direct Potency assay “(b) (4) \_\_\_\_\_” and for the Indirect Potency assay “(b) (4) \_\_\_\_\_”.

Please provide detailed step by step explanations how you derived equations (a), (b) and (c), and provide one example each of the calculation of (b) (4) \_\_\_\_\_ for the Direct and Indirect Potency assays based on your results.

Please submit your response by 6 April 2018. If you are unable to do so, please provide us the time-line for submission of the requested information.