



Certificate of Quality

Product number: 91015
Lot number: 20200271
Product description: Centrifuge tube 15 ml, conical
Expiry date: 06/2026

Processed Material

Granulate yellow	Highest grade, virgin raw material - Free of stripping agents, softeners or heavy metals - Does not contain substances of animal origin and is therefore free of TSE/BSE
Polyethylene (PE)	Highest grade, virgin raw material - Free of stripping agents, softeners or heavy metals - Does not contain substances of animal origin and is therefore free of TSE/BSE
Polypropylene (PP)	- Material is tested and passes USP class VI requirements and guide lines 2007/47 EC Highest grade, virgin raw material - Free of stripping agents, softeners or heavy metals - Does not contain substances of animal origin and is therefore free of TSE/BSE - Material is tested and passes USP class VI requirements and guide lines 2007/47 EC

Quality Management System

Clean Room Conditions	Manufactured in clean room conditions, in accordance with the valid specifications.
GMP	Production cGMP oriented
ISO Certification	Certified ISO 9001:2015 scope no: 14 issued on: 2017-07-15 validity date: 2020-07-17 registration number: CH-12483

Biological Safety

Cytotoxicity	Non-cytotoxic, proven by representative test according to ISO 10993-5:1999 and USP chapter 88
DNA/RNA	Free of detectable DNA/RNA and ATP
DNase/RNase	Free of detectable DNase/RNase
Level of Endotoxins <0,06 EU/ml	Free of detectable endotoxins (pyrogens) Representative product test with Limulus Amoebocyte Lysate test (LAL) resp. bacterial endotoxins test (BET) according to the guidelines United States Pharmacopeia (USP) general chapter and European Pharmacopoeia (EP) general chapter 2.6.14. Detection limit: <0,06 EU/ml
Sterility	Product was sterilized, process validated in accordance with EN ISO 11137 and crosslinking modification of polymers

Functional Attribute

Centrifugal Acceleration 15'500 x g	Max. 15'500 x g with appropriate centrifuge-adapter, in accordance with the specifications
Leak Test	No leakage detected; in accordance with the valid specifications
Leak Tightness	Result of leak test in accordance with the valid specifications
Leak Tightness of Cap	In accordance with the valid specifications
Leak Tightness of Pouch	In accordance with the valid specifications
Lot Number	8-digit lot number printed on each product pouch and case label
Volumetric Accuracy	+/- 2 %; in accordance with the valid specifications

Visual Attribute

Integrity	Product samples passed visual inspection according to the valid specifications
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