Purpose
Orodispersible films (ODFs) dissolve quickly in the buccal cavity, circumventing the need for swallowing. No standard time and disintegration test methods for ODF have been mentioned in the pharmacopoeias. The European Pharmacopoeia 8.0 (EP 8.0) states that ODFs should “disintegrate rapidly”. The United States Pharmacopoeia (USP37-NF32) stipulates 30 sec as disintegration time for orodispersible tablets. The USP disintegration test for tablets and capsules poses significant challenges for end-point determination when used for the disintegration of ODFs. The objective of this study is to evaluate a novel disintegration test unit (DTU) to improve disintegration end point for ODFs.

Methods
The DTU is a modification to the USP disintegration test and is to be used as an accessory to the USP disintegration apparatus. The DTU is inserted into the basket from the top and holds the ODF in a horizontal position which allows ODF to move vertically in the bath (Figure 1). This affords easier viewing of the ODF movement from the top allowing a clear view of the end-point. The quality control capabilities of the DTU and the USP disintegration system were compared utilising marketed ODF products in purified water. Its precision was then tested by conducting disintegration tests in three different media - purified water, buffer (pH 6.8), and simulated saliva fluid (pH 6.8). The formulation differentiation capability of the DTU was determined using several commercial products in purified water.

Results
The DTU exhibited improved repeatability and reproducibility compared to the USP disintegration system with percent relative standard deviation of 2.3% versus 18.5% respectively. It offered reduced operator-to-operator variability. Test media had an effect on the disintegration time of commercial ODFs while retaining precision. The DTU was able to discriminate among several marketed ODFs affording formulation differentiation.

Conclusion
This novel DTU provides a simple and intuitive set up as an accessory to the USP disintegration test apparatus. It affords clear end point determination and exhibits good repeatability and reproducibility. Its use may aid future development of a standard pharmacopoeia method.

Figure 1 – Top view of the DTU in the USP disintegration system