

QUERY 1

Based on previous query on request to declare content of polyvinyl alcohol on the outer carton, the BoH has asked for calculation to get the value 1.28% w/w for the polyvinyl alcohol content

RESPONSE 1

The polyvinyl alcohol content is calculated using the following formula:

$$(44.00\%*A)/B = 1.28\%$$

Where:

A is the weight of Opadry® II 85F30716 blue from [Table 3.2.P.1-1](#)

B is the weight of the Total Finished Tablet from [Table 3.2.P.1-1](#)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

Section 3.2.P.1 Description and Composition of the Drug product