

Topic of report: A study of primary packaging for pressurised inhalers and sprays

Speakers:

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Company:

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Report outline:

- In the registration dossier, a report should be submitted in CTD format on pharmaceutical development. The report should justify the choice of primary packaging in view of its functional characteristics, the application of the pharmaceutical product, and its suitability for storage.
- According to the results of a study of extractable substances conducted with the company Coster Technologie Speciali S.p.a. (Italy), the materials chosen for dosing valves for inhaled drugs with Freon 134a and for spray pumps ensure the stability of various medicines for more than 2 years while in storage.
- During the development of the aerosols Salbutamol and Beclomethasone, dosing valves and sprayers were studied by Coster Technologie Speciali S.p.a. It was shown that by varying the volume of the dosing chamber and the diameter of the holes in the spray, it was possible to manage the dose of fine particles and the effectiveness of the action. Valves and sprayers ensure compliance with the requirements of the European Pharmacopoeia regarding the uniformity of the delivered dose. Valves and pumps also provide a uniform metered dose according to the weight and content of the active substances.

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