

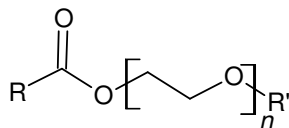
CLAIMS

1. A process for quantifying at least one polysorbate-~~derivative~~ in a sample, said process comprising:-

- The step of performing a LC-MS analysis of said sample based on the signal of the dioxolanylium ion;
- The step of performing an internal calibration with an internal standard of said polysorbate-~~1~~;

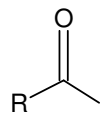
~~2. The process according to claim 1 wherein said polysorbate is PS20 or PS80.~~

~~3. The process according to claim 1 or 2 wherein said internal standard is an ethoxylated fatty acid of formula (I):~~



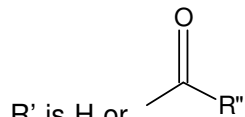
(I)

wherein:



represents a fatty acid residue

Where R represents a C3-C24 linear or branched saturated alkyl;



where R'' represents a C3-C24 linear or branched saturated alkyl; and

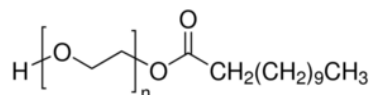
n is comprised between 1 and 100;

and the mixtures thereof.

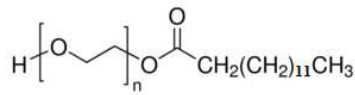
2. The process according to claim 1 wherein said polysorbate is PS20 or PS80.

4.3.

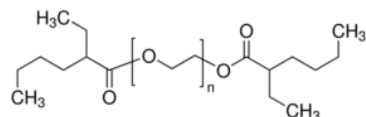
The process according to anyone of the preceding claims wherein said internal standard is chosen from:



PEG-C12



PEG-C14



Poly(ethylene glycol)bis(2-ethylhexanoate)

where n is comprised between 1 and 100.

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5.4. The process according to anyone of the preceding claims wherein said

internal standard is $\text{H} \left[\text{O} \text{---} \text{CH}_2 \text{---} \text{CH}_2 \right]_n \text{O} \text{---} \text{C}(=\text{O}) \text{CH}_2(\text{CH}_2)_{11}\text{CH}_3$ n is comprised between 1 and 100.

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6.5. The process according to anyone of the preceding claims wherein said LC-MS analysis involves a single quadrupole mass detector (QDa).

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7.6. The process according to anyone of the preceding claims wherein the LC-MS mobile phase comprises a gradient of formic acid.

8.7. The process according to anyone of the preceding claims wherein the LC-MS mobile phase is a ternary mobile phase.

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9.8. The process according to claim 8.7 wherein ternary mobile phase comprises water, acetonitrile and formic acid.

10.9. The process according to anyone of the preceding claims wherein said sample is a biopharmaceutical formulation.

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11.10. The process according to anyone of the preceding claims wherein said sample comprises at least one protein.

12.11. The process according to anyone of the preceding claims wherein said sample comprises at least one monoclonal antibody.

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~~13.~~12. The process according to anyone of the preceding claims wherein said process also includes the step of detecting the oxidation and/or hydrolysis of said polysorbate.

5 ~~14.~~13. A process of monitoring the degradation of at least one polysorbate in a sample comprising implementing the process according to anyone of the preceding claims.