|  |
| --- |
| **Chemical Imaging by Raman Spectrometer for Particle Characterisation of an Aqueous Nasal Spray** |
| Vaishnavi Kapileshwari, Memory Jiri, Lee Warren & Mridul Majumder |
| M2M Pharmaceuticals Ltd., Unit 125 (Gr Fl) Wharfedale Road, Winnersh Triangle RG41 5RB, Berkshire, UK |
| **Background:** Nasal sprays are widely used to treat allergic rhinitis. This experimental study evaluates a commonly used nasal spray, Beconase® 0.05% (GlaxoSmithKline, UK) indicated for treating Hay fever, using a Raman spectrometer. Raman spectroscopy has previously been used for investigating nasal formulations. However, most formulations delivered by the nasal route are very small in size or even micronised. Therefore, in this study Raman Chemical imaging (CI) has been employed as a characterisation tool for identification, quantification, particle size distribution (PSD) and overall distribution.  |
| **Methods:** A method was developed for analysing the nasal formulation using RA802 Raman Pharmaceutical Analyser (Renishaw, UK). Three experiments were carried out from the same formulation to ensure repeatability. The sample preparation was done by spraying the Beconase formulation two times in an upright position onto a mirror slide, held 10mm above the nozzle. The two sprays represented the dose as per the product labeling. The samples were air-dried before analysing. |
| **Results:** The data analysed from the mapped images detected various components present in the formulation, which is confirmed by the reference spectra of each as Beclometasone dipropionate (BDP, API here) at 1664cm-1, dextrose at 518cm-1, microcrystalline cellulose (MCC) at 1095cm-1, sodium carboxymethyl cellulose (CMC) at 907cm-1, polysorbate 80 at 848cm-1, phenylethyl alcohol (PEA) at 1003cm-1 and benzalkonium chloride at 1462cm-1. The chemical image represents homogeneous dispersion of API with various excipients within the formulation on spraying twice to represent a single dose in each nostril. The Chemical image-based particle statistics of each component are shown by different colour and can be seen as different concentration, size, shape of particles in the formulation that are detected and quantified. The results show a relatively higher concentration for MCC, which may be due to the similar spectral shifts observed with Sodium CMC at 1095cm-1 and 1124cm-1, in addition to the overlap with other components. The higher concentration of 0.5% for the BDP, higher than the expected values, could be explained by the sensitivity of RAMAN for picking up highly intense spectral signals. The particle statistics of polysorbate 80 and PEA, which were present in liquid state, couldn’t been established. Knowing accurate concentration used in the formulation by the manufacturer would enable scientists to understand more insights into this technique to quantify each component in confidence. |
| **Conclusions:** This study shows that Raman spectrometer can effectively be used as a characterisation technique for analysing an aqueous nasal spray formulation. Thus, data generated from Raman provides detection of each component, concentration estimate and size distribution. Based on this study, it can be inferred that the technique is powerful in characterising formulations containing particles of small sizes of less than 1µm and in low concentrations, which are often used in respiratory drug delivery. Additional studies will be performed to demonstrate the translational application of the technique to efficiently investigate and characterise other respiratory formulations like nebulisers, dry powder inhaler and other nasal products. |