Confirmation of conformity of packaging material for pharmaceutical agents

Supplier's name:

Production site:

Product description:

SAP number:

The above-mentioned packaging material complies with the below-mentioned conditions, till cancelled. The consolidated current versions of the following rules and regulations are applicable:

1. European Pharmacopoeia, monographs “3.1.3 Polyolefines”
2. European Pharmacopoeia, “3.1.4 Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations” OR “3.1.5 Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations”
3. U.S. Pharmacopoeia (USP) General Chapters: <661> CONTAINERS
4. Bundesinstitut für Risikobewertung (BfR) – Polyethylen
5. Food and Drug Administration (FDA), 21CFR177.1520 Olefin polymers
6. REGULATION (EU) No 10/2011
7. REGULATION (EC) No 1935/2004 including REGULATION (EC) No 2023/2006
8. CPMP/QWP/4359/03 of EMEA, point 3.1 and 3.2
9. Directive 94/62/EC
10. Free from phthalate
11. Free from latex
12. Free from substances, which, according to REGULATION (EC) 1907/2006 (REACH), article 59 are on the Candidate List.

The suitability of the packaging material to the packaging (direct contact) of dry pharmaceutical agents (NaCl, KCl, K_2SO_4, $MgSO_4$) is hereby confirmed.

Date	Name	Stamp/Signature

Regulation authority: K-TQ, S-OQ

Regulatory responsibility: K-TQ, S-OQ