

Clarification statement of the expression of Colistin Units

Formulation:

<u>Ingredients</u>	per vial	per 2ml of reconstituted solution*
Colistin sulfomethate sodium** (equivalent to colistin USP activity of	approx. 421mg 181mg	157.5mg)
Water for injection ***	q.s.	q.s.

* when the vial contents are reconstituted with 2.0ml of water for injection, the total volume is approximately 2.3ml. this allows a 2ml dosage to be drawn out comfortably by syringe.

** based on an assayed activity of 430ug (12,900 BP units) per mg. The quantity used during manufacture is adjusted based on assay results on the raw material to deliver product at 157.5mg colistin activity (4,725,000 BP units) per 2ml of reconstituted solution. (5% excess).

*** most of the water for injection used to prepare the aseptic bulk solution during manufacture is removed during lyophilization.