Letco Medical, LLC.

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CERTIFICATE OF ANALYSIS

Letco Item:	696113	696114	696115			
Letco Lot:	2406050019	2406050020	2406050021			

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Naltrexone Hydrochloride USP Anhydrous	3130924	September 7, 2024	August 31, 2027

TEST	SPECIFICATION	RESULT
Appearance	White or almost white powder, very hygroscopic	Complies
Identification		
IR spectrum	Corresponds to IR spectrum of reference standard	Positive
HPLC	Concordant retention time	Positive
Assay (calculated on anhydrous and solvent free substance)	98.0% to 102.0%	100.8%
Residue on ignition	NMT 0.1%	0.0%
Total solvents	NMT 5.0%	3.1%
Related substances HPLC		
Noroxymorphone	NMT 0.5%	< 0.05%
10-hydroxynaltrexone	NMT 0.5%	< 0.05%
Related compound A	NMT 0.5%	0.06%
2,2'-bisnaltrexone	NMT 0.5%	ND
10-ketonaltrexone	NMT 0.5%	ND
Unspecified impurity	NMT 0.10%	< 0.05%
RRT	---	NA
Total impurities	NMT 1.5%	0.06%
Content of chloride (calculated on anhydrous and solvent free substance)	9.20% to 9.58%	9.30%
Specific rotation (calculated on anhydrous and solvent free substance)	-197º to -187º	-190º
Water	NMT 5.0%	0.43%
Clarity of solution	NMT 3 NTU	0.48 NTU
Residual solvents		
Ethanol	NMT 30,000 ppm	26742 ppm
Cyclopentyl methyl ether	NMT 150 ppm	2 ppm
Cyclopropylmethyl bromide	NMT 10 ppm	ND

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

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CERTIFICATE OF ANALYSIS

Letco Item:	696113	696114	696115			
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Microbiological quality Ph.Eur. (5.1.4)		
Total aerobic microbial count (TAMC)	NMT 1,000 CFU/g	0 CFU/g
Total combined yeasts/molds count (TYMC)	NMT 100 CFU/g	0 CFU/g

ADDITIONAL INFORMATION

Letco Medical performed identification testing of this material using a validated method.

Per the manufacturer, the product conforms to specification.

The manufacturer hereby confirms that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control at site fully operating in compliance with EU GMP requirements, the local Regulatory Authority and the marketing authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

This product was manufactured by Saneca Pharmaceuticals a.s., 3345/100 Nitrianska, Hlohovec, Slovakia 92027, Slovakia (SVK)

LETCO QA REVIEW: Essence Martin

Digitally signed by Essence Martin
DN: cn=Essence Martin, o=Letco Medical, ou=Quality Assurance, email=Essence.Martin@fagron.us, c=US
Date: 2024.10.29 12:24:59 -05'00'

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis