



To Whom It May Concern

Basel, 15. April 2025

KADCYLA® 100 mg powder for concentrate for solution for infusion
KADCYLA® 160 mg powder for concentrate for solution for infusion

Dear Sir/Madam,

Please find below information about the minimum and maximum fill weight and overfill volume for Kadcyla 100 mg/vial and Kadcyla 160 mg/vial:

	Fill volume (by weight) ^a	Overfill volume ^b
Kadcyla 100 mg/vial	min. 5.277 g max. 5.603 g	min. 5.143 mL max. 5.461 mL
Kadcyla 160 mg/vial	min. 8.526 g max. 9.054 g	min. 8.31 mL max. 8.825 mL

^{a)} Fill weight, as a measure of fill volume, is measured automatically at specific intervals during the filling process to control the amount of drug product solution filled into vials within the fill weight acceptable range.

^{b)} The Overfill volume is calculated considering the density of Kadcyla 100 mg/vial and 160 mg/vial (lyophilized powder for concentrate for solution for infusion) reconstituted with WFI at room temperature, which is 1.026 g/mL.

On behalf of Roche Registration GmbH,

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