

Product Information

TROGAMID® CX7323, TROGAMID® CX9710

Registration according USP XXIII Class VI

Due to its combination of properties such as :

- high level of chemical resistance,
- good transparency,
- good UV-stability,
- high impact strength,
- low water absorption

TROGAMID CX7323 is widely used for applications in the field of medical technology, e. g. as containers, packaging, connectors etc.

Numerous chemical resistance tests have shown that TROGAMID CX7323 is superior to all other transparent materials such as PC, PMMA and all commercial amorphous nylons as well.

Particularly the performance in alcohol containing solutions and lipid systems or other equally aggressive media and solvents, for example in cancer therapy, is outstanding.

USP XXIII Class VI

In its Pharmacopoeia –23rd Revision (USP XXIII) the United States Pharmacopoeia Convention provides regulations that guide the plastics and polymer industry in the manufacture of medical devices. Tests to determine the biological reactivity of elastomers, plastics and other polymeric materials are detailed in USP's general chapters.

Plastics are classified in 6 classes: Class I to Class VI. The biocompatibility tests vary from class to class, with Class VI having the highest requirements.

To qualify a plastic device, extracts of the test material are generated in various media and are injected by systemic and intracutaneous injections into rabbits or mice to evaluate the biocompatibility. An additional level of testing – implantation – can also be performed.

Plastic mouldings not requiring implantation testing are graded Class I, II, III or V and those mouldings requiring implantation testing are graded IV or VI.

According to test results – prepared by an independent test institute – we have achieved Class VI, the highest possible level of classification for a polymer used in medical devices for our TROGAMID CX9710.

TROGAMID CX9710 is based on TROGAMID CX7323 with an additional mould release agent.

This registration is also valid for TROGAMID CX7323.

Depending on the legal requirements of the various countries an additional registration of each single device might be necessary before a device can become commercial. To accelerate this procedure we will pass on the test results to our potential customers – if requested.

The USP XXIII Class VI registration is accepted worldwide and will strongly support the use of TROGAMID CX7323 for applications in medical technology.

For further information, please contact our experts in the department Market Development of the High Performance Polymers Business Line.

® = registered trademark

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