
 <b>Pharmaceutical Division</b>	<b>Fulvestrant Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 22NOV2019	SDS No.: SDS035	Revision No.: 1.0	Page: 1 of 15


### Section 1 - Identification

- (a) **Product Identifier:** Fulvestrant Injection
- (b) **Product Code:** 70860-211
- Common/Trade Name:** FASLODEX<sup>®</sup>
- Chemical Name:** 7-alpha-[9-(4,4,5,5,5-penta fluoropentylsulphinyl) nonyl]estra-1,3,5-(10)- triene-3,17-beta-diol
- Chemical Family:** Estrogen Receptor Antagonist
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Single-dose prefilled syringes
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification


- (a) **GHS Classification of substance or mixture:**
- Flammable liquids: Category 3
  - Acute toxicity (Oral): Category 4
  - Reproductive toxicity: Category 1B
  - Effects on or via lactation: N/A
  - Chronic aquatic toxicity: Category 2

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
<b>GHS Signal Word:</b>	Danger
<b>GHS Hazard Statement:</b>	H226 Flammable liquid and vapor. H302 Harmful if swallowed. H360 May damage fertility or the unborn child. H362 May cause harm to breast-fed children. H411 Toxic to aquatic life with long lasting effects.
<b>GHS Symbols:</b>	

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<b>GHS Precautionary Statements:</b>	<p><b>Prevention:</b></p> <p>P201 Obtain special instructions before use.</p> <p>P202 Do not handle until all safety precautions have been read and understood.</p> <p>P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.</p> <p>P233 Keep container tightly closed.</p> <p>P240 Ground/bond container and receiving equipment.</p> <p>P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.</p> <p>P242 Use only non-sparking tools.</p> <p>P243 Take precautionary measures against static discharge.</p> <p>P264 Wash skin thoroughly after handling.</p> <p>P273 Avoid release to the environment.</p> <p>P280 Wear protective gloves/ eye protection/ face protection.</p> <p>P281 Use personal protective equipment as required.</p> <p><b>Response:</b></p> <p>P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.</p> <p>P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.</p> <p>P308 + P313 IF exposed or concerned: Get medical advice/ attention.</p> <p>P391 Collect spillage.</p> <p><b>Disposal:</b></p> <p>P501 Dispose of contents/ container to an approved waste disposal plant.</p>
<b>Other Hazards</b>	None known.

(d) **Unknown Acute Toxicity** N/A

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### Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure*	(c) CAS No.	(d) Impurities / Stabilizing Additives
7-alpha-[9-(4,4,5,5,5-penta fluoropentylsulphinyl) nonyl]estra-1,3,5-(10)- triene-3,17-beta-diol	Fulvestrant	5% w/v	129453-61-8	N/A
Ethyl Alcohol, USP	Ethanol	10% w/v	64-17-5	N/A
Benzyl Alcohol, NF	Benzyl Alcohol	10% w/v	100-51-6	N/A
Benzyl Benzoate, USP	Benzyl Benzoate	15% w/v	120-51-4	N/A
Castor Oil, USP	Castor Oil*	Add to 100%	8001-79-4	N/A
Nitrogen, NF	Nitrogen	q.s.**	7727-37-9	N/A

\*Castor Oil, USP used as a co-solvent and release rate modifier.

\*\*q.s. – Quantity Sufficient

### Section 4 – First Aid Measures

- Eye Exposure:** Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
- Skin Exposure:** Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
- Ingestion:** Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.
- Injection:** In cases of accidental injection, wash and disinfect area, seek emergency medical attention.

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**Inhalation:** Remove patient from exposure, keep warm and at rest. Obtain medical attention.


**Notes to Physician:** Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media**      Foam, CO2 or dry powder. Water spray should be used to cool containers. Do not use water jet.
- (b) **Hazardous Combustion Products:**      Not available.
- (c) **Special Protective Equipment / Precautions:**      A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.  
Prevent fire extinguishing water from contaminating surface water or the ground water system.
- (d) **Specific Hazards During Firefighting**      Flammable liquid and vapor.  
The vapor is heavier than air and may travel a considerable distance to a source of ignition and flashback.  
Combustion will evolve toxic vapors.

### Section 6 - Accidental Release Measures

- Spill:**      Ensure suitable personal protection during removal of spillages. Absorb spillages onto sand, earth or any suitable adsorbent material. Do not adsorb onto sawdust or other combustible materials. Transfer to a container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.
- Release to Air:**      Not available.
- Release to Water:**      Prevent entry into drains, sewers or watercourses. Collect spillage.

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### Section 7 - Handling and Storage

- General Handling:** Avoid contact with skin and eyes.  
Avoid inhalation of vapor/mist.  
Take precautionary measures against static discharges.
- Storage Conditions:** Refrigerate, 2° to 8°C (36° to 46°F). To protect from light, store in the original carton until time of use. Keep container tightly closed, in a cool, well ventilated place. Keep away from sources of ignition - No Smoking.

### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits**


Compound	Issuer	Type	Exposure Limit
Ethanol	OSHA	PEL	NE
	ACGIH	TLV	NE
		STEL	1,000 ppm
	AIHA	WEEL	1,000 ppm
	AU OEL	TWA	1,880 mg/m3
Fulvestrant	OSHA	PEL	NE
	ACGIH	TLV	NE
	AIHA	WEEL	NE
	HYG	TWA	0.001 mg/m3

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit.  
ACGIH TLV; STEL: American Conference of Governmental Industrial Hygienists – Threshold Limit Value; Short Term Exposure Limit.  
AIHA WEEL: Workplace Environmental Exposure Level.  
AU OEL TWA: Australia Occupational Exposure Limit – Time-Weighted Average.  
HYG TWA: Industrial Hygiene – Time Weighted Average.

**(b) Engineering Controls**

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.


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**(c) Individual Protection Measures**

Respiratory Protection:	Use an air fed hood if the risk assessment does not support the selection of other protection.
Eye Protection:	Use safety glasses to protect against direct contact with the liquid if the risk assessment does not support the selection of other protection.
Skin Protection:	Use impervious clothing to protect against direct contact with the liquid or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.
Other Protective Equipment:	<p>Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.</p> <p>All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.</p> <p>The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.</p>

**Section 9 - Physical and Chemical Properties**

<b>(a)</b>	<b>Appearance</b>	clear, colorless to yellow, viscous liquid
<b>(b)</b>	<b>Odor</b>	Ethereal
<b>(c)</b>	<b>Odor Threshold</b>	Not available
<b>(d)</b>	<b>pH</b>	Not available
<b>(e)</b>	<b>Melting Point:</b>	Not available
<b>(f)</b>	<b>Initial Boiling Point:</b>	Not available

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(g)	<b>Flash Point</b>	29 °C
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Upper: 3.5 %(V) Lower: 19 %(V)
(k)	<b>Vapor Pressure:</b>	Not available
(l)	<b>Vapor Density:</b>	Not available
(m)	<b>Relative Density</b>	Not available
(n)	<b>Solubility(ies)</b>	Not available
(o)	<b>Partition Coefficient: n-octanol/water</b>	Not available
(p)	<b>Auto-ignition Temperature</b>	365 °C
(q)	<b>Decomposition Temperature</b>	Not available
(r)	<b>Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	No known reactivity hazard under normal conditions.
(b)	<b>Chemical Stability</b>	Stable under normal conditions.
(c)	<b>Possibility of Hazardous Reactions</b>	None known.
(d)	<b>Conditions to Avoid</b>	No conditions producing hazardous situations.
(e)	<b>Incompatible Materials</b>	None known.
(f)	<b>Hazardous Decomposition Products</b>	None known.

### Section 11 - Toxicological Information


#### 11.1.1 ACUTE TOXICITY

Harmful if swallowed.

##### **Product:**

Acute oral toxicity: Acute toxicity estimate: 2,000 mg/kg  
Method: Calculation method  
Remarks: May cause effects as described under single exposure.(STOT)

Acute inhalation toxicity: Acute toxicity estimate: > 20 mg/l  
Exposure time: 4 H  
Test atmosphere: vapour  
Method: Calculation method

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Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity: Remarks: May cause effects as described under repeated exposure.(STOT)

**Components:**

**Fulvestrant:**

Acute oral toxicity: Remarks: Low acute oral toxicity.

Acute inhalation toxicity: Remarks: May cause effects as described under repeated exposure.(STOT)

Acute dermal toxicity: Remarks: No information available.

**11.1.2 SKIN CORROSION/IRRITATION**

Not classified based on available information.

**Product:**

Remarks: May cause skin irritation.

**Components:**

**Benzyl benzoate:**

Remarks: May cause skin irritation.

**Fulvestrant:**

Result: Mild skin irritation.

**11.1.3 SERIOUS EYE DAMAGE/EYE IRRITATION**

Not classified based on available information.

**Product:**

Remarks: The vapor and liquid are irritant. May cause strong stinging and burning sensation. Permanent damage is unlikely.

**Components:**

**Benzyl benzoate:**

Remarks: May cause eye irritation.


**Benzyl alcohol:**

Remarks: The vapor and liquid are irritant.

**Fulvestrant:**

Remarks: May cause eye irritation. Unlikely to be a severe irritant to the eye.



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#### 11.1.4 RESPIRATORY OR SKIN SENSITIZATION

##### **Skin sensitization**

Not classified based on available information.

##### **Respiratory sensitization**

Not classified based on available information.

##### **Product:**

Remarks: Rare cases of skin sensitization have been reported.

##### **Components:**

##### **Benzyl benzoate:**

Remarks: Repeated and/or prolonged contact may cause skin sensitization.

##### **Fulvestrant:**

Remarks: Unlikely to cause skin sensitization.

#### 11.1.5 GERM CELL MUTAGENICITY

Not classified based on available information.

##### **Components:**

##### **Fulvestrant:**

Germ cell mutagenicity - Assessment: The substance is not considered to be genotoxic.

#### 11.1.6 CARCINOGENICITY

Not classified based on available information.

##### **Components:**

##### **Fulvestrant:**

Carcinogenicity - Assessment: A lifetime study in animals has shown that repeated doses produce benign tumors of the ovaries and testes in rats. These effects are related to the compound's hormonal activity.

#### 11.1.7 REPRODUCTIVE TOXICITY


May damage fertility or the unborn child.

May cause harm to breast-fed children.

##### **Components:**

##### **Fulvestrant:**

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments. Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Repeated exposure may produce adverse effects on the reproductive systems of men and women. Studies in animals have shown that low doses produce embryo/foetotoxic effects in the absence of maternal toxicity. (including embryo/lethality). Effects on or via lactation

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### 11.1.8 STOT - SINGLE EXPOSURE

Not classified based on available information.

**Components:**

**Benzyl alcohol:**

Remarks: May cause irritation to the upper respiratory tract. Ingestion may cause irritation of the gastrointestinal tract. The vapor has anesthetic properties and when inhaled at concentrations above the occupational exposure limit it may cause headache, fatigue, dizziness, incoordination and loss of consciousness.

**Fulvestrant:**

Remarks: No specific effects reported.

### 11.1.9 STOT - REPEATED EXPOSURE

Not classified based on available information.

**Components:**

**Benzyl alcohol:**

Remarks: Repeated and/or prolonged contact with the skin may have a degreasing action and cause dermatitis.

**Fulvestrant:**

Exposure routes: Oral

Remarks: An ingestion study in animals has shown that high doses produce adverse effects on the heart.

### 11.1.10 ASPIRATION TOXICITY

Not classified based on available information.

**Components:**

**Fulvestrant:**


No information available.

### 11.1.11 FURTHER INFORMATION

**Product:**


Remarks: This health hazard assessment is based on a consideration of the composition of this product.

(d) **Hazardous Chemical Listings** - Not Available

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**Section 12 - Ecological Information**

<b>(a)</b>	<b>Ecotoxicity</b>	<p><b>Product:</b>  <b>Ecotoxicology Assessment</b>  Chronic aquatic toxicity: Very toxic to aquatic life with long lasting effects.  Remarks: This environmental hazard assessment is based on information available on the components of the formulation. Information refers to Fulvestrant.</p> <p><b>Components:</b>  <b>Fulvestrant</b>  Toxicity to algae:  NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): 0.047 mg/l  Exposure time: 72 H  Method: OECD Test Guideline 201  Remarks: No toxicity at the limit of solubility</p> <p>Toxicity to fish (Chronic toxicity):  NOEC (<i>Pimephales promelas</i> (fathead minnow)): 0.0000057 mg/l  Exposure time: 42 d</p> <p>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  NOEC (<i>Daphnia magna</i> (Water flea)): 0.01 mg/l  Exposure time: 21 d  Method: OECD Test Guideline 211  Remarks: No toxicity at the limit of solubility  M-Factor (Chronic aquatic toxicity):10,000</p> <p>Toxicity to bacteria: IC50 (Sewage sludge organisms): &gt; 100 mg/l  Exposure time: 3 H  Method: OECD Test Guideline 209  Ecotoxicology Assessment</p> <p>Chronic aquatic toxicity:  Very toxic to aquatic life with long lasting effects.</p>
<b>(b)</b>	<b>Persistence and degradability</b>	<p><b>Components:</b>  <b>Fulvestrant:</b>  Biodegradability: aerobic  Inoculum: activated sludge  Concentration: 100 mg/l  Biodegradation: &lt; 5 %  Exposure time: 28 d  Method: OECD Test Guideline 301F  Remarks: Not rapidly degradable.</p>

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<b>(c) Bioaccumulative potential</b>	<p><b>Components:</b>  <b>Fulvestrant:</b>  <b>Bioaccumulation:</b>  Species: <i>Oncorhynchus mykiss</i> (rainbow trout)  Bioconcentration factor (BCF): 355  Concentration: 0.0001 mg/l  Method: OECD Test Guideline 305</p> <p>Species: <i>Oncorhynchus mykiss</i> (rainbow trout)  Bioconcentration factor (BCF): 357  Concentration: 0.001 mg/l  Method: OECD Test Guideline 305  Remarks: The substance has low potential for bioaccumulation.</p>
<b>(d) Mobility in soil</b>	<p><b>Components:</b>  <b>Fulvestrant:</b>  <b>Mobility:</b>  Remarks: The substance is essentially insoluble in water.</p> <p><b>Distribution among environmental compartments:</b>  Remarks: No information available.</p>
<b>(e) Other Adverse Effects</b>	No data available.

### Section 13 - Disposal Considerations

**Waste from residues**

Disposal should be in accordance with local, state or national legislation.  
Solvent residues must not be allowed to enter drains, sewers or watercourses or to contaminate the ground.  
Dispose of contents/ container to an approved incineration plant.  
Large volumes may be suitable for redistillation by solvent contractors.


**Contaminated packaging**

Empty container will retain residue. Observe all hazard precautions.

### Section 14 - Transport Information

**ICAO/IATA**

<b>UN Number</b>	1170
<b>UN Proper Shipping Name</b>	Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
<b>Transport Hazard Class(es)</b>	3
<b>Packing Group</b>	III

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### IMO/IMDG

<b>UN Number</b>	1170
<b>UN Proper Shipping Name</b>	Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
<b>Transport Hazard Class(es)</b>	3
<b>Packing Group</b>	III

### ARD

<b>UN Number</b>	1170
<b>UN Proper Shipping Name</b>	Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
<b>Transport Hazard Class(es)</b>	3
<b>Label(s)</b>	3
<b>Packing Group</b>	III
<b>Marine Pollutant</b>	Environmentally hazardous

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.


### U.S. Regulations:

TSCA – Listed  
 CERCLA - Not on this list  
 SARA 302 - Not on this list  
 SARA 311/312: Immediate (acute) health hazard  
 SARA 313 - Not on this list  
 OSHA – Not on this list

## Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


For additional information contact:

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Athenex Pharmaceutical Division  
10 N. Martingale Road, Suite 230  
Schaumburg, IL 60173  
847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet

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STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

## Signature Manifest

**Document Number:** SDS035

**Revision:** 01

**Title:** Fulvestrant Injection

All dates and times are in Eastern Standard Time.

### SDS Approval

#### Change Request

Name/Signature	Title	Date	Meaning/Reason
Emily Means (EMEANS)	QA Document Specialist		
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV	20 Nov 2019, 08:50:12 AM	Approved

#### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	22 Nov 2019, 09:06:52 AM	Approved

#### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	22 Nov 2019, 01:09:53 PM	Approved