

To Whom It May Concern

Basel, 11. April 2025

POLIVY® 30 mg powder for concentrate for solution for infusion
POLIVY® 140 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 Polivy 30mg/vial and Polivy 140mg/vial:

	Fill volume (by weight) ^a	Overfill volume ^b
Polivy 30mg/vial	min. 1.84 g max. 1.99 g	min. 1.80 mL max. 1.95 mL
Polivy 140mg/vial	min. 7.510 g max. 7.816 g	min. 7.36 mL max. 7.66 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 Polivy 30 mg/vial and 140 mg/vial (lyophilized powder for concentrate for solution for infusion) reconstituted with WFI at room temperature, which is 1.02 g/mL.

On behalf of Roche Registration GmbH,

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