



ANALYSIS REPORT

Determination of Nicotine in sbPBS by LC-HRAM-MS isotope dilution technique

| | |
|-----------------------------|---|
| Program Name | BSR |
| Project / Work Package Name | S179800_MP1_3R4F_RunE1E2_THS2.2_RunF1F2 |
| Responsible Unit | Complex Matrix Analysis |
| Responsible Author | Rhouma Mounir |
| QA Check | Q.Dutertre |
| Calendar Week | CW 11 (2016) |
| Project Number | S179800 |
| Date | 14 th Mar 2016 |

QC results on March 14th 2016:

Passed: within 85-115% accuracy
Failed: outside 85-115% accuracy
Ratio: NO for <2/3

| Nicotine | | | | | |
|----------------------|--------------|------------|--------|--------|-------|
| Sample Name | n injections | Exp. Conc. | Passed | Failed | Ratio |
| QC1_dilx1 | 3 | 27.18 | 3 | | |
| QC2_dilx1 | 3 | 317.15 | 3 | | |
| QC3_dilx1 | 3 | 906.15 | 3 | | |
| QC4_dilx1 | 3 | 2718.44 | 3 | | |
| Average quality (%): | | 100.00% | ok | | |

Results:



DETERMINATION OF NICOTINE IN SBPBS BY LC-HRAM-MS

Doc No: Nicotine: Study Number: S179800

Version N°: 1.1

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| Sample- ID | calculated concentration | calculated concentration | Average | STDEV | RSD |
|---------------------------|--------------------------|--------------------------|-------------|---------|-----|
| | ng/mL | (ng/insert) | (ng/insert) | | % |
| Nico_sham_3R4F_E1_NA_61 | N.A | N.A | N.A | N.A | N.A |
| Nico_sham_3R4F_E1_NA_62 | N.A | N.A | | | |
| Nico_sham_3R4F_F1_NA_75 | N.A | N.A | | | |
| Nico_sham_3R4F_F1_NA_76 | N.A | N.A | | | |
| Nico_3R4F_E1_0.25_57 | 60753.93 | 6075.39 | 6297.44 | 2311.41 | 37% |
| Nico_3R4F_E1_0.25_58 | 44615.60 | 4461.56 | | | |
| Nico_3R4F_F1_0.25_71 | 96166.60 | 9616.66 | | | |
| Nico_3R4F_F1_0.25_72 | 50361.51 | 5036.15 | | | |
| Nico_3R4F_E1_0.35_59 | 91416.09 | 9141.61 | 8590.14 | 441.23 | 5% |
| Nico_3R4F_E1_0.35_60 | 80629.49 | 8062.95 | | | |
| Nico_3R4F_F1_0.35_73 | 85488.20 | 8548.82 | | | |
| Nico_3R4F_F1_0.35_74 | 86071.87 | 8607.19 | | | |
| Nico_sham_THS2.2_E2_NA_69 | N.A | N.A | N.A | N.A | N.A |
| Nico_sham_THS2.2_E2_NA_70 | N.A | N.A | | | |
| Nico_sham_THS2.2_F2_NA_83 | N.A | N.A | | | |
| Nico_sham_THS2.2_F2_NA_84 | N.A | N.A | | | |
| Nico_THS2.2_E2_0.5_63 | 11461.64 | 1146.16 | 1756.82 | 603.03 | 34% |
| Nico_THS2.2_E2_0.5_64 | 14412.64 | 1441.26 | | | |
| Nico_THS2.2_F2_0.5_77 | 19121.04 | 1912.10 | | | |
| Nico_THS2.2_F2_0.5_78 | 25277.56 | 2527.76 | | | |
| Nico_THS2.2_E2_0.7_65 | 56512.13 | 5651.21 | 6644.25 | 1044.00 | 16% |
| Nico_THS2.2_E2_0.7_66 | 61432.07 | 6143.21 | | | |
| Nico_THS2.2_F2_0.7_79 | 67143.33 | 6714.33 | | | |
| Nico_THS2.2_F2_0.7_80 | 80682.43 | 8068.24 | | | |
| Nico_THS2.2_E2_1_67 | 102106.23 | 10210.62 | 11197.01 | 869.55 | 8% |
| Nico_THS2.2_E2_1_68 | 110962.03 | 11096.20 | | | |
| Nico_THS2.2_F2_1_81 | 111514.57 | 11151.46 | | | |
| Nico_THS2.2_F2_1_82 | 123297.70 | 12329.77 | | | |

N.A.: non applicable