

P.3.2 BATCH FORMULA FOR DRUG PRODUCT

The batch quantities shown represent the full scale manufacturing process for which the batch size is approximately 130 kg, producing approximately 722,000 tablets.

	mg/tablet	Kg/batch
Active Ingredient:		
Active drug salt	15.2	10.98
Other Ingredients:		
Mannitol	145.0	104.72
Maize starch	13.8	9.98
Calcium carboxymethylcellulose	4.0	2.90
Magnesium stearate	2.0	1.44
Total Weight	180.0	127.12