

REGULATORY ARTWORK CHECKLIST MSD ANIMAL HEALTH

Regulatory artwork checklist

This checklist is part of the request for artwork introductions, artwork changes, and the artwork review process. It must be filled out by the requestor or reviewer, and stored and archived locally. It can be requested in case of audits, issues, or investigations.

Version 1

Generic information	TO BE FILLED
Local product name and presentation:	Rotavec Corona vet
ID of national license under review	41975
ID of local Artwork under review:	192328 R2
Type of local Artwork under review:	IN
Locally registered shelf life:	-

General review	COMPLIES YES/NO	
Item number on artwork	Yes <input checked="" type="checkbox"/>	No
Are all requested changes included	Yes <input checked="" type="checkbox"/>	No
Is artwork free of typographical errors	Yes <input checked="" type="checkbox"/>	No

Checklist local Artwork vs. reference information	COMPLIES WITH LOCAL LICENSE YES/NO	
Registered product name	Yes <input checked="" type="checkbox"/>	No
Active ingredients	Yes <input checked="" type="checkbox"/>	No
Active strengths	Yes <input checked="" type="checkbox"/>	No
Dosage form	Yes <input checked="" type="checkbox"/>	No
Dosage strength	Yes <input checked="" type="checkbox"/>	No
Target species	Yes <input checked="" type="checkbox"/>	No
Indications	Yes <input checked="" type="checkbox"/>	No
Withdrawal period	Yes <input checked="" type="checkbox"/>	No
Precautions/warnings	Yes <input checked="" type="checkbox"/>	No
Special storage condition	Yes <input checked="" type="checkbox"/>	No
Name and address of marketing authorisation holder	Yes <input checked="" type="checkbox"/>	No
Name and address of manufacturer	Yes <input checked="" type="checkbox"/>	No
Imprint legends "batch", "exp", and others if applicable	Yes <input checked="" type="checkbox"/>	No
Authority approval artwork required	Yes <input checked="" type="checkbox"/>	No
Correct implementation date in ARTIS	Yes <input checked="" type="checkbox"/>	No
Local required bar codes	Yes <input checked="" type="checkbox"/>	No

Additional Queries/Comments

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Review completed by (name + signature)	Nina Hyldgaard 
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Date	2018-07-16
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