

The quality of veterinary medicines and their implications for One Health

Supplemental material 13. Detailed results for the equivalence studies (n= 11) of veterinary medicines

In 11 equivalence studies, most of samples were tested for more than one quality attribute (85.1%, n= 160). All 188 samples were tested for API identification and API content, 118 samples (62.8%) for impurities/contaminant and 108 samples (57.4%) for dissolution test. Packaging analysis was conducted for 13.9% (n= 26) of 188 samples.

The failure frequency due to API content test failure (43.1%, 81/188) was the highest, followed by other physical tests (42.6%, 46/108) and dissolution test failure (23.1%, 25/108). In one study, out of 96 samples tested for API content, dissolution and impurities, there were no breakdown of the results by test for 60 (31.9%) samples.[1] None of the 26 samples tested for packaging inspection failed.

Of 81 samples that failed API content test, 49.4% (n= 40) contained lower API amount than stated on the packaging and 6.2% (n= 5) higher API. For 44.4% (n= 36) of the samples there was not enough details in the publication as to whether they contained higher or lower amounts of API.

Failure frequency by quality test in equivalence studies	
Quality test	Failure frequency % (n/N)
API content	43.1% (81/188)
Package/label/physical appearance inspection	32.5% (13/40)
Dissolution	23.1% (25/108)
Impurities/contaminants/related substances	1.0% (1/96)
Uniformity of units*	57.9 (11/19)
Other physical analysis**	29.3% (12/41)
Other chemical analysis***	8.0% (18/224)
Other techniques****	0.1% (3/38)
* Includes content uniformity, weight/mass uniformity, uniformity of mass, and weight variation.	
**Includes crystal size, disintegration, friability, hardness.	
***Includes API identification, pH and zinc content.	
****Includes bacterial susceptibility, infectious agents contamination, insulin concentrations in the supernatant and pyrogenicity.	
<i>Note: One sample may have been tested for one or more quality tests</i>	

Failure frequency by version of drugs in equivalence studies	
Version of drug	Failure frequency % (n/N)
Compounded	50.4% (63/125)
Generic	12.5% (1/8)
Unknown	67.3% (37/55)

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Total	53.7% (101/188)
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Reference:

- 1 Farah C, D'Aoust PM, Krantis A, et al. Analysis of ciprofloxacin in fish antibiotic products available from the Internet. *PeerJ Prepr* 2016;4:e1856v1. doi:10.7287/peerj.preprints.1856v1