

PR#	MDR#	Consent Y/N	Batch	Issue	Comment
8018324	038-01/23	Yes	FN1665	Particulates (Black)	<p>Our investigation could not indicate a probable root cause for the complaint to be related to the production process of the involved batch. All reviewed records for the involved batch indicated that the batch met the established requirements at time of release.</p> <p>However, without complaint sample and based on the available information it is not possible to perform a more profound investigation and/or root cause analysis.</p> <p>No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. Investigating site concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable.</p> <p>Pfizer is committed to providing quality pharmaceuticals and regrets any inconvenience caused by this incident. We appreciate customer feedback and take these issues seriously, placing the utmost importance on the quality of our products and patient safety.</p>