

To Whom It May Concern

Basel, 27 January 2025

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

Dear Sir/Madam,

The nominal weight (without overfill) per vial Kadcyla 100 mg is:

Trastuzumab emtansine (drug substance):	106 mg
Excipients:	327,8 mg
Total:	433,8 mg

The nominal weight (without overfill) per vial Kadcyla 160 mg is:

Trastuzumab emtansine (drug substance):	171 mg
Excipients:	529,7 mg
Total:	700,7 mg

The density of Kadcyla 20 mg/ml reconstituted in sterile water is 1.03 g/ml at room temperature

On behalf of Roche Registration GmbH,

ppa.



Dr. Holger Raviol
Pharma Technical Regulatory

ppa.



Dr. Andreas Emmendoerffer
Pharma Technical Regulatory

Roche Registration GmbH

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