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Ocular, Otic, Nasal, Rectal and Vaginal Formulation Innovations and Regulatory Considerations

Welcome to the first editorial of 2018.

The theme of this issue is *Ocular, Otic, Nasal, Rectal and Vaginal Formulation Innovations and Regulatory Considerations*.

Cataract, glaucoma, corneal disorders and macular degeneration contribute noticeably to sight loss worldwide. Drug administration to the eye aims at treating conditions of the precorneal area (tear film conjunctiva, cornea and sclera) anterior segment (aqueous humour production and drainage, uvea and lens) and posterior segment (choroid, retina, macula and optic nerve).

Medicated ocular bandages and corneal health; reducing systemic absorption of the ocular hypotensive drug brimonidine and formulating the non-steroidal anti-inflammatory drug Aceclofenac as oil drops for management of ocular inflammatory conditions are covered within this issue. Preparation and *in vivo* evaluation of polymeric implants aimed at optimising dexamethasone delivery to the posterior segment of the eye; Profiling extractable and leachable inorganic impurities in ophthalmic drug containers by ICP-MS are addressed.

Antibacterial drugs, antifungals and steroids are the main therapeutic agents used for the treatment of the external auditory canal disorders such as otitis media. They are also widely used in ophthalmic formulations for treatment of various ocular conditions. Such APIs are handled and manufactured in multipurpose shared facilities where residues are likely to pose toxicological threats. Hence the importance of the manuscripts entitled: Topical otic drugs in a multi-purpose manufacturing facility: a guide on determination and application of permitted daily exposure (PDE) and Determination and application of the permitted daily exposure (PDE) for topical ocular drugs in multipurpose manufacturing facilities.

The nasal route of drug delivery aims at either local or systemic effects. Drops, sprays, gels, powders and various devices have been developed for intranasal drug administration and deliver. Three manuscripts of this issue report on innovative nasal formulations, they are: Revisiting the role of sucrose in PLGA-PEG nanocarrier for potential intranasal delivery; Metoclopramide nasal spray evaluation and pharmacokinetic studies; Intranasal drug delivery devices and interventions associated with post-operative endoscopic sinus surgery.

Drugs administered via the rectal route exert local as well as systemic effects. Rectal dosage forms include solutions, suspensions, gels, suppositories, and ointments. The rectal route is a viable option for drug administration when the condition of the patient does not allow utilising the oral route. This is particularly useful for paediatric and geriatric patients as well as in emergencies when the patient is unconscious. Development of rectal dosage forms with silver-coated glass beads for local-action application in lower sections of the gastrointestinal tract is described.

The use of microbicides for providing protection against sexually transmitted diseases including those caused by HIV infection is well established. Such practice is adopted by health authorities around the world and is highlighted as a priority by the WHO HIV and Hepatitis department. Two manuscripts of this issues report on the development and patient perception of such formulations. They cover the Design and evaluation of tenofovir vaginal gels and Using visual and tactile evaluations among potential users of vaginal films to inform product design.

Thank you for your interest in Pharmaceutical Development and Technology; I hope you will find this issue relevant to your own research, teaching, professional practice, educational or CPD needs.

Sincerely,

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