

2.1.P.3.4 Control of Critical Steps and Intermediates

1 In-process controls

1.1 IPC I. - Granules

<i>Tests</i>	<i>Requirement</i>
Appearance	White to off-white granular powder
Loss on drying:	1.0 % - 2.0 % (dried to constant weight at 80 °C)

1.2 IPC II. – Final blend

<i>Tests</i>	<i>Requirement</i>
Appearance	White to off-white granular powder
Hydroxychloroquine content:	200.0 mg/306.0 mg blend \pm 5% RSD < 6%

1.3 IPC III. –Tablet form

<i>Tests</i>	<i>Requirement</i>
Appearance:	White or almost white, round, biconvex tablets with plain surfaces on both sides.
Dimensions:	
- diameter:	9.0 \pm 0.2 mm
- height:	4.0 – 4.6 mm
Average mass:	306.0 mg \pm 5 %
Uniformity of mass:	18/20 average mass \pm 5 % 20/20 average mass \pm 10 %
Hardness:	NLT 70 N
Friability:	NMT 1.0 %
Disintegration:	NMT 15 min

1.4 IPC IV. –Film-coated tablet form

<i>Tests</i>	<i>Requirement</i>
Appearance:	White or almost white, round, biconvex film-coated tablets with plain surfaces on both sides.
Dimensions:	
- diameter:	9.0 ± 0.2 mm
- height:	4.0 – 4.7 mm
Average mass:	315.0 mg ± 5 %
Uniformity of mass:	18/20 average mass ± 5 % 20/20 average mass ± 10 %
Disintegration:	NMT 30 min

1.5 In-process control V. – Primary packaging

Bottle closing control:

<i>Tests</i>	<i>Requirements</i>
Bottle closing	conforms

1.6 In-process control VI. – Secondary packaging

Check that boxes contain the specified number of blisters or container and one leaflet.

Both, the leaflet and box must conform in size and print to the specifications. The box must carry a mark showing the batch number and expiry date.

1.7 IPC VII. - Finished product control

During packaging the following items have to be checked:

- Identification of the packaging materials and the product
- Entirety checking of packaging units
- Checking of readability and markings
- Parameter checking of the equipment

<i>Tests</i>	<i>Requirements</i>
Finished product	comply

2 Finished product control

Tablets are tested according to drug product specifications according to part of *2.1.P.5 Specifications*. The specifications are for release and end of shelf-life.