



S . A . L . A . R . S . S . p . A .

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**CONFIRMATION OF CONFORMANCE TO GUIDELINE ON
RESIDUE OF METAL CATALYSTS OR METAL REAGENTS
ACCORDING USP <232> and <233>**

We, S.A.L.A.R.S. S.p.A., declare hereby that *NALTREXONE HYDROCHLORIDE DIHYDRATE* is a semi synthetic alkaloid obtained by chemical modification of Oxymorphone (starting material).

The absence of carry-over of catalysts (Palladium, a Class 2B catalyst used in the synthesis of starting material Oxymorphone), into Noroxymorphone Hydrochloride (the last intermediate) has been demonstrated by using a suitably validated test method according to USP <233> Elemental Impurities - Procedures.

According to the results and to USP <232> Elemental Impurities - Limits, we perform the Palladium content determination on each batch of Noroxymorphone Hydrochloride manufactured, the specification for Palladium content is < 5 ppm (half of the limit prescribed by USP <232> for oral exposure: 10 ppm).

S.A.L.A.R.S. S.p.A.
Qualified Person
(Dr. Claudio Caraffi)

Como, 03rd August 2020