

Change Notification

Date:	14 July 2016
Material Description:	0.25% Trypsin, 1X ; 0.05% Trypsin, 0.53 mM EDTA, 1X ; 0.05% Trypsin, 0.53 mM EDTA, 1X [-] sodium bicarbonate; 0.25% Trypsin, 2.21 mM EDTA, 1X [-] sodium bicarbonate; 2.5% Trypsin, 10X [-] phenol red
Catalog Number(s):	25-050, 25-051, 25-052, 25-053, and 25-054
Change Description:	Device Manufacturing Record (DMR) and Certificate of Analyses: Specification Clarification

The DMRs, Device Master Records, have been updated to clarify that mycoplasma testing pertains only to the trypsin raw material lots used in the formulation of the product. Updates were made to align with current established procedures for mycoplasma testing of SKUs beginning with the following prefixes: 25-050, 25-051, 25-052, 25-053, and 25-054.

There is no change being made to how these products are tested as they have historically been held to the same standard – the specification language is simply being expanded to clarify the claim.

The change is limited only to the DMR and CoA generation. There are no changes to any qualified processes or established procedures. Due to the changes being a clarification of the mycoplasma testing, validation and verification is not necessary and all changes are effective immediately.

Below is an example of the old and new CoA revisions.

Older Revision

TEST PARAMETERS	SPECIFICATION
pH	7.6 ± 0.4
Osmolality	275 ± 20 mOsm/kg H ₂ O
Mycoplasma	Tested Negative
Sterility	Pass
Cell Line	
MRC-5 (Trypsin Activity)	Pass
VERO (Trypsin Activity)	Pass
Porcine Parvovirus and Circovirus (9CFR testing)	Not detected (trypsin precursor lots)
Irradiated	Pass - Minimum of 25 kGy (trypsin precursor lots)

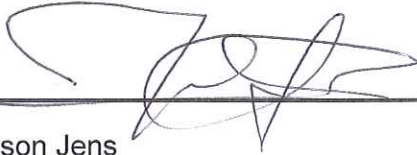
Updated Revision

TEST PARAMETERS	SPECIFICATION
pH	7.6 ± 0.4
Osmolality	275 ± 20 mOsm/kg H ₂ O
Mycoplasma	Tested Negative (trypsin raw material lots)
Sterility	Pass
Cell Line	
MRC-5 (Trypsin Activity)	Pass
VERO (Trypsin Activity)	Pass
Porcine Parvovirus and Circovirus (9CFR testing)	Not detected (trypsin precursor lots)
Irradiated	Pass - Minimum of 25 kGy (trypsin precursor lots)

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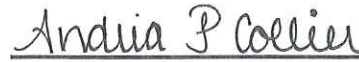
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19 Jul 2016

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