Test report

Inactivated Split Influenza Vaccine (seasonal, trivalent) produced by the "Saint-Petersburg scientific research institute of vaccines and serums and the enterprise for the production of bacterial preparations" of Federal medical and biologic agency (FSUE SPbSRIVS FMBA), Russian Federation

Table 1: Vaccines under test by WHO

Vaccine under test	Lot no.	Presentation	Manufacturing date	Expiry date
Inactivated split influenza vaccine	N0010220	10-dose	10/02/2020	31/01/2021
	N0020220	10-dose	10/02/2020	31/01/2021
	N0030220	10-dose	13/02/2020	31/01/2021

Background information

Name of the medicinal product: Inactivated split influenza vaccine.

Inactivated split influenza vaccine (seasonal, trivalent) is a colourless, slightly opalescent liquid packaged in 10 multi-dose vials containing 5 mL. A single human dose (0.5 mL) contains 15 µg hemagglutinin of each of the three inactivated split monovaccine influenza strains type H1N1, type H3N2 and type B cultured in chicken embryos.

The vaccine is intended for the active immunisation for the prevention of influenza disease in adults and children over 6 years old. A single human dose of 0.5mL should be administered only once by intramuscular route.

The shelf life of the single dose presentation of the influenza vaccine consists of 12 months calculated from the manufacturing date of the final bulk.

Three final vaccine lots were made available and have been tested by two different WHO contracted laboratories for their haemagglutinin (HA) contents of the 3 influenza strains, their endotoxin content and have been visually inspected. All test results are compiled in below Table 2.

Test outcome – Visual inspection

The visual inspection of the samples reported by WHO laboratory 1 and laboratory 2 confirmed the adherence to the manufacturer's specification as reflected in the dossier as a "colourless, slightly opalescent liquid".

Test outcome – Endotoxin content

The endotoxin content performed by both laboratories confirmed compliance with the manufacturer's specifications of lower than 100 endotoxin units (EU) per millilitre (mL).

Test outcome – Haemagglutinin content

The HA content for the 3 strains, A/H1N1, A/H3N2 and B strain, tested on all batches N0010220, N0020220 and N0030220 performed by two laboratories, complied with the specification of greater / equal 15 µg per strain per single human dose.

Table 2: Compilation of test outcome - WHO laboratories and manufacturer

Lot no.	Test	Results WHO lab 1	Results WHO lab 2	Results manufacturer (at release)	Specification (manufacturer)
N0010220	HA content A/H1N1	18	18	17	≥15 µg/shd
	HA content A/H3N2	22	21	19	≥15 µg/shd
	HA content B	18	19	18	≥15 µg/shd
	Endotoxin content	< 2	< 0.2	< 100	< 100 EU/mL
	Appearence	complies	complies	complies	Colorless slightly opalescent liquid
N0020220	HA content A/H1N1	19	18	17	≥15 µg/shd
	HA content A/H3N2	22	20	19	≥15 µg/shd
	HA B content	19	19	18	≥15 µg/shd
	Endotoxin content	< 2	< 0.2	< 100	< 100 EU/mL
	Appearence	complies	complies	complies	Colorless slightly opalescent liquid
N0030220	HA content A/H1N1	18	17	18	≥15 µg/shd
	HA content A/H3N2	21	19	19	≥15 µg/shd
	HA B content	18	16	19	≥15 µg/shd
	Endotoxin content	< 2		< 100	< 100 EU/mL
	Appearence	complies	complies	complies	Colorless slightly opalescent liquid

Conclusion

The WHO requirements for influenza vaccine are laid down in the “Recommendations for the production and control of influenza vaccine (inactivated)”, Technical Report Series, No. 927, 2005, Annex 3. The section A.5. “Control test on the final lot” and especially section A.5.3: Haemagglutinin content” provide guidance regarding the potency of the vaccine, the haemagglutinin antigen concentration: “The vaccine should contain in each human dose at least 15 µg of haemagglutinin of each strain…” and … “the lower confidence interval (P=0.95) of the assay should not be less than 12 µg of haemagglutinin of each strain per dose”.

The independent testing by WHO laboratories confirmed the compliance of all the strains with the WHO specification for haemagglutinin content. Furthermore, adherence to the manufacturers specifications was shown for endotoxin content and appearance.

The WHO testing outcome supports the acceptability of Inactivated Split Influenza vaccine (seasonal, trivalent) produced by FSUE SPbSRIVS FMBA, Russian Federation, for prequalification.

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