

E.C.G-505 & NS-300 do not contain peroxide

About peroxide

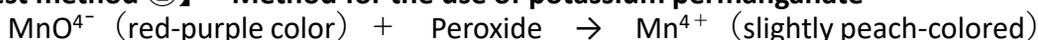
In general, peroxide has high reactivity and the mechanism of oxidizing what contacted by it. Such an example has been reported that if peroxide is contained in excipients, when the excipient becomes mixed with API, preparation of related substances is advanced by the oxidation.

Method for investigation

Qualitative tests were conducted by making use of the following reactions. Ion-exchange water as controlling, E.C.G-505 & NS-300 as test objects, H₂O₂ *1 as comparative controlled study, and crospovidone were used.

* 1 Not used in test method ③

【Test method ①】 Method for the use of potassium permanganate



【Test method ②】 Iodine reduction method



【Test method ③】 JP 17 Crospovidone (4) Application of peroxide, method 1

Results

In the test methods ① and ②, the reactions of showing the existence of peroxide were observed, regarding H₂O₂ as peroxide and Crospovidone including peroxide.

While, the reactions were not observed, regarding E.C.G-505, NS-300 and Ion-exchange water(control).

In the test method ③, absorbance was scarcely observed, as to E.C.G-505 & NS-300.

【Test method ①】

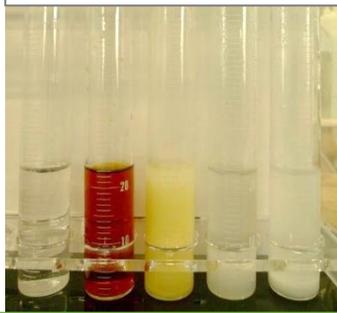
If peroxide exists, peach color fades.



From the left: : Ion-exchange water, H₂O₂, Crospovidone, E.C.G-505 & NS-300

【Test method ②】

If peroxide exists, brownish-red color appears.



【Test method ③】

Peroxide exists. → Absorbance increase

Product name	Absorbance
Crospovidone Type A	0.151
E.C.G-505	0.003
NS-300	0.004

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We have stability monitoring data and SDS, etc. to meet your request.