2.1.P.3.4 Control of Critical Steps and Intermediates

1 In-process controls

1.1 In-process control I. – Blend for compression

Tests	*Requirements*
Appearance:	White or almost white powder
Ivermectin content:	3 mg / 60 mg ± 5%
RSD (%):	NMT 6%

1.2 In-process control II. -Tablets

Tests	*Requirements*
Appearance:	White or almost white, round flat-faced tablet of bevelled edge on both sides with marked “I” on one side and without sign on the other side.
Dimensions:	Diameter: 6.0 ± 0.2 mm Height: 1.5 – 2.2 mm
Average mass:	60.0 mg ± 5 %
Uniformity of mass:	18/20 average mass ± 10 % 20/20 average mass ± 20 %
Hardness:	NLT 25 N
Friability:	NMT 1.0 %
Disintegration:	NMT 15 minutes

1.3 In-process control III. – Primary packaging

Blistering

Tests	*Requirements*
Blister integrity	comply

1.4 In-process control V. - 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

Tests	*Requirements*
Finished product	comply

2 Final product control

Stromectol 3 mg placebo tablets are tested according to drug product specifications according to *Section 2.1.P.5.1 Specifications*. The specifications are for release and end of shelf-life.