Moulds associated with contaminated ocular and injectable drugs: FDA recalls, epidemiology considerations, drug shortages, and aseptic processing

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**Abstract**

Recent (2012) grave but rare outbreaks of fungal meningitis and endophthalmitis associated with drugs contaminated with select environmental moulds (*Exserohilum* and *Fusarium*, respectively) have exacerbated mycology concerns for formulation, good laboratory practices (GLP), and use of the final drug product. Intensified investigations (2013–2015) by the Food and Drug Administration (FDA) that included added responsibilities for specialty compounding laboratories have prompted at least nine voluntary mould-related drug recalls during 2014–2015. Both primary manufactures (five recalls, two companies) and secondary-processing compound laboratories (at least eight recalls, six companies) and near 0.8 million units were involved. These constituted minor fractions of recalled drug products in an estimated 2500 recalls among other causes during this time period. Recalls of similar drugs in 2016 were indirectly related to fungi. None of the mould-related-drug-recall episodes during 2014–2016 have been identified with fungal disease outbreaks. The recalls included drugs in short supply worldwide such as injectable sodium chloride- and related saline solutions as well as ocular formulations. Insufficient environmental monitoring and GLP compliance,
particularly for aseptic processing of non-preserved formulations, appeared to be underlying factors in the fungal contaminations. Observations of mould growth in drugs during their processing should be accurately recorded and investigated; cryptic listings under “particulate” designations should be avoided. Confirmed identifications for chronic contaminants are recommended. Heat-tolerant moulds with resistant morphotypes are prime concerns.

**Keywords:** Mould contamination, drug recalls fungi, FDA enforcement reports, aseptic processing

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