

مرسوم رقم ٥٧١

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European Agency for the Evaluation of Medicinal Products (EMA)

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Food and Drug Administration (FDA)

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World Health Organization (WHO)

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" / (Product License Holder) "

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(Marketing Authorization Holder)

Manufacturer of the Pharmaceutical/Dosage) "

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.(MPF/MDF) (Form

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Packager / Final Releaser

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Manufacturer of the Pharmaceutical/Dosage) "

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(MPF/MDF) (Form

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Mother (Holding) Company, Société Mère -
(MPF/MDF) (Manufacturer of the Pharmaceutical/Dosage Form) " / " -
Marketing) " " / (Product License Holder) " -
(Authorization Holder
(Applicant for Certificate) -
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Final)

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Mother (Holding) Company, Société Mère

Mother (Holding) Company, Société Mère

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Manufacturer of the Pharmaceutical/ dosage Form

.GMP

(Final Release/Batch Release)

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Manufacturer of the Commercial form
Final Release/ Batch Release

.GMP

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Product license holder / Marketing Authorization Holder

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.GMP

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GMP

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CPP or CMP "	" -
FSC "	" -
Summary of Product Characteristics SPC	-
.() Technical File	-
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Certificate Of	
	Analysis
	.(Final Release/Batch Release)
Mock ups	
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.() Technical File -

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Certificate Of

Analysis

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Combined Batch Number

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.au Pro-Rata / Packaging

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Good () Plant Profile Manufacturing Practice (GMP)

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Bulk

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Plant profile

Bulk

primary

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(Type II variations)

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